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Developing Medical Device Programs based on Modular Platform Architectures

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Compliance Driven Modularization

Developing Medical Device Programs based on Modular Platform Architectures

A Ph.D. Thesis

Submitted to

the Academic Committee

By

Troels Victor Jensen

In Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Department of Mechanical Engineering

Technical University of Denmark

August 2019

Compliance Driven Modularization

Developing Medical Device Programs based on Modular Platform Architectures

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EXECUTIVE SUMMARY

Within the medical domain, manufacturers are challenged with the ability to manage the growing complexity of the regulatory environment while handling the inherent complexity of their product programs. Meanwhile, manufacturers experience a constant increasing demand for launching divergent new medical device variants while public authorities require extensive compliance for new medical device developments and medical devices already launched to the marketplace, which accelerates the pressure on medical manufacturers.

Although, case examples in literature point towards the opportunity for advancing the research area of modularization consider regulatory and compliance matters, a comprehensive literature study by this research found that although significant research has been carried out on modularization, little to no emphasis has been on modelling the regulation and compliance aspects from a modularization point of view.

By applying a mixed research methods approach, reviewing existing theories and by conducting multiple case studies in industry, this thesis explores the concept of compliance driven modularization. This research suggests that medical device manufacturers should concurrently view their product program considering both product and compliance aspects. In continuation hereof, the research of this thesis suggests the use of the so-called Compliance Architecture Concept Exploration (CACE) tool. This modelling tool emphasizes analysis and synthesis of the product variants based on a concurrent product and compliance view of the medical device program.

The CACE tool offers four uses that support analyzing the program for rationalization and synthesis for new medical device variant creation. Namely, the tool enables (1) traceability and prioritization by analyzing change and effect between the market and program design, (2) discrepancy analysis based on the Delta-Domain Mapping Matrix (ΔDMM), (3) the ability to create and evaluate a modular platform architecture based on compliance driven modularization, and (4) a structural approach to evaluate new medical design proposals – all by its ability to approach the program design from a product and compliance point of view.

An explanatory case study revealed that by applying the CACE modelling tool, a company can gain substantial competitive advantages. In the specific case example, a program of arterial blood gas samplers was analyzed and a proposal for a new modular platform architecture was made using the CACE tool. Evaluating of the outcome, it was found that the company would achieve significant reduction in resource consumption, lower time-to-market, and higher probability of success, when acting upon the findings of applying the CACE modelling tool.

Keywords: Product program, architecture modelling, platform design, modularization, regulation, requirements, compliance testing and documentation, medical devices

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'If I have seen further, it is by standing on the shoulders of giants.'
– Sir Isaac Newton

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Kgs. Lyngby, August 2019 Troels Victor Jensen

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"If you want the answer — ask the question."
– Lorii Myers

Chapter 1

SETTING THE STAGE FOR DEVELOPING MODULAR PLATFORM ARCHITECTURES UNDER REGULATORY CONSTRAINTS

This chapter will set the stage for the research study by (1) introducing the research area, hereunder (a) the industrial challenges highlighting the current issues of businesses operating within the medical domain followed by (b) the academic interests of the research study unfolding the existing body of knowledge within the research area. Further, this chapter introduces (2) the response to the identified challenges and interests while (3) declaring the research focus, (4) the research scope of the thesis, and (5) outlining the research questions that will guide the research study. Finally, this chapter describes the delimitations of the research and provides an overview of the thesis structure.

1.1 INTRODUCTION TO THE RESEARCH

Globalization of businesses is at its stance – technology innovations and operations are leading to a continuously growing number of competitors threatening companies' market positions, which is one of the main drivers for enhanced market complexity (Clark and Fujmoto 1991). Market complexity is one of four complexity catalysts found in literature, namely market, product, organizational, and process complexity, described by Maurer (2007). Companies operating within the medical domain are further challenged with the complex and ever tightening regulatory requirements set by public authorities. Here, requirements are not only related to customers' needs, but the public authorities' demands, as these acts yet as another very dominating and strict market player who influences the entire end-to-end value chain of medical businesses. Thus, medical companies must not only cope with the global fluctuations

caused by changes in customers' behavior and the resulting needs; they must also comply with the ever changing and tightened requirements set by the authorities, which vary across the geographical landscape. These regulatory requirements demand medical companies to have increasingly extensive verification and validation (V&V) testing and documentation in place bringing new products to market (Gibson and Corns 2012), which excessively adds to the end-to-end cost when bringing new medical devices to market (Fig. 1.1). Therefore, improvements to the engineering design and product development process, which can optimize compliance-related aspects, can have a high impact on medical businesses.

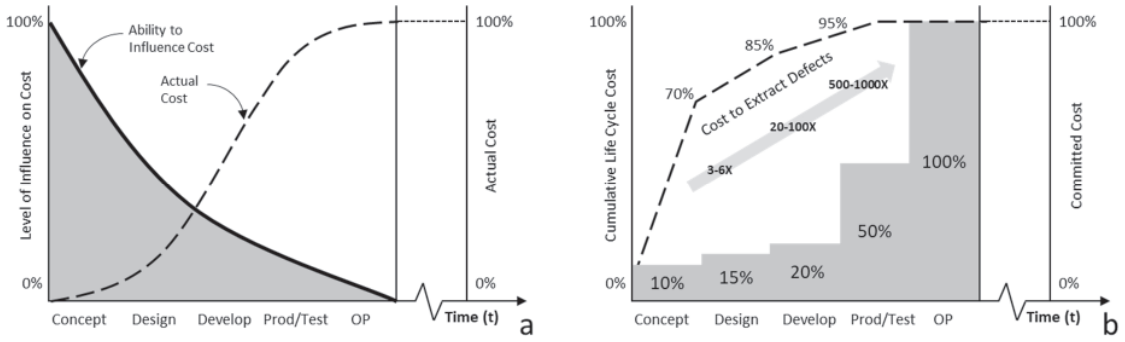


Fig. 1.1: The ability to influence life cycle costs decreases substantially over time (a), while the cost associated with extracting defects increases exponentially over time (b) by Haskins et al. (2006)

Many design philosophies, strategic approaches, and methodologies, such as lean thinking, six sigma, mass customization, and platform design have emerged over the past decades. These all have various angels of attack to execute business improvement and through the years many companies have applied one or more of these with great success. Applying such as lean thinking and six sigma allows for developing products for the support of a company's strategy and attempts to improve a company's business, but the philosophies do not automatically create the basis for successive development of multiple products – instead they primarily focus on the design of single products in one-product-at-a-time development projects (Harlou 2006). It is an inherent need in todays' competitive market for medical manufacturers to undertake multi-product development while staying in control of the growing product complexity. Mass customization seeks to meet the concerns of the growing market complexity as it facilitates increased product differentiation, but in order to achieve competitive advantages of this business strategy, a company must gain full knowledge of the product complexities, which when working within the medical domain is seen as a prerequisite for initiating mass customization. Architecture-based platform development, on the other hand, tries to leverage the effects of lean thinking, six sigma and mass customization and at the same time allows for internal complexity control and reduction by standardization of products while it allows for simultaneous development and market launch of multiple complex products (Meyer 1997). That stated,

platform development has many similarities to the previous mentioned philosophies, initiatives and strategies, especially it poses many of the same value generators while it built on many of the same principles as applied by mass customization. Whereas the principles of product platform and product family design are well understood and described in literature, still it lacks maturity in the compliance dimension (V&V testing and documentation). Currently, little to no effort has been made investigating the regulatory and compliance aspects of developing modular platform architectures for product programs.

This research seeks to investigate the complexities involved in developing and launching new medical devices to the marketplace. The research study seeks to treat three clustered and inter-related subjects founding the research field of interest, namely (1) business marketing and sales, (2) engineering design and product development, and (3) compliance testing and documentation, while using the more holistic systems thinking as a cross-boundary approach to the research analysis, development and establishment. In more commercial terms, this research study treats and seeks to bridge the three predominant functional units of a medical manufacturing company, i.e. sales and marketing, research and development, and regulation-/quality-centered departments. These are of specific interest given the overall research objective: To establish a foundation by which medical manufacturers can efficiently develop and successfully launch medical devices to the global marketplace while staying in control of products already brought to market.

Having declared this, a healthy foundation of developing successful new products requires end-to-end analysis followed by rationalization. Therefore, this research is in fact two-sided – at one side, it seeks to enable new innovative products to be brought to market, and at the other, it seeks to establish a healthy foundation for executing rationalization initiatives, which is thought to be a prerequisite paving the road for the overall aim of this research: To achieve profitable growth of medical companies.

1.2 The Business Challenge: "Uncontrollable Growth of Compliance Driven Complexity"

Within the medical domain, the ability to meet regulatory requirements by means of design and process documentation control has become an increasingly important parameter for the success rate of bringing new product variants to market. Companies that operate within this domain, as well as other regulation-driven industries such as aerospace, automotive, nuclear, and oil and gas, are subject to restrictive requirements enforced by regulations, which highly influence the entire end-to-end value chain of their businesses. It is said that an airplane will not receive permission to take off before the documentation for its safety exceeds the weight of the airplane itself. This certainly is to bring matters to a head, but within the medical domain, this association

seems merely the case. A study by Linden and Wijinstra (2002) revealed that the complexity of the medical device and drug regulatory frameworks and the processes by which companies are to follow in order to bring new products to market are highly complex. In continuation hereof, a recent study concluded that these frameworks and processes might significantly delay manufacturers time-to-market, and potentially result in patients not receiving timely benefits of new the evolutionary products to come (Masterson and Cormican 2013).

"The last time we submitted a new drug application to the authorities in the US, we compiled almost 14M pages, and if you chew on that number for a while – it is like, if you print them out and put them end-to-end, it will take you from New York to San Francisco."

– Program Manager, Regulatory Affairs

Medical manufacturers undertake highly risk sensitive and complex development projects that aim at designing products and/or systems for the human health and safety, which by means is of great interest to the public authorities. It has been found that these companies must not only cope with the complexity of their products but also the ever-growing complexity of the regulatory frameworks (Gibson and Corns 2012). Thus, these manufacturing companies operate within a multifaceted complex environment enforcing numerous requirements, both of internal and external substance.

"We work in a heavily regulated environment and our products are becoming more and more complex –new technologies, more features, further disciplines, etc. are coming into play – we are simply unable to grasp the consequences of the decisions we make early in our development process."

– Director, Systems Engineering

Hence, it is evident that medical device manufacturers continuously are challenged with the ability to manage the growing complexity of the regulatory environment while handling the inherent complexity of their products, and these conditions make it highly difficult to foresee the consequences of decisions made early in the development process. Further, regulatory requirements play a substantial role in the shaping of activities and decisions in the medical industry (Pietzsch et al. 2009), and these contribute significantly to the lead time of even very simplistic medical devices.

"We have several years of experience in not delivering products to market on time and within budget. We still – all too late – get surprised at how much resources are required and the time it takes to get our products approved by the public authorities."

– Senior Director, Global Product Management

As an example, a study concluded that more than 900 standards currently apply to the medical device industry, to which medical manufacturers must comply in order to attain the required

certifications needed to stay at market (Becker 2009). Tightening regulatory requirements demands medical device companies to have increasingly extensive documentation processes in place – processes which are excessively costly compared to the engineering design effort needed to develop the product itself.

"Our department spends over 75% of its time on handling documentation – we have only little time to design new products, and the last years, we have been hiring more personal than ever before for the main purpose to take care of the continuously growing burden of the stay-in-compliance documentation related to just our simplest devices."

– Director, Research & Development

The regulatory requirements thus contribute significantly to R&D resource consumption, which play a considerable role when allocating resources to new product development projects. Thus, medical companies must not only prove compliance with regulatory requirements when bringing new products to market but also when maintaining market clearance for devices already brought to market.

"A few years ago, the FDA decided to reclassify our products, and as we had insufficient control of the design documentation, we were forced to pullback our products from the US market – we have still not reached a level by which we are able to comply with these regulations."

– CEO, General Management

This implies that medical manufacturers should not only care about the regulatory subsets when applying for market clearance of new products, but certainly they should also keep up with changing regulations for products already brought to market – if not, this can have severe consequences for the entire business. In the past decade, averagely one company a year is subject to a 10 percent decrease in share price as a result of a single regulatory event (Fuhr et al. 2013). Thus, the risk that a major quality incident will cause critical, long-term value reduction to the medical manufacturer is high and rising. Meanwhile, being under this market-related threat, medical companies are facing an increasingly challenging situation with longer development cycles and thereby time-to-market caused by the increasing compliance work needed to meet regulations (Taylor et al. 2014).

This situation, a constantly increasing need for launching divergent new medical device variants while public authorities requiring extensive testing and documentation for new medical devices and devices already launched to the marketplace, accelerates the pressure on medical manufacturers. A continuously growing burden rests on these companies who aim at developing products for the human health and safety.

1.3 THE BUSINESS OPPORTUNITY: *"REGULATION-DRIVEN MODULAR PLATFORM DESIGN IN INDUSTRY"*

In the past decades, companies like Compaq, EMC, Gillette, HP, and Hon have gained substantial competitive advantages through internal product standardization while offering a wide range of diverse product variants to the marketplace (Meyer 1997). In the following, it is the objective to shed light on some of the more rigid industrial examples, which is found in literature, and that show the results of applying the principles of modular platform architecture design under regulatory constraints. The industrial examples are found based on reviewing the literature within the research area of more heavily regulated businesses. In the following, two historical cases that point in the direction of regulation-incented development of modular platform architectures are highlighted.

1.3.1 SUCCESSFUL INDUSTRY CASE EXAMPLES

In literature, Simpson et al (2005) found numerous examples of interesting industrial case examples are found describing successful platform implementation (Simpson et al. 2005): Sony Walkman (Sanderson and Uzumeri 1997), Canon copiers (Rothwell and Gardiner 1990), Lutron electric lighting control systems (Spira 1993), Nippondenso automotive panel meters (Whitney 1993), Swiss army knives and Swatch watches (Ulrich and Eppinger 1995), Xerox copiers (Paula 1997), Anderson Windows (Stevens 1995), Hewlett-Packard printers (Lee et al. 1993), and Kodak single use camera (Clark and Wheelwright 1993).

The following case examples from Black & Decker and Boeing and Rolls-Royce exemplify successful design of product families based on modular platform architectures and have been chosen based on their regulatory substance. The industrial case examples are characterized by the emphasis on overcoming regulatory challenges and describe how these two companies have successfully navigated through the tension field of legislative demands by introducing modular platform architecture initiatives.

Black & Decker – Universal Motor Platform

In early 1970s, the Black and Decker Corporation faced an immense challenge: regulatory authorities in Europe had recently implemented a legislative initiative to increase the human safety by requiring manufacturers to add a backup layer of insulation to their power tools protecting its users against electrical shock if the existing safety system failed (Lehnerd 1987). This regulatory demand was expected soon to gain acceptance in the US, the key consumer market of Black and Decker products, and thereby turn into an industrywide requirement with increased focus on human health and safety. At the time, this was perceived as an huge threat to the Black and Decker power tool business, as such demands would require the company to

update all of its 122 power tools, spanning across families of jigsaws and grinders to edgers and hedge trimmers, with hundreds of variants within each family. An analysis of the current program showed that products incorporated more than thirty different motors, sixty different motor housings, and dozens of different control systems – all with their own unique armature (Meyer and Utterback 1993), and top management estimated that redesigning the entire product portfolio one product at a time would take nearly a decade (Meyer and Lehnerd 1997).

In response to this perceived regulatory threat, Black and Decker decided to initiate the "Double Insulation" program; a vehicle for redesigning the entire product portfolio at once with the main objective to meet global customer needs and regulatory requirements. Hence, offering long-range performing and safe power tools at no increase in price to costumers. The Black and Decker Corporation decided to address the challenge at the products' core, the universal motor (Fig. 1.2, a), by developing a hexagonal copper wire wrapped motor field with standard electrical plug-in connections (Fig. 1.2, b). Through devotion to standardization, Black and Decker was able to vary the stack lengths of the motor, varying the input from 0.8" to 1.75" and the power output from 60 to 650 watts (Fig. 1.2, c), covering the entire product range of power tools.

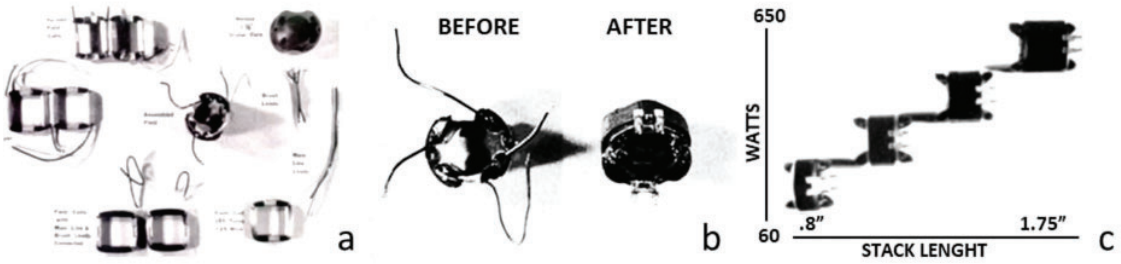


Fig. 1.2: The Black & Decker universal motor. From left: (a) the electric motor field components prior to redesign, (b) the motor configuration before and after to redesign, and (c) the stack length versus power range comparison of the new universal motor field, all adapted from Lehnerd (1987)

In retrospect, new regulatory requirements drew Black and Decker to radically alter its product portfolio; the company foresaw forthcoming regulatory changes, and as a response they initiated the "Double Insulation" program. By developing and manufacturing product families based on shared components and modules, they achieved shorter, what in this research is referred to as time-to-compliance (TTC), which is a key concept in this research. In return, Black and Decker gained significant advantages over competitors, as product costs declined by 50%, market share increased from 20% to a dominant one, and the number of competitors went from over twenty to just three (Lehnerd 1987).

Creating commonality and standardization across multiple products enabled new product designs to evolve and retire over time at a minimum product development cost by applying the

principles of modular product platforming, in this case scaling the stack length of the universal motor platform to vary the output power of the motor for a wide variety of applications. In conclusion, this case shows how a company can achieve significant competitive advantages if responding to regulatory changes in timely manner and with a profitable reply – by modular platform-based product architecture design.

Boeing & Rolls-Royce – Aircraft Frame and Engine Platform

In the mid-1960s, airline operators, like Pan Am Airways, began to demand new generations of airplanes with substantial increased freight and seat capacity. At the time, two major aerospace companies were competing over the military and civilian airplane market, i.e. Lockheed and Boeing. Interestingly, twenty years earlier, Boeing had with great success double-decked its B-29 Superfortress for strato-freighters/tankers and civilian strato-cruisers, and therefore initially intended to meet the new customer requirements by developing a double-decked version of the Boeing 707-serie, as further stretching of the existing 707-serie would result in an overpriced product.

During the development of the new double-decked 707-version, Boeing ran into problems with public authorities, as the Federal Aviation Administration (FAA) had applied some strict regulatory requirements for civilian airplane launches that specifically focused on the safety of the end users. The design had to allow for evacuation of all passengers within 90 seconds under unintended flight conduct. Boeing was not able to create a redesign that complied with these requirements and therefore was forced to reject the double-decked configuration of the 707-serie (Gardiner and Rothwell 1985).

While the airplane operators and regulatory authorities laid excessive pressure on Boeing's new product development team, Boeing was equally pushing its engine suppliers to the limit. At the time, three aircraft engine manufacturers; General Electric Aviation, Pratt and Whitney, and Rolls-Royce, were competing to win contracts with the aerospace companies, each with its own family of engines, i.e. the CF6, JT9D, and RB211, respectively.

The RB211 engine family consisted of seven sub-assemblies (Fig. 1.3, a): The LP fan module, IP compressor module, Intermediate module, HP system module, IP and the LP turbine module, HS gearbox module, and the LP fan case module. This modular engine design facilitated product and production flexibility, which founded the basis for a large family of up-rated, de-rated and re-rated engines (Fig. 1.3, b), each variant with differentiated product characteristics, meeting the customers' thrust and performance requirements. By this, Rolls-Royce was able to broaden its market basis (Rothwell and Gardiner 1983).

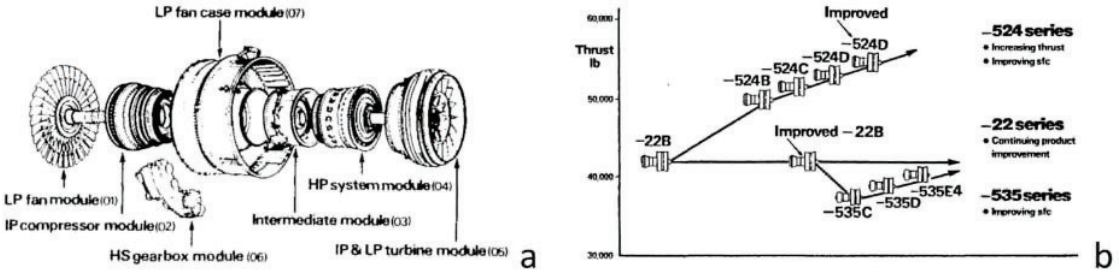


Fig. 1.3: The Rolls-Royce aircraft engine family. From left: (a) the modular RB211 engine construction, adapted from Parkes (1988) and (b) the evolution of the Rolls Royce RB211 family, adapted from Rothwell and Gardiner (1988)

In regard to regulation, Rothwell and Gardiner (1985) characterizes regulatory authorities as a tough 'albeit proxy' customer and shows how regulations significantly influence new product development – if the manufacturer is entitled to such. Further, they argue that tough customers plus robust design equals good design, where robustness is defined as "one that has sufficient inherent design flexibility or technological slack to enable it to evolve into a significant design family of variants" (Rothwell and Gardiner 1988). The evolution of the Boeing 747 aircraft frame and the Rolls-Royce aircraft engine is an excellent example of such coherence.

1.3.2 Observations on Opportunities in Developing Modular Platform Architectures

The cases from Black & Decker and Boeing & Rolls-Royce, exemplify different approaches to multi-product design. Each company redesigned or consolidated a group of diverse products to create a more efficient and effective program of products to overcome regulatory challenges. Here, efficient and effective associated with increased capabilities, e.g. economies of scale, product variety, as each company was able to realize by standardizing components to reduce manufacturing costs without significantly compromising product quality and performance.

The previous case examples point towards the opportunity for advancing this promising research area: To overcome the regulatory challenges facing medical companies by developing multiple products based on platforms (Tab. 1.1). This is confirmed by Simpson et al. (2005) who find that "product platforms can promote better learning across products and reduce testing and certification of complex products". As an example, within the aircraft industry, it has proven beneficial to introduce platform-based design as it can bring advantages in reuse of test and related certificates.

Consideration	Initiative	°F	Reported effects	Rationale (exemplification)	References
Regulation	Platform-based development, modularization, standardization	○	Shorter time-to-market (TTA, red), better product control, improved flexibility	Meet new customer needs and regulation by means of modularization in consumer industry, i.e. power tools.	Lehnerd (1987), Meyer and Utterbach (1992), Meyer and Lehnerd (1997)
Documentation	Module-based platform scaling, standardization, Modularization	◑	Shorter time-to-approval, better control, improved organizational knowledge sharing	Reuse of regulatory compliance tests eases approval process. Certificate reuse based on shared documentation in aircrafts.	Rothwell and Gardiner (1990), Sabbagh (1996), Caffery et al. (2002)
Testing	Modularization, and interface standardization	◑	Steeper learning curve, reuse of certificates, knowledge sharing	Sharing of tests for safety reusing certificates across products in the automotive industries.	Simpson (2005), Eichhorn (2001), Kruschwitz et al. (2000),

Legend: ● Fully formalized ◑ Partly formalized ○ Not/barely formalized

Tab. 1.1: Summation of state-of-the-art in industry with indication of the degree to which the initiative/approach is formalized (degree of formalization [°F]) published in literature

Boeing planned to expand its basic aircraft model to include various seat capacities and reach different target cruise ranges by replacing the engine (Sabbagh 1996). This similarity-based design approach used in the aircraft industry is called 'stretch' and referred to as the similar module design scheme. The overall situation of aircraft design planning includes the choices of independent, similar and common module design schemes (Fujita and Yoshida 2004). When stretching the basic aircraft model, it was possible to reuse test equipment and the certificates approving the equipment. Boeing 777 was the first flight to be designed fully by computers and the resulting simulations enabled thorough documentation while changing the specifications of the aircraft to include more seats and extending the cruise range.

As Cameron and Crawley (2014) states "platform-based development has an undeclared potential for direct reuse of regulatory compliance tests and can save years in time to market". Thus, it seems that developing multiple products based on modular platform architectures for the regulatory and documentation domain can bring substantial competitive advantages for companies operating within heavy-regulated industries, which found the basis for the following research study.

1.4 THE ACADEMIC INTEREST: "*MODELING AND ALIGNING MULTI-DOMAIN ARCHITECTURES FOR MEDICAL DEVICES*"

Research within the field of engineering design and product development is primarily aiming at studying the development of products from the first idea to the manufacturing of products. The aim of this research study is to provide insight and support, which can improve medical manufacturing companies' performance. Years ago, primary research focused on development processes with a one-product-at a-time perspective. More recently, increasing attention has

been given to the phenomenon of developing multiple products concurrently and several research communities have contributed to the field of developing multiple products based on modular platform architectures. While looking into the past decades of state-of-the-art literature studies on the front-end part of modular platform architectures, which is the focal point of this research, great potential effects of multi-product design have been identified and quite a few resulting achievements have been reported (Geershenson et al. 2003, 2004; Jose and Tollenaere 2005; Jiao et al. 2007; Fixson 2007; Salvador 2007; Doran and Hill 2009; Campagnolo and Camuffo 2010; Bask et al. 2010; ElMaraghy et al. 2013; Zhang 2015; Pashaei and Olhager 2015; Piran et al. 2015; Otto et al. 2016; Bonvoisin et al. 2016; Frandsen 2017). While looking into the literature, much has been achieved through the last decades, but still quite a lot is still to be investigated – the literature fundamentally declares an eminent need for further research within the field of modular platform-based architectures. Especially, seen from the perspective of developing modular platform architectures as a means for improving competitiveness and reducing complexity within heavy regulated industries, literary contributions still lack maturity in a number of dimensions, namely accounting regulatory requirements as a critical complexity driver and bringing the compliance aspect of developing new products to the front-end of the design process. Overall there is a need for the development of tools and methods that enable quantified decision support in the early front-end synthesis of the modular platform architecture design of medical devices. Therefore, this thesis treats the following:

Front-end design modelling – Systems architecting (Crawley et al. 2004; Hölttä-Otto et al. 2014; Crawley et al. 2015) is one of the topics that treats the early-stage part of the engineering activity, which deal with functional and physical decomposition and integration of system elements. This holistic approach to modeling indicates that regulation, standards and laws should be considered while considering the system architecture. Though, very little effort has been made on investigating the impact of such external influencers. Operational modeling tools are available for architecture- and platform-based product development and are the subject of ongoing research, particularly within engineering design and product development (Harlou 2006; Andreasen et al. 1996; Mortensen et al. 2008; Kvist 2010; Pedersen, 2010). Though, these modeling techniques do not incorporate regulation nor the resulting compliance work as a driver for evaluating architecture-based platforms and product families, which is found to be the main cost driver within the medical industry.

New product modularization – Generally modularization refers to the ability to encapsulate elements and re-use these over a variety of products in a range of products. There exists a thorough consensus of the validity of the methods available for modularization, which cluster functional and structural elements of systems into modules, and optimize designs based on drivers for modularization e.g. cost, time-to-market, product quality etc. (Baldwin and Clark 2000; Eppinger and Browning 2012; Meyer and Lehnerd 1997; Ulrich 1995; Ericsson and Erixon

1999). Much has generally been achieved within the field of modularization, including development of a multitude of products and related derivatives (ElMaraghy et al. 2013; Jiao et al. 2007). However, no driver exists for the encapsulation and re-use of compliance entities (V&V testing and documentation), which here is seen as main catalyst for modularization in the medical industry.

Quantification of new initiatives – Many platform optimization metrics has been developed the past decades. These can generally be separated into two types according to their objective (Simpson 2005): The market-facing metrics and the production-facing metrics. The market-facing metrics include multiple use (Ericsson and Erixon 1999), used variety (Piller 2002), platform efficiency and platform effectiveness (Meyer et al. 1997), and customizable attributes (Blecker et al. 2003). Whereas the production-facing metrics include a variety of so-called commonality indices (Martin and Ishii 1997; Thevenot and Simpson 2005, 2009; Feitzinger et al. 1997; Kota et al. 2000), production process commonality (Blecker et al. 2003), setup duration (Martin and Ishii 1996), capacity utilization (Mueller 2001) work-in-process turnover (Pine 1993), delivery time (Blecker et al. 2003), and multi-criterion evaluation techniques (Otto and Hölttä-Otto 2007). As indicated, numerous indices exist, which can provide useful information regarding the extent of similar and unique elements when developing a family, line or even a program of products. However, these metrics have little applicability in the front-end part of the life-phase system. Further, none of the mentioned optimization indices are targeting compliance as a critical parameter in the quantification of new initiatives, neither have regulatory requirements been a subject to the available evaluation techniques, which has been identified as one of the main complexity drivers in the medical industry.

Alignment and dispositioning – According to the theory of dispositions, the fit between the product design and the product life system determines the overall performance of the product throughout the entire life cycle (Olesen, 1992). Authors such as Sawhney (1998), Andreasen et al. (2004), and Mortensen et al. (2008) shed light on the importance and advantages of aligning products and their life-phases. The product design and the life-phase system should be fitted to each other and/or designed concurrently to achieve optimum performance. Though, most research has been carried out exploring the connection between product and production enabling new product variant creation (Salvador et al. 2002). Little to no research has been done on the alignment between product and compliance meeting with the regulatory requirements, as the key enabler optimizing the performance of the product throughout its life-phases.

Thus, in today's research it is found that an increasing focus is put on how to develop products more efficiently through architecture-based product platform design. Though, very little academic effort has been made targeting the inherent complexity of developing multiple products under regulatory constraints.

1.5 Research Objectives and Contributions: A Response to the Challenges and Interests

The aim of this research is to contribute to and enhance the understanding of the research phenomenon of developing modular product platform architectures under regulatory constraints. Within the medical device industry, manufacturers are under constant pressure to meet new customer needs while complying with regulatory frameworks. Restrictive requirements are set by public authorities, who continuously demand increasing V&V testing and documentation for the approval of new products as well as products already on market. Even though this situation has emerged over years, only few authors have reported about this progression. In addition, although significant research has been carried out on architecture-based platform design and complexity management enabling the development of multi-products, no apparent focus has been on addressing these problematics, and limited emphasis has been put on solving the compliance burden of manufacturers subject to restrictive regulations.

This research primarily focuses on the phenomenon of modelling modular platform architectures for the development of multiple products under regulatory constraints. The fundamental **objectives** of this research are to enhance the platform architecture and product program design body of knowledge by means of (O1 – O3):

O1. Addressing a novel topic to this professional and academic domain, by exploring the phenomenon of requirements and compliance, and the impact on product program design and explore the relation between product and compliance view in new medical device development while investigating the existing solution space to the challenges identified within the industry.

O2. Extending current availabilities within the research field of design science by establishing a product and compliance view of a medical device program, identifying relations between the views, and thereby providing support to model and understand these conditions. Providing targeted support to manufacturers subject to regulatory constraints by means of introducing a modelling tool that incorporate compliance to the analysis and synthesis of medical device programs.

O3. Providing insights into the applications of the research contributions, hereunder show how the proposed tool can be applied for the support and enhancement of traceability across product and compliance aspects of a medical device program, show the utilization of the modelling tool as an analytical instrument for rationalization while illustrate applications of the modelling tool for the front-end synthesis part in the medical device development process based on an empirical case study in industry.

These objectives found the basis for the overall objective of establishing a foundation by which medical manufacturers can efficiently develop and successfully launch medical devices to the global marketplace while staying in control of products already brought to market. In relation to the three research main objectives stated above, more specifically, this research **contributes** with (C1 – C3):

C1. A clarification of the regulation-driven compliance testing and documentation domain providing insight into the key aspects of the phenomenon. Namely, the complexity drivers in medical industry and the multiple cross-domain dependencies in new medical device development. Provide a state-of-the-art literature review of current tools and methods at hand designing modular platform architectures. Provide a literature gap identification creating the foundation for the research.

C2. A modelling tool that enable control of the extensive testing and documentation burden, i.e. evaluating the medical device program based on its complex inter-related dependencies across the product and compliance aspects. A tool, which can be used as support for carrying out cross-domain analysis of dependencies during development and maintenance of medical device programs. Further, enable the tool should enable evaluation of the flexibility and sensitivity towards changing market conditions.

C3. A tool that enable modularization for compliance bringing the compliance aspect of new medical device design to the front-end of the development process. Bringing a new conceptual catalyst for compliance driven modularization to the table, namely the a catalyst for compliance test and documentation reuse that is, by perspective, to enable encapsulation of product design elements for the cross-product variant sharing of compliance test and documentation packages.

C4. A modelling tool that enable the design team to carry out comparative studies quantitatively evaluating new medical device designs and thereby make qualified decisions during the early stages of new medical device development based on time and cost impact caused by compliance work, i.e. a modelling tool for the assessment early front-end concept evaluation based on later dispositioned resource and cost consumption related to compliance test and documentation.

C5. A case study that bring the prescribed generics of the proposed modelling tool into industrial context revealing the benefits of applying such a tool to the front-end processes of a medical device manufacturing business. To show both the analytical and synthesis aspects of using the modelling tool in an industrial context and thereby verify its usefulness.

The objectives and contributions of this research both relate to the theoretical and practical applications. The first objective (O1) and its contribution (C1) seek to explore the theoretical and practical problem, while objective (O2) with its related contributions (C2), (C3) and (C4) seek to solve the challenges identified in industry while closing the gaps in current available design research literature. The last objective (O3) and its related contribution (C5) seek to show the practice applying the contributions (O2), (O3) and (O4) of this research study in industry.

1.6 RESEARCH QUESTIONS

The overall **research question** of this thesis is: *"How can a program of products be efficiently and effectively modeled and synthesized to support medical manufacturing companies?"*. Pursuant to this question, a number of broader contextual questions have been raised following the design research methodology for the staging of this research study. The research questions have been instrumental to the structuring and execution of the research study. Thus, the research questions collectively frame the area of research ranging from exploratory, descriptive questions, to more prescriptive questions (Tab. 1.2).

P#	Purpose		RQ#	Research Question		O#	C#
P1	Understand the medical industry, its challenges and needs.	>	**RQ1.1** **RQ1.2**	What are the challenges of the medical industry, and what are the specific needs of the medical manufacturers? What options does the industry have addressing its challenges and what possibilities do medical manufacturers have meeting its needs?	>	**O1**	**C1**
P2	Establish the required support for medical device manufacturers.	>	**RQ2.1**	How can a medical device program be modelled with regards to compliance test and documentation considering the market conditions of the medical domain?	>	**O2**	**C2** **C3** **C4**
P3	Support the medical industry and the manufacturers' needs.	>	**RQ3.1**	How can modularization of a product architecture be applied to address a medical device company's dependence of regulatory compliance?	>	**O3**	**C5**

Tab. 1.2: Declaration of research purposes (P#), and formulation of the related research questions (RQ#) with the respective research objectives (O#) and derived contributions (C#)

The established research questions have been clustered according to three purposes. The first purpose (P1) is about understanding the medical industry, its challenges and needs, and exploring possible solutions to these, and is subject to the following research questions:

- The first research question (RQ1.1) asks for an understanding of the challenges in medical industry, the phenomena concerning compliance test and documentation in new medical device development. To answer this question, initial surveys followed by detailed discussions, literature study on the subject and finally explorative case studies have been executed in order to get a broad and detailed understanding of the challenges that medical manufacturing companies face in today's world. Further, this research question treats the exploration of product and compliance views from a structural complexity management perspective, clarifying the regulation-driven compliance domain.

- Following the exploration of the challenges and problems, the second research question (RQ1.2) is about getting insights into the solution space readily at hand meeting the identified challenges and thus, is more prescriptive by nature. The research question attempts to shed light on the specific elements of this research area that could accommodate the situation. The question is answered based on a review-based literature study. Hence, this study primarily focusses on the predominant tools and methods available. It attempts to lay the foundation for gap-identification and meanwhile identify if opportunities exist for meeting the challenges identified within the medial domain.

The first two research questions (RQ1.1 and RQ1.2) addresses the first research objective (O1), namely, to treat a novel topic to the professional and academic domain, by exploring the compliance testing and documentation impact on new medical product development and investigating the existing solution space to the challenges identified while contribution (C1) is made clarifying the phenomenon under investigation from a modelling perspective. Following the initial exploration loop, the second purpose (P2) of this research study treats the establishment of the support that seek to help manufacturers within the medical domain and imply the following:

- The second research question (RQ2.1) is prescriptive and is about creating a holistic modelling tool that explores the dependencies identified. It builds on well-known methodology to capture and manage diverse domains, while it extends the current methodology by providing a new applications that enable medical device program analysis, the second contribution (C2) of this research. Further, it seeks to develop and apply a new catalyst for modularization that is to enable re-reuse of test and documentation packages, the second research contribution (C2). Meanwhile, it provides

a modeling tool that enables early front-end concept evaluation based on later dispositioned resource and cost consumption related to regulation-driven test documentation, the third research contribution (C3). The research question and its subsequent contributions is sought answered by detailed discussions with industrial practitioners while carrying out case studies in industry, which together found the basis for answering the question.

The above research question (RQ2.1) addresses the second research objective (O2), namely extending existing research by providing a new to the world support for the analysis and synthesis of product programs subject to regulations and subsequent compliance testing and documentation. The objective is to provide extensive support to manufacturers subject to restrictive regulatory requirements by means of introducing a new methodological approach to modular platform architecture development. The last purpose (P3) is about showing how the proposed support can help the medical industry and the manufacturers' needs. To guide this purpose, the following research question has been raised:

- The last research question (RQ3.1) is descriptive by nature and is to demonstrate implementation and applications of the tool developed resulting from the second research purpose. It identifies readiness / utility level of the tool developed, and at last it provides verification of the method. This question is answered through logic deduction from existing review-based literature study on theories within design science as well detailed discussions with relevant experts and finally by executing a case study in industry, which together found the basis for answering the question.

This research question (RQ3.1) addresses the third and final research objective (O3); namely, to provide insights into the applications of the research contributions hereunder show the utilization of the support that is to be developed, both as an analytical tool for rationalization of medical companies and show applications for the front-end synthesis of new medical device development based on empirical studies in industry.

The research study is conducted based on a basic assumption about the design process for medical devices, and the need for making decisions in an environment where many different stakeholders are involved, and design efforts span a multitude of subjects:

A1. Explicit and quantitative modelling of modular platform-based architecture for compliance test and documentation enables better decision-making regarding the design of medical device programs.

Developing architectures for medical devices requires handling of a wide range of requirements by many different stakeholders involved with the design of both the architecture and subsequent compliance test and documentation based on the architecture. The assumption states that

explicit modeling by visual means enhances the medical manufacturer's ability to absorb and complex design problems and allow for thorough decision making.

1.7 RESEARCH SCOPE

The research study has both a theoretic and practical scope that guides the research activities. The scope of this research is not to solve all the identified business challenges or address every aspect of the academic interest, but to contribute with insight to the phenomena that can be of benefit to both academia and business. In order to do this, this research seeks to develop and test a modelling tool that aim at supporting this growing request from both academia and industry. This research primarily focuses on the phenomenon of modelling modular platform architectures for the development of medical device programs under regulatory constraints providing the above-mentioned research contributions.

1.7.1 THEORETICAL SCOPE

The theoretical scope of the thesis is founded within engineering design science. However, being a composite area of research there are very strong links to the management of structural complexity management as well as product sale, marketing and product planning, as the benefits of successful implementation of architectures and the subsequent initiatives are to be harvested across adjoining parts of the value chain and product program life-phases, i.e. the compliance aspects of bringing new medical device variants to market while maintaining the product program and its derivatives already brought to market.

Therefore, it is relevant to include the theoretical literature revealing the predominant tools and methods derived from these disciplines. In terms of excluded theory, although being closely related, the areas of organization theory and decision theory are outside the theoretical scope of the thesis. Minor parts of business and market strategy theory have been included to get insight into the staging of platform architecture modeling and strategic positioning of such platform thinking.

1.7.2 PRACTICAL SCOPE

The case companies included in the research work are all chosen to cover a wide spectrum of European industrial companies – all exclusively operating within the medical domain. The companies operate across different product ranges, i.e. consumer goods, laboratory equipment, healthcare equipment, analytical instruments, implants, diagnostics, combination products, and surgical instruments.

The companies vary in business type in the sense that they address both consumer and professional markets. The case companies are largely product-based and thus tend to develop a range of commercial variants of which they have complete control. The reason for choosing companies with such characteristics is that project-based companies tend to develop solutions to match specific requirements from customers resulting in customers retaining the final specification and design, which is not suitable for this research setup, where direct access and changeability is key to the success of proving the research results. Further, within the medical industry, companies tend to run by product and not project given the nature of this industry.

1.8 AREAS OF RESEARCH AND CONTRIBUTION

The approach introduced in this thesis is a result of a combination of concepts, methods and techniques which originate from several different scientific disciplines (Fig. 1.4).

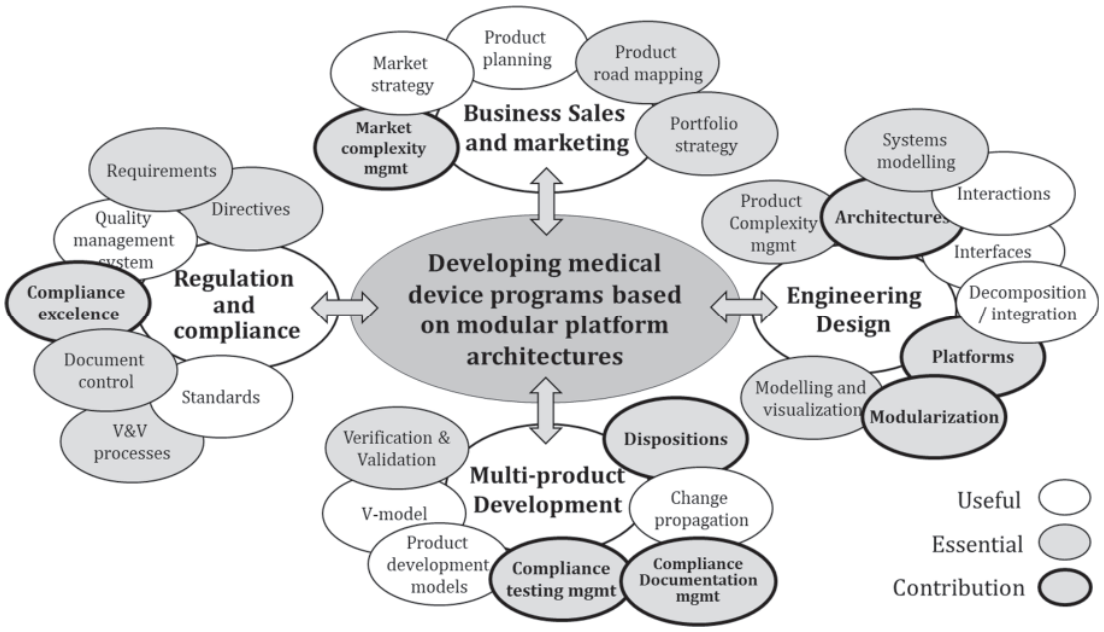


Fig. 1.4: Areas of research and contribution, based on the formalism by Blessing and Chakrabarti (2009)

The main areas of this research are founded within engineering design, multi-product development, regulation and compliance, and business sales and marketing. The main contribution of the thesis relates to the intersection of these four areas. The model is rather subjective and is solely intended for the illustration of the positioning of this research study relative to existing areas of research.

1.9 DELIMITATIONS OF THE RESEARCH

Despite the relatively broad scope of the study, the thesis is a result of a research project with definite time and resource constraints, which implies several delimitations:

- The empirical studies are only carried out in medical manufacturing companies with a strong engineering focus, disregarding other areas such as organization, human factors, socio-technical aspects, etc. are out of scope of this research.
- Investigating the medical domain, only medical devices are considered. Thus, offerings such as pharmaceuticals are not a part of the research. Combination products in the sense of medical devices that interact with biomaterials, pharmaceuticals, drugs etc. are considered, but only from the medical device perspective.
- The research study focuses on the earlier part of the life-phase system, i.e. market, product, verification and validation tests, and the related documentation. The research study, the cases which have been conducted, do not treat back-end issues per se, i.e. production systems, supply chain systems, deliveries, and maintenance. The study does not include new technology development projects.
- Business sales and marketing aspects, such as market share, promotions, competitive landscaping and price strategies are not considered central to the research. Only customer preferences, use activities and market targeting is considered conceptualizing the contributions of this research study.
- Regulation, standards and directives are mainly considered in the United States and European Union, others such as China and Japan are considered, but not treated in depth. All other regulatory substances are disregarded this research study.
- Methodologies for engineering change propagation and management are not considered thoroughly, but still considered as related methods are targeting specifically the support of engineering design and product development.
- The empirical investigation is performed with industry partners located in Europe, which depending on the nature of their products and strategic initiatives partly operate globally.

1.10 STRUCTURE OF THE THESIS

This section provides an overview with the structure of the thesis. The overview is provided to guide the reader thorough the research work presented in this thesis (Fig. 1.5).

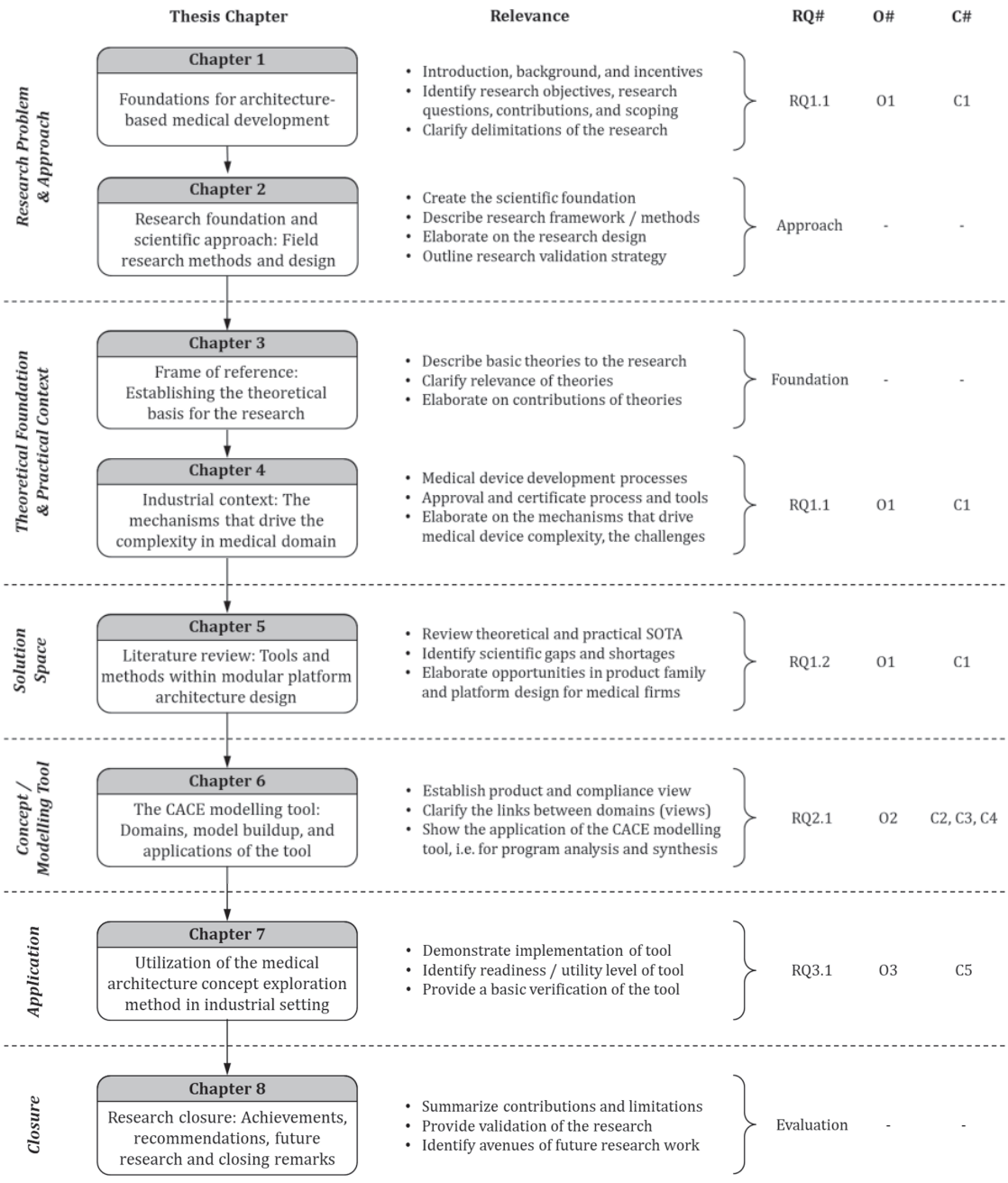


Fig. 1.5: Overview of the thesis

"Gedanken ohne Inhalt sind leer, Anschauungen ohne Begriffe sind blind."
– Immanuel Kant

Chapter 2

Research Foundation and Scientific Approach: The Field Research Methods and its Design

The objective of this chapter is to (1) describe the research field study, hereunder (a) to give an introduction to the research methods used, their interconnections and implications on the research foundation, and (b) to introduce the research design of the study conducted and the research activities. Further, this chapter describes (2) the verification and validation strategy of the research, the justification challenges, its conduct, and its implications on the research.

2.1 Introduction to Field Research

This research can broadly be framed as a descriptive effort, aiming at clarifying the challenges within the medical domain upon which a modelling tool is proposed by which manufacturing companies, who develop products under regulatory constraints, can efficiently design multiple products and bring these to the marketplace, and thereby achieving shorter time-to-approval by the public authorities. A number of potential research methods exist supporting such a research study, which have been applied in this research (see 'Research Methods'). The research design chosen for this research study follows the design research methodology by which a mixed methods approach has been applied (Greene et al. 1989), where both qualitative information based on interviews and qualitative data obtained from databases has been collected from projects investigated during the case studies at the different stages of the research. Information applied in this research has been gathered from diverse sources, both of practical and theoretical substance. Collectively an explorative collection of data has been composed (Yin 2009) – from

descriptive study, over prescriptive study, to final descriptive study conducted during this research (see 'Research Design and Activities').

2.2 Research Methods

As described, the aim of this research is to contribute to and enhance the understanding of the research phenomena of developing product platforms based on modular platform architectures, which according to Hubka (1976) and Roozenburg and Eekels (1995), can be achieved by means of modelling the design and the engineering process. This research belongs to the class of applied research, where at least two objectives are set, i.e. a theoretical and a practical objective (Ropohl 1971).

Various methods have been applied given the nature of the phenomenon, all belonging to the area of applied research, though with different focus points all relevant to this research study. This section presents the research methods used in this research study.

2.2.1 Problem-based and Theory-based Research

Jørgensen (1992) describes research as being both problem-based and theory-based, and hence may have different starting points for reasoning (Fig. 2.1). Given the nature of the research area, the problem-based part, is realized by participation in industrial projects (case studies) and continuous correspondence with the companies through detailed discussions.

By analyzing empirical data and mapping the phenomena linked to the research area, a diagnosis is to be reached, and by synthesizing solutions addressing the phenomena explored during the diagnosis, a new scientific discovery may be achieved. The theory-based aspect has to do with the involvement in academia. Through the application of research methods, a new theory or model of understanding can be synthesized, and by bringing this new research contribution to practice it is possible to state its usefulness to the real world, and if so, a new scientific discovery can be achieved. Hence, this research study has taken an iterative process approach to reach new research results.

The research method suggested by Jørgensen (1992) is rather sequential in its format, but in reality and so with this research, several loops between analysis and synthesis have been taken, and so with the problem-based and theory-based part of this research method. Through a continuous interplay between the two during the research study, new scientific discoveries are to be achieved and consensus can be reached in industrial practice and so in academia.

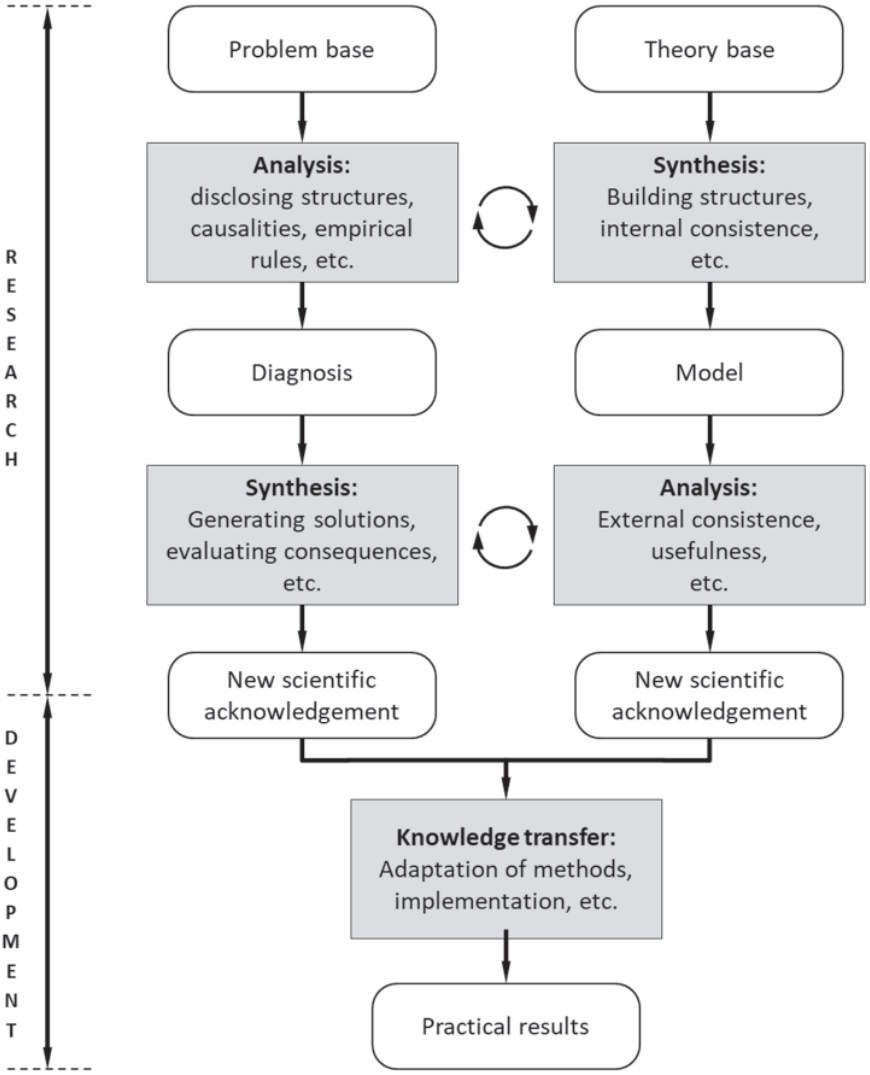


Fig. 2.1: Work paradigm for research and development activities recognizing the interaction between theory and practice in scientific research, adapted from Jørgensen (1992)

In this research, the problem-based research is applied by means of an actions research approach (see 'Actions Research'), which is based on not only having an interest to observe, but also to influence and control real-life cases under investigation (Harmsen 1994). Meanwhile, the theory-based research is applied by means of the critical rationalism approach, where existing models and methods are enhanced in order to give a better description of the empirical reality behind the phenomena, which can be achieved through literature studies, logical reasoning, empirical observations, etc. (Mørup 1993). As described, both the problem-based and theory-based aspects of the method have been applied this research.

2.2.2 Actions Research

The actions research approach belongs to the class of qualitative methods and is characterized by the researcher taking an active role and being actively involved in the environment where the research takes place. Dahler-Larsen (2007) states three main motivations for using a qualitative method: (1) the area of study is still relatively unexplored, (2) the area of study is composed and complex, or (3) the area of study is part of a cultural construction that has been created by the area of study itself. The actions research approach has been followed during this research as it aims *"to contribute both to the practical concerns of people in an immediate problematic situation and to the goals of science by joint collaboration within a mutually acceptable ethical framework"* (Rapoport 1970).

In actions research, improvement and involvement is central elements (Robson 2011) and the emphasis is on the researcher acting, which is different from the objective researcher, who passively studies the action (Coughlan and Coghlan 2002). Thereby, the researcher has a dual role, being active participant changing the system and meanwhile generating critical knowledge about that system (Middel et al. 2006).

According to Checkland and Holwell (1998), the preliminary elements of relevance (Fig. 2.2, a) are driven by research containing a framework of ideas [F], which is based on methodologies [M], and these are then applied in the area of concern – the real world problem situation [A], which eventually generates learning about the area of concern, the methodologies, and the framework of ideas. With this newly gained knowledge, the researcher enters the actions research process with research themes (Fig. 2.2, b). Taking its point of departure in the problem situation, the researcher establishes its role in the context, while having declared [F] and [M] from the preliminary study.

The researcher acts in the situation by taking part in the change process, the researcher reflects on the involvement based on [F] and [M], which eventually leads to new research themes and findings. In this research study, the preliminary establishment of methodologies (Fig. 2.2, a) has to a large extent been developed along the research study and therefore at this point deviate from the suggested approach. The methodology development has been developed during the actions research process (Fig. 2.2, b). Thus, generally the approach has been followed swapping between the preliminary elements and the actions research process.

Coughlan and Coghlan (2002) provide a useful explanation of the underlying continuous actions research cycle (Fig. 2.2, c), which consist of: (1) A preliminary step, which has the purpose of getting to know the context, (2) gather, give feedback and analyze the data, and after which the action is planned, implemented, and at last evaluated, and (3) the meta-step, which is concerned about monitoring the process, which based on the work by Lewin (1946), can be described as the ongoing action-reflection cycle (McNiff 2013).

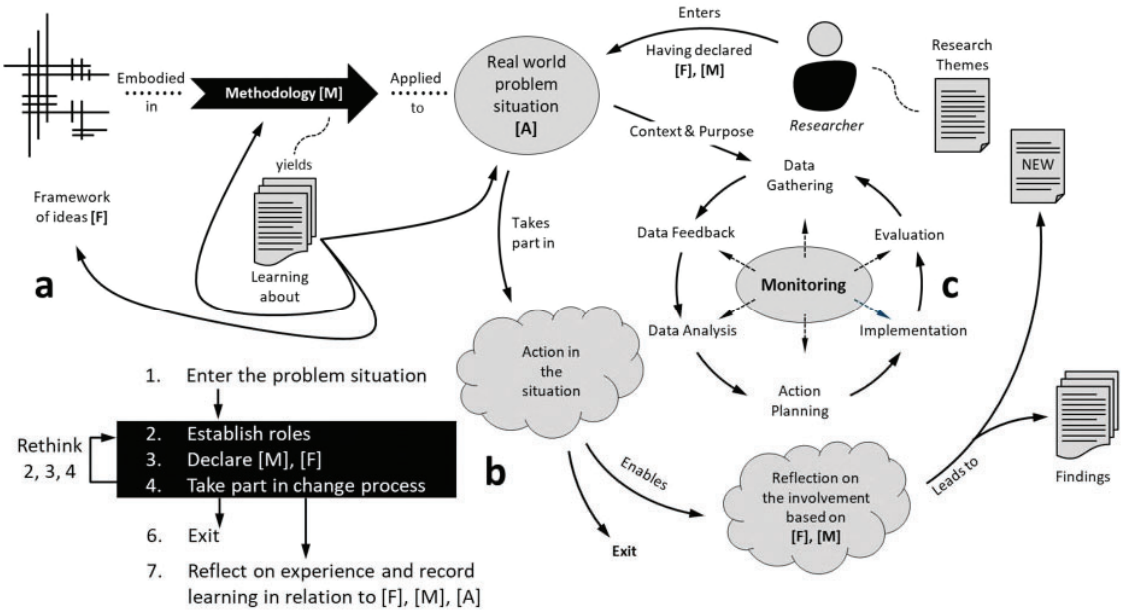


Fig. 2.2: Actions research. From left: (a) the preliminary elements relevant to the research, (b) the actions research process, adapted from Checkland and Holwell (1998), and (c) the underlying continues actions research cycle, adapted from Coughlan and Coghlan (2002)

In alignment with the overall actions research process described by Checkland and Holwell (1998) and in accordance with Coughlan and Coghlan (2002), Kemmis and Wilkinson (1998) describe the actions research process as a spiral of cycles. This spiral of cycles propose an iterative process, which reflects the aim of the design research methodology, where iterations build on the previous one, i.e. the actions research cycle is comparable to the iterative process of swapping between the descriptive and the prescriptive stages of the design research methodology suggested by Blessing and Chakrabarti (2009), increasing the knowledge base with each iteration (see 'Research Approach').

The actions research cycle iterations in this research study comprised sequential data gathering, data feedback from participants, analyzing data, planning action, acting and evaluating the effects (Coughlan and Coghlan, 2002).

Performing such real-world research within the design research methodology framework, is also acknowledged by Blessing and Chakrabarti (2009). The actions research approach is applied with regards to the problem-based paradigm of the applied research framework by Jørgensen (1992), to which this research belongs.

2.2.3 CASE STUDY RESEARCH

Through a smaller amount of cases, this research seeks to clarify the nature of a broader phenomenon. A multiple-case study format has been chosen for investigating the phenomena, as case study research is useful when investigating contemporary phenomena in their real-world context and benefit from theoretical propositions for guidance (Yin 2009). Evidence from multi-case design can be considered more robust (Herriott & Firestone 1983), but rationales from single case designs cannot usually be satisfied by multiple cases (Yin 2009).

As the name suggests, a multi-case analysis consists of several individual cases conducted independently and sometimes in parallel (Stake 2006). In this research, some case studies have been conducted independently, but most have been conducted in parallel including continuous interactions of the numerous assistants (engineering master thesis students with mechanical and management engineering background), who have helped gathering data in the case studies. Following the case studies, a cross-case analysis is performed on the individual cases in order to produce cross-case findings enhancing the understanding of the phenomenon under investigation.

In this research, generalized findings about the high-level themes have been emphasized over the unique aspects of the individual cases. The individual cases have contributed to the high-level themes while also providing specific examples in support of generalizing the observations. The high-level case study process has entailed both overall study design, case selection, individual case study execution, and cross-case analysis (Fig. 2.3).

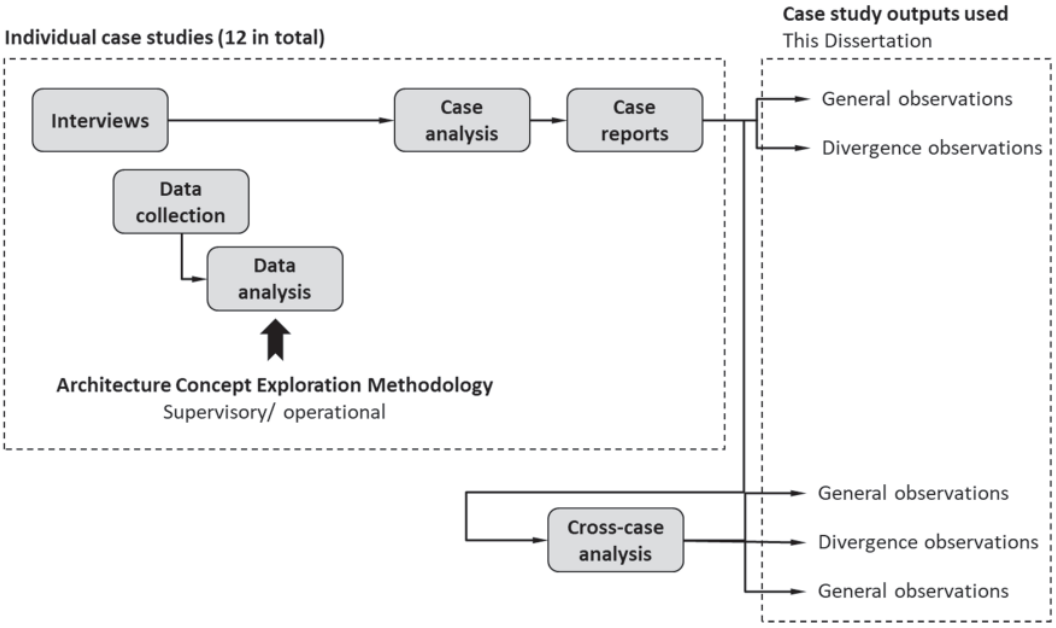


Fig. 2.3: Basic case study research process flow diagram as of this research study

Outputs from the individual cases included confidential case study reports for each participating company and non-confidential versions released to the public domain that are to be presented in the next volume of the 'Radikal Forenkling via Design' ('Simplimize', Eng. ed.) booklet. The cross-case analysis has led to general observations and contributed to the more detailed descriptions and development and testing of a modelling tool that meet the challenges identified during the research clarification phase of this research study.

2.2.4 DESIGN RESEARCH METHODOLOGY

The design research methodology proposed by Blessing and Chakrabarti (2009) provides a holistic framework for carrying out an engineering design research process. Design science is generally a very broad field and may cover different scientific disciplines driving the complexity of carrying out such studies, which makes it difficult to pursue (Blessing and Chakrabarti 2009). The design research methodology, however, outlines a structural way of doing engineering design research based on several iterative phases (Fig. 2.4).

The framework seeks to link the research questions and bring these into a process by which these are to be addressed in a systematic way. Because of its holistic approach to scientific research studies, this methodology has been applied designing and planning this research (see 'Research Design and Activities').

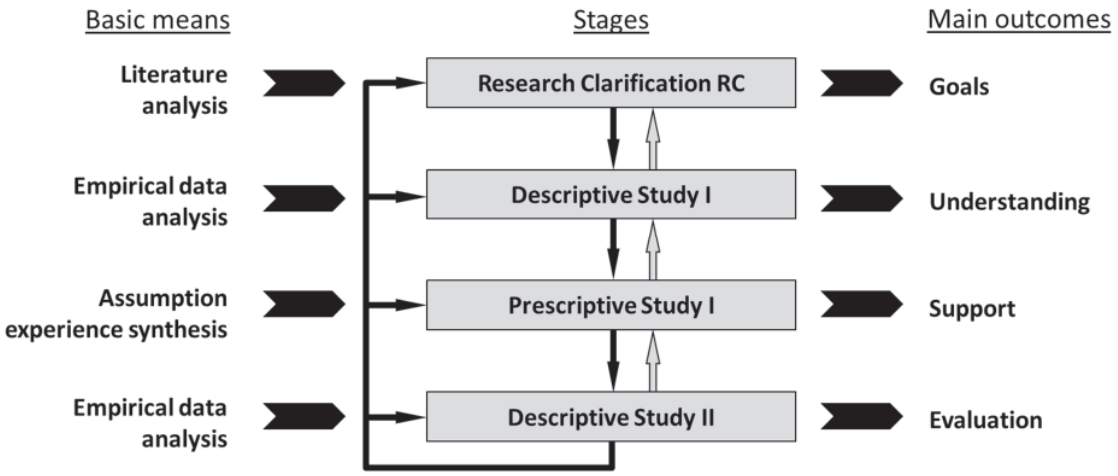


Fig. 2.4: The design research methodology framework, adapted from Blessing and Chakrabarti (2009)

The research clarification phase intends to support researchers in finding evidence to support an initial assumption in order to formulate a research goal and make an overall research plan. The main outcome of this stage is formulating the existing situation and to define a description

of the desired situation, including research goals and the criteria against which the research can be evaluated.

In the descriptive study I stage the researchers review the literature for more influencing factors to elaborate the initial description of the existing situation and to identify the factors that influence the preliminary described situation. This provides a basis for the effective development of support that addresses those factors that have the strongest influence on success.

The prescriptive study I is used for synthesizing support which will improve the existing situation and lead to the realization of an improved situation, by addressing one or more influencing factors. Here the actions research approach (Middel et al. 2006) is applied, where the intension is to affect the situation under investigation and generate critical knowledge about it (see 'Actions Research') and is achieved by means of case study research (see 'Case Study Research'). The intended support must be realized to such a degree that valuation can take place.

In descriptive study II the impact of the support is validated, and necessary improvements are identified. Thus, this stage closes the first round of design research by clarifying the foundation for initiating a second loop of the methodology.

2.3 Research Design and Activities

The following section will describe the main research activities in relation to the above-mentioned research methods applied this study. The research study has followed the design research methodology (DRM) proposed by Blessing and Chakrabarti (2009) as it provides a holistic framework for the engineering design research process, which this research study has taken greatly part in.

As this design science research initially has had a broad scope of investigation and through the research study has encompassed different scientific disciplines, driving the complexity and diversity of the research, the design research methodology proposed by Blessing and Chakrabarti (2009) has been followed as it outlines a structural way of doing engineering design research based on a number of consecutive phases with specific levels of detail (Fig. 2.5).

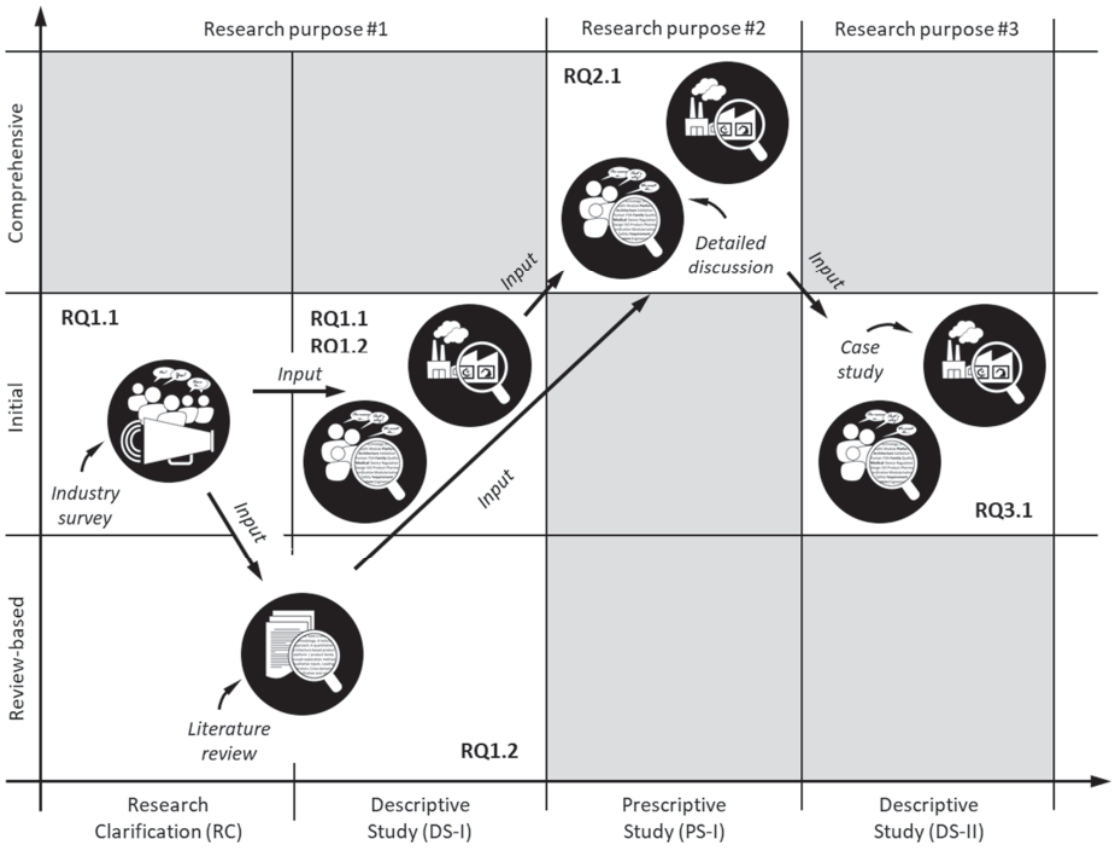


Fig. 2.5: The design research project and its focus during the process based on the design research methodology framework (Blessing and Charkrabarti 2009)

As the illustration above indicates, the four main activities that have been incorporated during the research project along the different research phases are:

Broad survey – An initial broad survey has been carried out in the beginning of the research study so as to clarify the challenges and opportunities that could be pursued along the study – it has had both synthesis and rationalization aspects applied to it in order to shed light on critical aspects and their impact within the frame of the project (see 'Broad Survey'). Thus, the survey supports the first research purpose: "Understand the medical industry, its challenges and needs" and specifically seeks to answer the first research question RQ1.1: *"What are the challenges of the medical industry, and what are the specific needs of the medical manufacturers?"*.

Literature review – Review of current tools and methods readily at hand have been executed during the initial research clarification, while it has supported the first descriptive study. The objective of the review has been, continuously, to use existing literature to guide this research study while evaluating related research against the objective of this research study. The literature review supports first research purpose to understand the medical industry, its

challenges and needs, while it specifically seeks to answer research question RQ1.2: *"What options does the industry have addressing its challenges and what possibilities do medical manufacturers have meeting its needs?"* and thereby supports the first contributions of this research, namely to reveal the current solution space meeting the challenges identified in industry.

Detailed discussions – In this research, discussions are characterized by the direct interaction with research participants, being both informal and more formal (interviews). These have been conducted both to clarify the situational awareness of the case companies – to get in-depth insight into various aspects related to the different research study stages – and to get immense insight during the research process, from the first descriptive study (DS-I), over development of the proposed tool during the first prescriptive study (PS-I), to establishment of validity of the results obtained during the second descriptive study (DS-II). Domain experts have played a central part to the development and finally the verification of the proposed modelling tool along the research journey (see 'Detailed Discussions'). Thus, detailed discussions have supported all research questions of the thesis, namely RQ1.1, RQ1.2, RQ2.1 and RQ3.1, and thereby have laid the foundation for reaching consensus about the overall research question of this thesis: *"How can a program of products be efficiently and effectively modeled and synthesized to support medical manufacturing companies?"*.

Case studies – Cases have been executed industry from the first descriptive study over the following prescriptive study to the final descriptive study. Case studies have played a serious role in shaping the research clarification and so, the final contributions (see 'Case Studies'). Like with the detailed discussions, the case studies have been carried out along both descriptive study (DS-I), the first prescriptive study (PS-I), and during the second descriptive study (DS-II). While this is the case, it should be noted that the predominant number of cases have been carried out during the two latter stages of the research study. Hence, the case studies have primarily been focusing on answering research question RQ2.1: *"How can a medical device program be modelled with regards to compliance test and documentation considering the market conditions of the medical domain?"*, and research question RQ3.1: *"How can modularization of a product architecture be applied to address a medical device company's dependence of regulatory compliance?"*.

As the illustration (Fig. 2.5) shows, the DRM methodology has been used to guide the research study and indicates that the process has been highly iterative throughout the study. The following sections provide more detailed descriptions of the activities conducted in relation to the broad survey, detailed discussions and case studies.

2.3.1 BROAD SURVEY

The research was set out by an initial investigation with the main objective to clarify the challenges that medical manufacturers face when developing new products and maintaining products already brought to market. Along with a literature review shedding light on the challenges from an academic viewpoint, the results have been obtained using a broad survey (Kelly et al. 2003) that had both a synthesis (growth) and an analysis (rationalization) dimension to it.

In total 12 companies were contacted with the aim of clarifying specific elements of dimensions crucial to the profitability or health of the companies running medical businesses. The companies surveyed were manufacturers of a broad spectrum of products, i.e. diagnostics, combination products, biomedicals, surgical instruments, implants, analytical instruments, health care equipment, laboratory equipment, and consumer goods (Fig. 2.6).

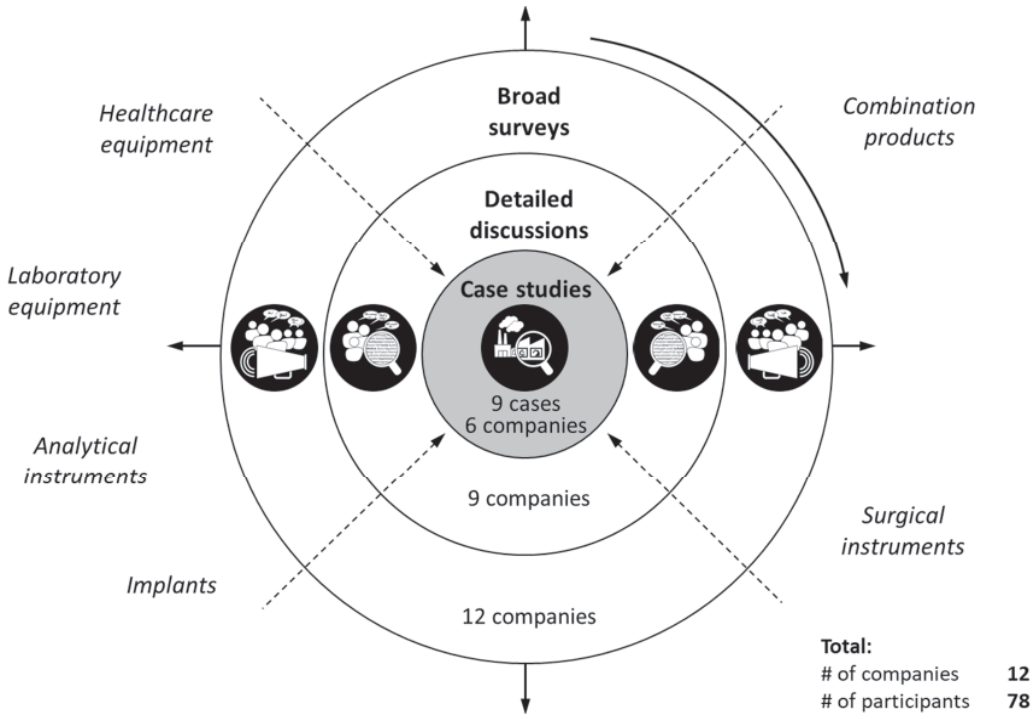


Fig. 2.6: Spectrum of product groups covered within the different levels and/or stages of the research study

The survey contained a broad variety of questions that were to set off the research. The questions additionally formed the basis for the requirements list during the company screening process used in selecting the case study companies (see 'Company Screening Process'). In general, the questions can be grouped into seven main areas of clarification based on, but not necessarily limited to, the DTU Simplimize approach described by Mortensen et al. (2012):

1) *Organization* – The structure, communication channels, and the organizational arrangement are all important parameters when investigating the efficiency of a company. Further, these parameters are subject to regulatory interests, and therefore of relevance when clarifying the subject matter.

2) *Market* – The medical market base is two-sided, at one the customer needs, while at the other the regulatory requirements – both to be met in order to successfully establish and maintain market manifestation. From local, over regional, to global appearance are important considerations, as so with the trends and tendencies of the markets. These factors influence the regulatory requirements to which the company must comply.

3) *Product program / portfolio* – The complexity of the product program, measured by number of products and technology base of these as well as the disciplines involved are subjects of interest when clarifying the challenges faced by the company – both for new product development but also maintenance of existing products.

4) *Production and/or supply chain* – The manufacturing disciplines, its arrangement and structure are subject to regulatory enforcement and are therefore important to this research study. Further, this dimension is crucial to investigate while this can give clear indications of the back-end health of the company. Besides the purpose of obtaining general information, the questions asked mainly concerned backfire issues that were related to upkeep with regulatory requirements of the product program.

5) *Key processes* – the key processes focus mainly on the regulatory influencers when handling new product development as well as maintaining the existing product program. Thus, this subject spans across the different disciplines of the company. Processes are to be established to the satisfaction of regulatory authorities and therefore are of interest to the clarification of the phenomenon.

6) *Data and documentation* – the data and documentation handling of a company is crucial to a company's ability to stay on the market within the medical domain. Documentation is to be thought as a codified mirror of the goodness of the process of a company. Thus, this is an important subject matter to the regulatory authorities.

7) *Economic performance* – the economic performance of a company is important when getting to understand the challenges of the business. Here, more specifically the budgeting, resource allocation and the costs compared to scope of initiatives have been in focus in order to get insight into present and future stance of balancing these delicate parameters. The economic performance does not exclusively relate to the medical domain, though while asking the companies, the regulatory and related test documentation effort played a central role.

Based on the results obtained through the *broad survey*, *detailed discussions* have been executed with nine of the twelve companies surveyed along the research study. After which, seven of the nine companies have participated as *case study* companies, where a number of projects have been investigated – in total, twelve case studies have been executed. During the entire research study, multiple employees with different backgrounds, 78 in total, have contributed as research participants to this research study.

2.3.2 Detailed Discussions

Detailed discussions with participants have been conducted so as to clarify 'in-depth along the way' questions that were not covered within the broad survey nor related to a specific project (case) under investigation, but rather subjects that arose in-between and were important in regard to answering the research questions of this study. In interplay with detailed discussions, the empirical findings have been obtained by pursuing a case study methodology (Eisenhard 1989, Flyvbjerg 2011, Yin 2009), which is claimed to have a distinct advantage when conducting research posing "how" and "why" questions and because it allows the researcher to retain holistic and meaningful characteristics of real-life events (Yin 2009). Further, case studies were chosen for their ability to capture rich descriptions of the problem. As Yin (1981) states, case studies are appropriate when *"the boundary between phenomenon and context is not clear"*, which is suited this examination, given the multitude of other sources of influencers on the subject, and the complexity of developing product programs and bringing the derivatives to the marketplace (see 'Case Studies'). The 78 research participants from twelve companies contributed in this research study from initial clarification, over development, and finally test of applicability of the proposed methodology in a multi-stage iterative research process. The research participants were selected along the research study having different backgrounds representing specific disciplines of interest to the research while situated at various organizational levels of the participating companies.

2.3.3 Case Studies

As mentioned earlier, this research applies a mixed research methods approach (Greene et al. 1989), where both qualitative data from interviews and qualitative raw data has been collected from projects investigated during the case studies at the different stages of the research. Further, the case study research uses multiple sources of evidence in the individual case studies to reach insightful understanding of the cases. As Yin (2009) characterizes, specific sources of evidence i.e. documentation, archival records, interviews, direct observation, participant observation, and physical artifacts, has certain strengths and weaknesses which is why multiple sources have been used during the case studies.

Relevant qualitative information about the current situation and company performance, e.g. market insights, the product functions, their building blocks, the regulatory influence and quality assurance efforts needed for new product development etc. has been obtained through detailed discussions (interviews) using the guidelines proposed by Kvale (1996).

Central quantitative data about the company has been selected by entering documentation and archival records, e.g. voice of the customer inscriptions, quality documentation, standardized operating procedures, product data and documentation, clinical trial documentation, bill of material, production setup and figures etc. These have been collected by accessing the case company's databases, enterprise resource planning system and quality management system. A central aspect to the case studies have been, at least preliminary, to investigate the physical artifacts under development (mockups, prototypes, trail products) and products already introduced to market. This together with obtaining in-depth knowledge about sales and marketing of the products to come (referred to as the portfolio pipeline) through direct observations and interview of the marketing personal, has provided a rich insightful understanding of the front-end challenges of the company.

Through one-to-three-day workshops, alignment within each case company as well as across individual case companies has been reached by undertaking a participant observation role, where different research participants have shared knowledge so as to give a rich understanding of individual cases as well as putting these into perspective of other companies (continuous cross-case analysis), i.e. by applying the philosophy of kaizen (Maurer 2012). The workshops held within each company were executed to reach commonality in information streams across multiple departments, i.e. quality assurance, regulatory affairs, sales and marketing, research and development, transfers and controlling, operations, etc. within the case company. Additionally, the workshops were used to align strategic decisions with the operational level of the company testing the proposed salvations suggested in this research. The workshops have been held with invited research assistants and representatives of the different participating companies to increase the learning curve of the individuals bringing the case studies forward. Moreover, these workshops have been a central part enabling continuous cross-case analysis, which has provided knowledge and description of the high-level themes of the phenomenon investigated in the research study.

Summing up, mixed methods have been applied both of qualitative and quantitative substance while multiple sources of evidence have been used to provide a rich and insightful understanding of the individual cases, while workshops have been held in order to align individual cases as well across the different case companies.

Case Company Screening Process

In total 12 companies were contacted with the aim of participating in the survey, out of which three were located out of personal reach within this research study. Thus, out of the twelve medical companies who participated in the survey, nine companies were approached with the purpose of conducting case studies, by which seven gave their formal acceptance.

The companies were contacted receiving a motivating letter with a description of the proposed case research along with a requirement check list set for participating case companies – the companies were formally invited to a preliminary meeting with the aim of establishing the foundation for participating in the case study research. All nine companies accepted to contribute to the research by participating in detailed discussions contributing to the research study out of which seven accepted to participate as case company. Thus, two rejections were received from companies who were unable to meet the requirements set for participating as case company in the research study. In one case, the CTO (the main source of R&D-related data) of a small medical company would be absent around 80% of the time during the case study period, which was unsatisfactory for either part. In the other case, the rejection was received from the R&D Director of a large-scale medical company owing to an upcoming acquisition of the business. The acquisition was believed to influence the entire organizational structure of the company and thereby affect the ability to obtain essential data from relevant personals of the different departments.

The high acceptance rate for participating as case company in the research study gave yet another good indication of the importance of the topic to the industry: The medical industry is interested in the topic of designing platform-based product families as they are challenged with the ability to execute multi-product development under regulatory constraints.

The smaller sample of companies were selected out of a larger population (an entire industry) based on their characteristics suitable to the research study. Two parameters were important to the selection, namely (1) the size of the company and (2) the level of the company's technology base (Fig. 2.7, a). This has been of immanent importance in the clarification stages of the research, so that issues could be covered representative to the larger population, which this research should justify. First, in relation to the size of the company, it is important when conducting this research to include diverse sizes, from small over medium-sized to large-scale companies, so to investigate the implications of sizing when developing multi-products. Though, no matter the size, the company should have a global reach – the reason is that regulatory requirements as of customer needs fluctuate over geographical markets, and this raises the complexity of launching products at a global base – an important implication of developing products in today's world. Second, the level of technology base has something to do with the inherent complexity of the product program and the new variants to be developed – while

multidisciplinary development raises the complexity, regulation tightens while complexity raises – another important subject in this research. Hence, the smaller sample of companies should be representative to the industry justifying the results of the research. While the companies have been selected with their characteristics in mind, the cases that have been selected within each company having their specific proportional characteristics (see Case Selection') in order to cover a representative mass of companies and cases covering a satisfactory population (Seawright and Gerring 2008), ideally the industry as a whole.

Case Selection

Cases have carefully been selected, undertaken a purposive case selection, so that these could represent the broader phenomenon (Gerring 2004), but as Gerring (2007) states, choosing well (representative) cases for a smaller sample is quite a challenging task – and so it has been. Chosen cases should ideally constitute (1) a representative sample, and entail (2) a useful variation on the dimensions of theoretical interest (Seawright and Gerring 2008). So, like the companies have been screened thoroughly (see 'Case Company Screening Process') the individual cases have carefully been selected representing the phenomenon to be investigated in view.

As Seawright and Gerring (2008) argue, the case selection and case analysis is tangled together during the case selection process when conducting small-*N* case study research – the researcher must set out the agenda as a prerequisite for the choice of cases during the case selection process. This has been the case for the research conducted throughout the research study presented in this thesis. Cases have been selected depending on the cross-case characteristics of the cases – how the individual case fits into the theoretically specified population. The cases have been selected so that they entail relevant dimensions of the phenomenon under investigation, and these have been separated into the multi-stages of this research, i.e. some cases have served as clarifying studies, others the development of methods, while the last have taken the role as utilization cases testing the applicability of the methods developed along the research, all being a part of an iterative process (see 'Individual Case Studies').

As multi-product (or product portfolio) development is the core subject of this research, the main focus has been on the front-end issues (Fig. 2.7, b), but two initial dimensions were important when selecting cases within the companies, (1) the assumed classification of the future medical products to be developed and (2) the issues treated, being it front-end or back-end related challenges. These dimensions were chosen based on the influencing that these have on new product development in medical industry, while these characterize the challenges (of different nature) that might occur during portfolio development of future variants.

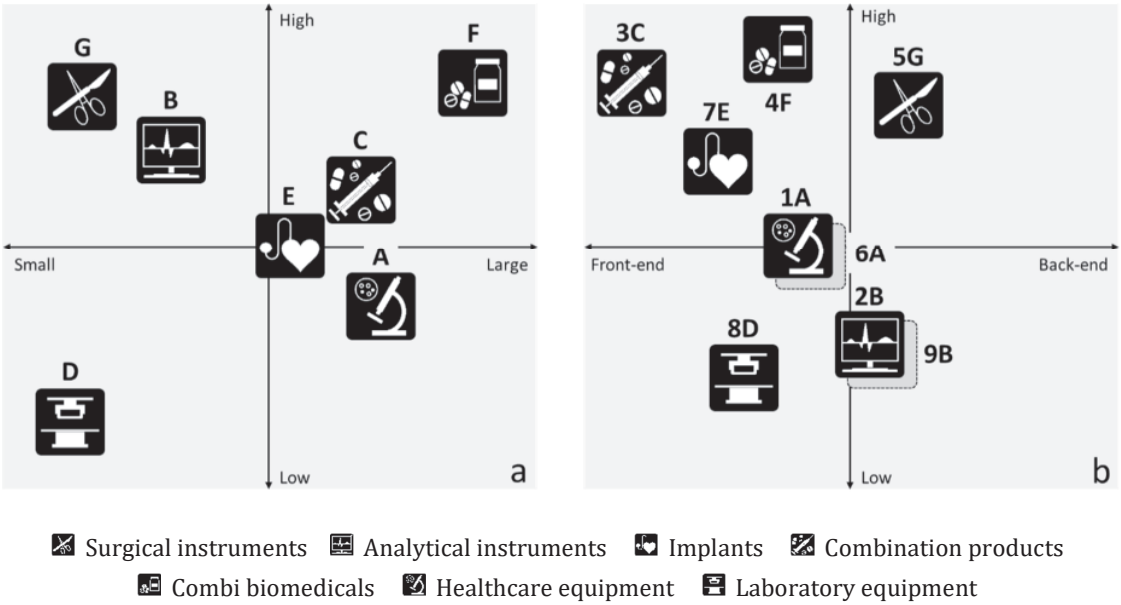


Fig. 2.7: Company and case study characteristics. From left: (a) Case companies characterized by its size as a function of the technology base level, and (b) Case studies characterized by regulatory classification as a function of the type of issues treated (end-to-end)

The case companies selected pose differentiated characteristics across the two main dimensions, i.e. size of the company under investigation and the technology level of products manufactured and brought to market (Fig. 2.7, a). This has been important as of the research study and its subsequent results should be applicable across these dimensions in order to target as large as possible business segment within the medical domain. Meanwhile, the case studies conducted in the case companies have been chosen, so that they widely span across the different risk classifications set by the regulatory domain while treating end-to-end issues, with focus on the front-end part of the value chain (Fig. 2.7, b). Thus, based on these characteristics, the cases selected are generally characterized as representative in the sense that all are in a multiple case design setup as defined by Yin (2009).

Individual Case Studies

The case studies conducted have had a wide-spread focus to cover important issues related to bringing new medical devices to market. The following declares the characteristics of each case study conducted during the research study (Tab. 2.1). The case studies have been conducted during the descriptive study I, prescriptive study I, and descriptive study II, and thus have supported research purpose I, II, and II during the design of the research study.

Product group icon	CS #	Product group	Description	Research focus	RQs	Duration* (Presence)
	1A	Health-care equip-ment	Phenomena exploration focusing on the internal product development process and its relation to regulatory requirements set by the public authorities.	• Product portfolio analysis • Quality systems exploration • Test documentation study • Regulatory implications	RQ1.1 RQ1.2	6 (5) months
	2B	Analy-tical instru-ments	New product portfolio investigation with the aim of getting insights into the correlation between product and compliance processes and the tools at hand to overcome the challenges.	• Product portfolio insights • Product complexity measure • Test documentation forecast • Regulatory compliance study • Available tools and methods	RQ1.1 RQ1.2	8 (7) months
	3C	Combi-nation product	Monitoring diverse product design projects – from product design to market approval across diverse departments and the methods and tools used during the entire process.	• New medical development and approval processes (TTA) • Methods and tools available along the process of bringing new devices to market	RQ1.2	3 (3) months
	4F	Combi bio-medical	Compliance test and documentation investigation, a holistic exploration of the required docs when applying for new market approval as well as the docs required when staying at market.	• Comparison of nodes (product, requirements, doc entities, etc.) and their strings (couplings across multiple domains) • Identification of inter-relations	RQ2.1	8 (4) months
	5G	Surgical instru-ments	Medical product to documentation investigation – layout of relevant dependencies in the architecture. Insights into the underlying systems.	• Development of new tool • Product requirements relations to product specifications • Coupling index identification	RQ2.1	28 (12) months
	6A	Health care equip-ment	Market requirements setup, the establishment of two-faced market enforcements, i.e. customer needs and regulatory requirements – identifying influencers on the product program.	• Market application and derived product program flexibility • Discrepancy analysis and development of structural approach to model these	RQ2.1	14 (5) months
	7E	Im-plants	Codification of test and documents in relation to new product development and market introduction. Analysis of possibilities and inherent constraints.	• Codification architecture investigation and establishment • Modular platform architecture tool development and analysis	RQ2.1	12 (5) months
	8D	Labora-tory equip-ment	Further investigation into the mirroring effects of the method, establishing utilization possibilities, and prediction of usability in practice – applicability of tool.	• Pre-utility test of new tool • Further investigation into the couplings across domains, i.e. market, product, documents	RQ2.1 RQ3.1	5 (5) months
	9B	Analy-tical instru-ments	Product portfolio establishment while measuring efficiency and effectiveness during the synthesis using the proposed modelling tool – verification of effects.	• Applications of the tool • Modular platform architecture utilizations – compliance driven modularization	RQ3.1	6 (4) months

*** Case *duration* indicates the total time span by which the case company has been involved in the research study, while the *presence* indicates the time of active engagement in the case company conducting the research (interviews, data analysis, group sessions, workshops, etc.).**

Tab. 2.1: Overview of case studies executed during the research study

The above described case studies conducted during this research study have been carried out so as to: (1) Build a comprehensive knowledge base of the environment in which medical device manufacturers operate, especially with regards to the regulatory requirements and the subsequent processes and documentation that they are to follow, (2) shed light on the current tools and methods available to meet the challenges faced by medical industry – while the investigation has focused on the engineering side of the activities carried out in medical companies, it has been important to identify possible solutions to the current situation, (3) develop new tools and methods for the support of medical manufacturers, and (4) to test and ensure (within the timeframe of this research study) that the proposed tools and methods are applicable and rigid in supporting medical manufacturers in developing new medical devices. Hence, the case studies conducted have had the objective of clarifying the research questions stated earlier in the thesis; from identification of current challenges in medical industry, over clarification of the phenomena including "state-of-the-art" tools and methods available, to identification possible new solutions to the challenges identified, and last but not least to solve, at least partly, the identified challenges.

Confidentiality and Anonymization

An established premise of conducting the research presented in this thesis, acting within the spinal cord of the participating industry companies, has been the trade-off between the accessibility to sensitive data and the companies' willingness to distribute results to the public domain. During preliminary discussions with potential case companies, confidentiality and/or non-disclosure agreements were signed with all participating companies, meaning that any data collected within the companies has automatically been considered in the category of being confidential. Thereby, it has been possible to work with genuine cases of critical importance to the case companies, which was also a part of the requirements checklist for participating companies. Further, this provided wide-range ability to access critical data of both codified and tacit know-how substance. Thus, due to this sensitivity nature of the data provided by the case companies, interviews have neither been taped nor coded, but thorough interview notes (Kvale 2007) were taken during the sessions.

The data obtained from research participants has been secured in a locked file cabinet, to which only the researcher and other competent personal have had access (Mack et al. 2005). All research participants have been informed what they were to take part in before the research took off, and all contributors to this research study have given their formal acceptance to the invitation, a subject matter often referred to as 'informed consent' in research (Angrosino and Mays de Pérez 2000; Fontana and Frey 1998; Hammerley and Atkinson 1995; Moustakas 1994; Stake 1995). All research participants have been fully informed about the purpose of the research and the role they were play in the research process.

Through anonymization, this research aims at protecting both the companies from disclosure of sensitive data to the public domain while protecting individual research participants from disclosure to both the company by which they were employed and the public domain. Hence, results published in this thesis are presented in a way so that it is not possible to trace results back to individual research participants. This premise, maintaining confidentiality while presenting rich, detailed account of the research, represents some unique challenges (Kaiser 2009). But, from a confidentiality and anonymization point of view, conducting multiple case studies supports the revealing of scientific results to the public domain while maintaining confidentiality and anonymity, as across case analysis avoids exploration of the individual company and/or research participant. Fortunately, in single cases, it has been decided to reveal specific case stories or parts hereof as well as quotes of research participants with approval from the executive management of those companies.

2.4 ROLE OF THE RESEARCHER

As Postholm and Madsen (2006) states in their comprehensive review of the ethical dimensions of the researcher's role in science, the researcher itself most be critical and should be conscious of its own subjectivity especially in qualitative research, the role of the researcher plays a critical part in shaping the scientific results (Lincoln and Guba 1985).

While participating in the various case studies, the author of this thesis (i.e. the researcher) has taken the role as process consultant, namely *"to work in a facilitative manner to help the clients inquire into their own issues and create and implement solutions"* (Schein 1987, 1995; Coghlan 1994; Coughlan and Coghlan 2002). The researcher has been, like Schein (1999) describes it, an external assistant to the client system. Thus, during the research, the 'process consultation model' was used rather than the 'doctor-patient model'.

Working as an integral part of the organizations, being actively engaged in the cord of the case companies, the author has been aware of the asymmetrical relation to the research participant, as the research participants, i.e. during interviews, group sessions, workshops, 'has been told', while the researcher 'has told' (Glesne 1999). The researcher has continuously been conscious and vigilant towards the researcher's articulated, written, and corporal appearance while engaging with research participants and generally while present in the case companies in order not to affect the data and results obtained during the research study.

The role of the researcher has been to facilitate methods for analysis and quantification of medical device development under regulatory constraints while providing initiatives to reduce future complexity of new product variant creation within the medical domain – all executed in close collaboration with relevant participants of the companies under investigation.

Development and testing of the proposed modelling tool involved several activities, including extracting and analyzing data, facilitating workshops for the evaluation of data and calculations, and synthesis. Despite the intensive involvement in practice, the prescriptive research has not been influenced using the theory-based approach while conducting the prescriptive studies. Thus, the role as an action researcher does not serve as a basis for concern.

2.5 RESEARCH VERIFICATION AND VALIDATION

One of the challenges of conducting research within design science is to obtain an unbiased verification and validation. This section discusses some of the methods, which have inspired the processes of verifying and validating the findings of this research.

Whereas verification is about creating the acceptance of the consistency of the research, and the way the contributions have evolved, validation is about the acceptance of the usefulness of the research based on the effects derived from the contributions. In popular terms: Verification is the answer to the question “Did we do things right?”. Validation is the answer to the questions “Did we do the right things?”. Due to the nature of the case projects, it has not been possible to set up a perfect test environment nor to compare the effects of the research contributions with a status quo situation.

Pedersen et al. (2000) propose a framework for validation of engineering design research, often denoted the validation square (Fig. 2.8). Design science and engineering design research is often characterized by few quantitative indicators, especially working within the front-end of the design process, which is the case for this research, which makes it hard to ensure a strict validation of the research results based on observations.

Pedersen et al. (2000) further elaborate the framework and provide a link between the square and the design method, i.e. in that case the research result that is to be validated. Note that the method in the top, in the case of this research, is the product platform model.

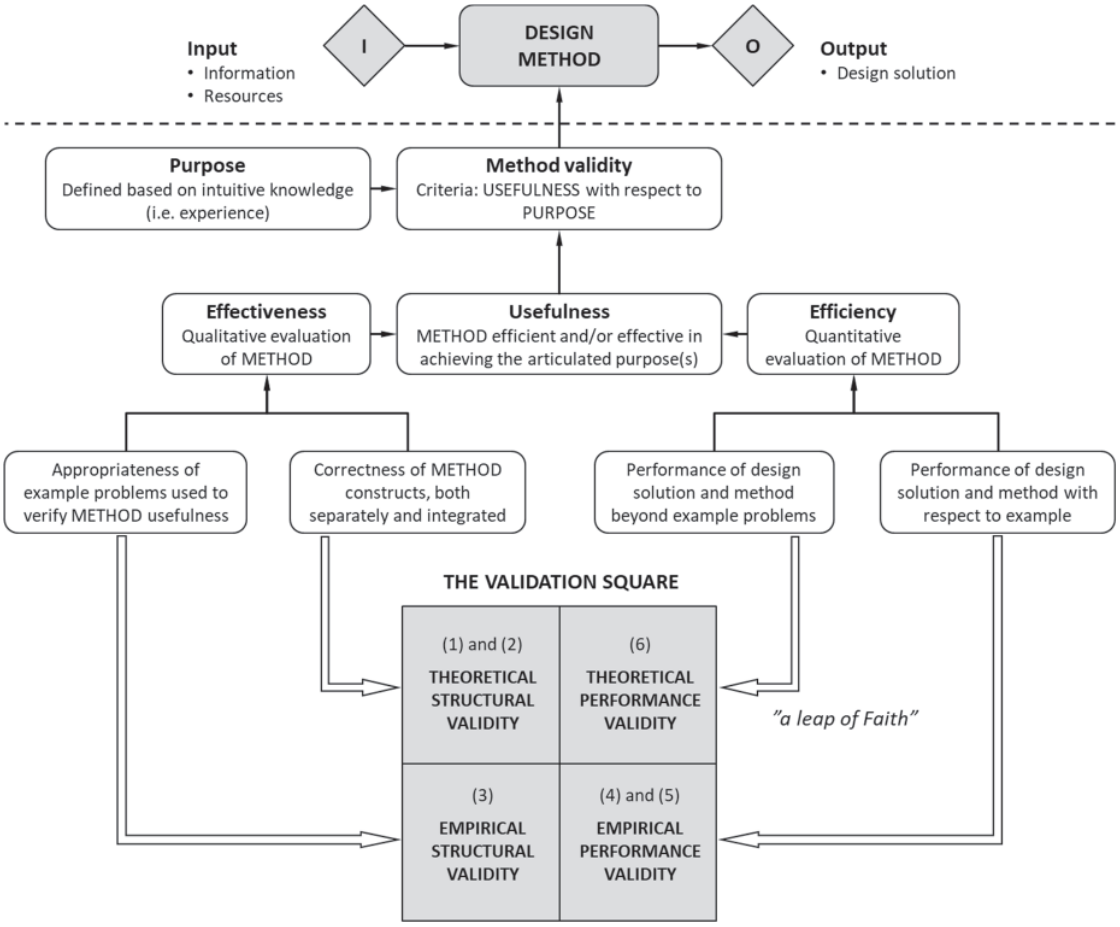


Fig. 2.8: The research study based on the design research methodology framework (Pedersen et al. 2000)

Applying the above illustrated methodical framework, the validation square is intended for the validation of the main contribution of this research, i.e. the proposed modelling tool.

2.5.1 Verification and Validation of Theoretical Aspects

Pedersen et al. (2000) defines validity as "confidence in usefulness". Buur (1990) suggests two approaches on how to verify a design theory, which is in line with the internal/external validity in the validation square of the research methodology framework:

Logical verification – A theory must be consistent so that there exist no internal conflicts between individual elements of the theory, while it must be complete, which means that relevant observed phenomena can be explained or rejected. Further, a theory has to support established and widely accepted methods as well as specific design problems.

Verification by acceptance – A theory must be accepted by a relevant scientific community, and it must be accepted by industrial practitioners, which means that statements of the theory are

acceptable to domain experts or experienced designers and so are the derived models and methods of the theory.

This thesis is based on the interpretation that verified results ensure that the process of obtaining them has been correct, and validated results refers to the assessment of the results or outcome being correct. Thus, the intention of the formulated research questions of this thesis is to contribute with explanatory elements within the phenomenon of concern and a justification of the relevance of the proposed modelling tool. Verification is further elaborated given five main characteristics that a research result may carry in order to be valid (Olesen 1992):

Internal logic – A research result is internally logic when consistency between the motivation, hypothesis and results exist and the research comply with well-known and accepted theory.

Truth – A research result can be claimed to be true when the theoretical and practical implications of the result can be used to explain a phenomenon that is in fact real.

Acceptance – A research result must be accepted by a research community and industrial practitioners in order to be valid.

Applicability – The research result must be applicable in practice and to a real industrial setting.

Novelty value – The research result must novel, i.e. it must provide new approaches or new realization to the existing world.

It is notable that both the internal logic and external acceptance are two fundamental ways to obtain verification/validation in the above approaches, which is also found in the split in a theory-based and problem-based model by Jørgensen (1992) as well as split between descriptive and prescriptive studies of the design research methodology by Blessing and Charkrabati (2009). Both have been applied this study to ensure rigor of the research process and the derived results.

"All theories are legitimate, no matter. What matters is what you do with them."'

– Jorge Luis Borges

Chapter 3

THE THEORETICAL BASIS: ESTABLISHING THE THEORETICAL FOUNDATION FOR THE RESEARCH

The objective of this chapter is to provide an overview of fundamental theories on which this research builds, namely theories related to (1) engineering design, which investigates the design object itself and (2) product development, which explore the development processes designing the product or design object. The primary purpose of this chapter is to describe theories that this research is based upon from the viewpoint of the school to which this research is related.

3.1 SCOPE OF THE THEORETICAL FOUNDATION

This chapter is to provide the audience an understanding of the theoretical foundation on which this research study builds. The topic of this research poses an inherent challenge in choosing the theoretical basis – thus, the objective of this chapter is to identify, describe and utilize existing theory areas, which are relevant to the theoretical bases for this research. Hence, in this chapter, scientific concepts, facts and theories, which best describe the domain and the phenomena will be described. The theory area also coves methods, which are useful in this domain, and which can handle the phenomena.

According to Olesen (1992) not only must existing theories be the starting point of a scientific investigation, an appropriate choice of school of thought must also be made. In this context, it is interpreted that the term appropriate relates to a clear relation between the choice of school of

thought and the formulated task. Thus, the theories presented in this chapter are largely based on research formulated by the "Copenhagen School" or theories to which the school has contributed, but also other theories are included to sufficiently found the theoretical basis on which the research rests. This chapter will present the theoretical background for this research covering three main scientific fields:

- Engineering Design Theory
- Product Development Theory

In total eleven theories, related to these two theory areas, have been identified constituting the basis for this research. This chapter provides a brief overview of the theory areas, and thus will not contain a comprehensive description of the theory areas, but the predominant once are described in more detail.

3.1.1 A MODEL OF DESIGN RESEARCH

Duffy and Andreasen (1995) have proposed a research approach for design science that explains how models of phenomena are based on "reality" of designing as well as on theories, which explains these phenomena – the model of design research (Fig. 3.1).

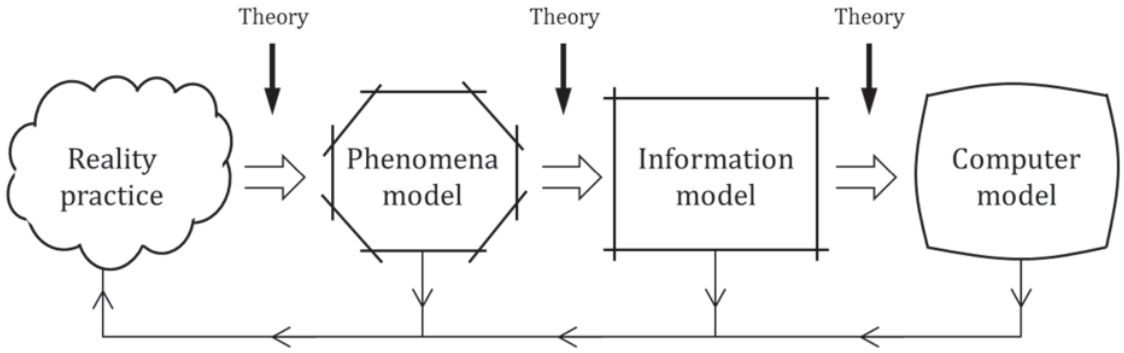


Fig. 3.1: From a design phenomenon to a computer model: In design science, models are derived from practice and models are developed for use in practice (Duffy and Andreasen 1995).

Unlike natural sciences (e.g. physics) where the purpose of a model is to improve predictiveness of the behavior of a certain phenomenon, the purpose of models in design science is to affect the behavior of designing as a phenomenon, into producing better and more consistent results (Andreasen 2011). The practice of designing is complex due to the complex pattern of influencing factors. The model by Duffy and Andreasen (1995) provides a mental framework for understanding the positioning of this project in a research context. It emphasizes that the descriptive part of this project relies on empirical evidence from practice to derive phenomena

models and the prescriptive part mainly is logically derived from physics (i.e. natural sciences). The prescriptive contributions from this project predominantly adds to the phenomena models.

3.2 ENGINEERING DESIGN THEORY

Engineering design research is about the product, artifact or technical system being developed. Theories within this area form an important basis for understanding design of objects, its different domains and the causality in-between domains, and thereby this theme holistically treats the nature of products and is of highly relevance to this research.

3.2.1 SYSTEMS THEORY

Systems theory is a meta theory about laws, methods and modeling for systems, i.e. objects, which have system nature, where systems can be abstractions, with the purpose of modeling and structuring a field of interests. It provides a conceptual basis for other theories (Mortensen 1999; Miller 2001; Andreasen et al. 2015), and gives a set of rules for abstract modelling of products and for the decomposition of such artifacts into sub-systems at hierarchical levels (Buur 1990). Andreasen et al. (2015) defines a system as *"a model of an object (a real or conceived product or activity) based on a certain viewpoint, which defines the elements of the system and their relations. A system carries structure, i.e. the elements and their relations (arrangement, architecture) and behavior, i.e. the system's response to a stimulus depending on stimuli, structure, and state"*. Further, they state that the basic rules for system modelling are that elements should be of the same kind and that relations should be consistent, which is in aligned with Buur (1990). Hubka and Eder (1988) states that a system has system border, which separates the system itself from the environment and the system receives input (stimulus) from the environment and creates output (response) to the environment (Fig. 3.2).

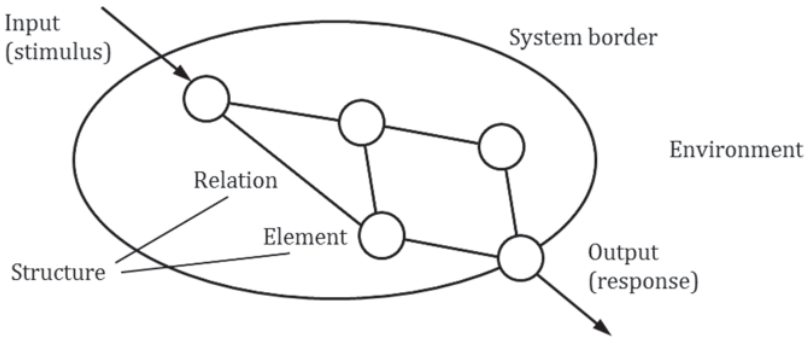


Fig. 3.2: A basic model of a system: Fundamental terms in systems theory (Hubka and Eder 1988)

A system has two classes of attributes, i.e. structure and behavior. The structure of the system denotes the elements and their relations and describes the system itself while the system's behavior is based on the way the output depends on the input provided to the system.

Systems may be hierarchical, and ordered in accordance with their origin, e.g. as natural or artificial systems (Fig. 3.3) and can be divided into partial systems called sub-systems (Blanchard and Fabrycky 1998) and may be classified according to their complexity (Pahl and Beitz 1996).

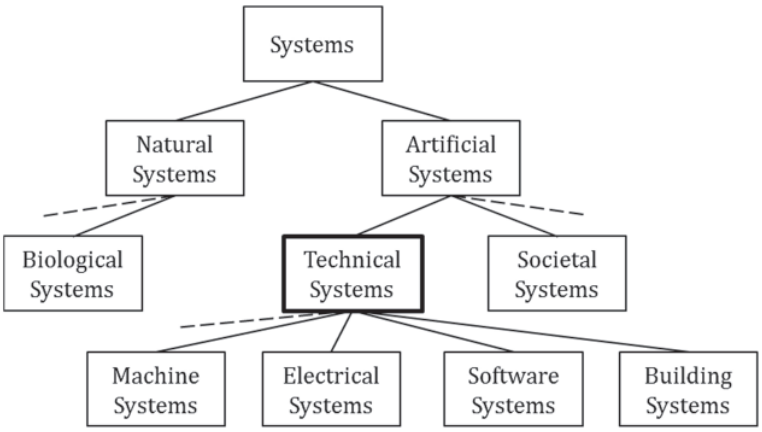


Fig. 3.3: Classification of systems: The hierarchy of systems according to their origin (Hubka and Eder 1988)

A core concept of systems theory is the notion of recursion, meaning that both the system and its elements are repetitive. Elements of a system may be considered as a system having elements and relations, and every system may be part of a larger system. This has later been denoted systems of systems (Haskins et al. 2006).

Systems theory is relevant for three reasons: (1) it is an important research tool, (2) it forms the basis for modelling of designs, and (3) it forms a basis for understanding existing design theories based on systems (Mortensen 1999). Systems engineering is closely related to systems theory, which divides the design process into sizable phases, and has led to new methods for design cost predictions, making design computations, evaluating design solutions etc. (Hall 1962). The power of systems engineering is that the basic features can be combined with technical theories and models to create more powerful models.

3.2.2 Theory of Technical Systems

The theory of technical systems is rooted in systems theory (Klir and Valeach 1965) with the primary aim to classify and categorize the knowledge about technical systems into an ordered

set of statements according to their nature, origin and development (Fig. 3.3). It is a theory that models structure and behavior of design and thereby provides an important basis for modelling and generalizing the nature of objects and processes in the real world. Technical systems may represent all human made artifacts, which describes the object as a result of engineering design and its realization. Thus, while the theory of technical systems treats several kinds of systems, the technical system itself, which performs the action process and the transformation system, which is where the technical process takes place, are the most predominant ones.

Transformation system

The transformation system encompasses all operators and processes required when transforming an input to an output, thus the transformation system is to transform the existing state of an operand, the input, into an output, the desired state during the transformation process (Fig. 3.4). A transformation takes place over a period where the operand, which can be perceived as any object, changes state during the process. An operand is any object, which is changed and might be classified according to its nature, i.e. biological, material, energy, or information (Hubka and Eder 1988). Operands are not independent, and in most cases, the operand will be a compound as e.g. information has both material and energy as a carrier. An important element is the undesired or unwanted inputs and outputs, also determined as disturbances, which are termed secondary inputs and outputs to the transformation process.

The transformation process is driven by the effects of a number of different operators interacting with each other, i.e. operators being technical, human, information, and management systems etc. Such effect is also termed a working/transforming effect delivered by the operators, which may interact with each other or the active environment. The entirety of all sub-processes in which the operands are transformed from input state to output state, is designated the purpose of the technical system.

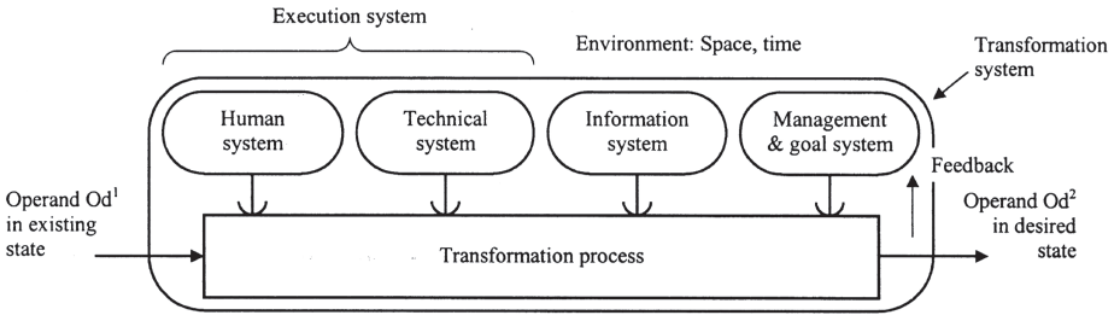


Fig. 3.4: General model of a transformation system (Hubka and Eder 1984)

Hubka and Eder (1988) seeks to narrow the scope by further characterizing the technical process, which is an installation of the transformation process, where a technical system is an active operator. The technical process involves the collective effort of a technical system, human system, and the active environment transforming the state of an input operand to the desired output state of the operand. The change (technical process) is aided by effects exerted by humans and/or technical systems and are therefore important operators of a technical process.

Technical system

A technical system is an artificial system that transforms an input to a desired output and has structure and behavior. According to Hubka and Eder (1988), there is a causal relationship from the structural characteristics of a technical system to its behavioral properties. The purpose of a technical system is to exert effects upon the operand and thereby, along with the other operators, contribute to the desired transformation of the state of the operand (Fig. 3.5). The technical system consists of two processes:

- *Technical process*, which represents the external tasks of the technical system: To create the effects of what the system should and can do when it is made to work, i.e. purposeful behavior, or output function.
- *Action process*, which represents the internal tasks of the technical system: The way in which the input to a technical system is converted into its output, or rather its effects, i.e. mode of action.

The concept of functions appears in the context of the action process, where: A function is a property of the technical system, and describes its ability to fulfill the purpose, and thereby providing the necessary effects to the technical process. Organs are considered functional carriers, and thereby is an abstraction of the technical system made to address functionality in the product. Thus, a product consists of organs that carry functions and is materialized by individual parts (see 'Theory of Domains'). Synthesizing a technical system ideally progresses from defining the intended behavior of the system realizing the technical system by finding suitable physical structures that exhibit the intended behavior (Jensen 1999).

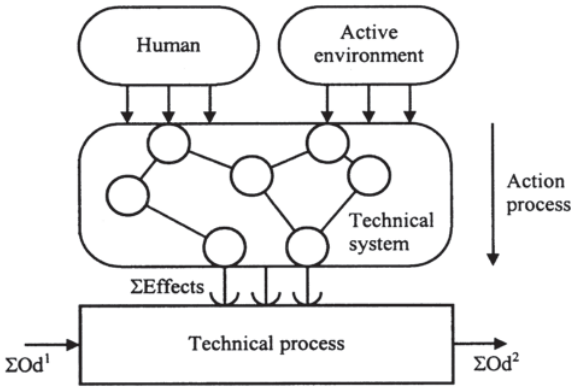


Fig. 3.5: General model of the technical process system: Two kinds of processes, technical process and action process, in a transformation system (Hubka and Eder 1988)

According to Hubka and Eder (1988), the behavior of a technical system depends not only on the behaviors of the elements, but also on the coupling relationships between the elements, which has later been denoted emerging properties (Crawley et al. 2004; de Weck et al. 2011; Crawley et al. 2015). A coupling occurs whenever an output from one element or system, is input to another element or system, and can be mechanical, electrical, chemical, magnetic, time, space couplings, or any useful combination hereof. A more generalized concept of couplings is that they are either material, energy, information (Hubka and Eder 1988). Thus, the structure (elements and relations) of a technical system influences its behavior. Conversely, a certain behavior does not determine a unique structure, but the same behavior (and function) can be achieved and realized by different structures.

The theory of technical systems provides a language and conceptual framework for understanding and relating systems theory, products and technical systems, and thus is relevant to this research as it explains how to read and model a design object, while it forms the basis for modelling of designs, which is of great importance to this research. Its importance to this research lies in how it describes systems behavior as being depended on structure (elements and relations), its generalization of coupling relations, and its declaration of functions being properties of the system describing its ability to fulfill the purpose. Finally, this theory contributes with the declaration that the same behavior (and function) can be achieved and realized by different structures, which is a fundamental viewpoint in the application of the later proposed modelling tool of this research.

3.2.3 THEORY OF DOMAINS

The theory of domains, which originates from Andreasen (1980), is a refinement of the theory of technical systems, which is based on a systems perception of design objects. It has laid the basis for various research contributions and has been subject to further development, i.e.

Andreasen (1992a), Andreasen (1998a), Jensen (1999), Mortensen (1999), and latest Andreasen et al. (2014).

The core contribution of the theory of domains is that a design object (the product) can be viewed from three perspectives, namely the transformation domain, the organ domain, and the part domain (Fig. 3.6), each domain corresponding to a (mental) working domain for the designer. To sufficiently understand and communicate a product, one must explore and describe it by a successful establishment of these perspectives (Andreasen 1980). Hence, the term "domains" in the theory of domains does not refer to an engineering discipline, but a specific viewpoint taken during the exploration and description of a product.

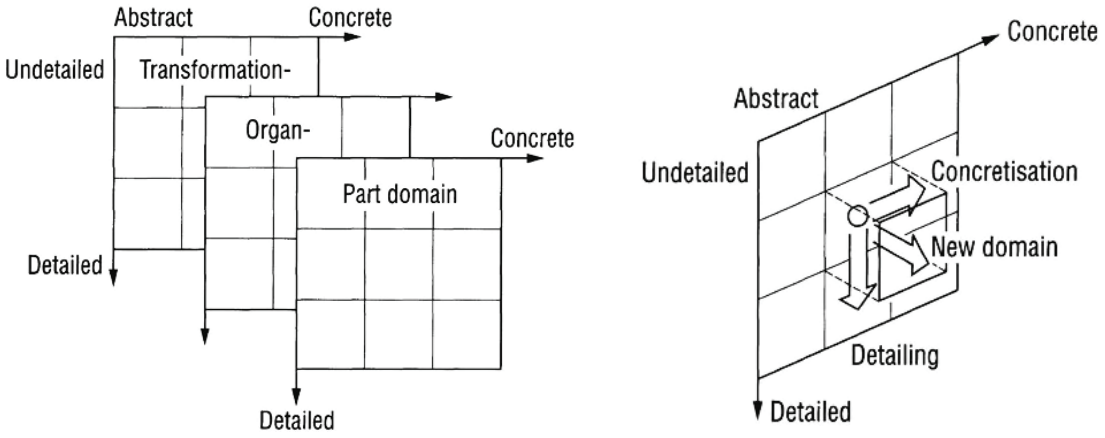


Fig. 3.6: The theory of domains: (a) The product and its related use activities seen as three domains, in which the synthesis of the product may progress (Andreasen 1980), and (b) Synthesis as a process of abstracting and detailing (Andreasen 1980)

Each domain (i.e. transformation, organ and part) should be regarded as a two-dimensional plane spanning across the parameters of abstracting and detailing (Buur 1990). As the design object is concretized, more attributes are determined, e.g. dimensions, materials, and surfaces etc., and as a design object is detailed, more elements are determined. The domains are considered interacting viewpoints allowing for structural and behavioral reasoning. Thus, the synthesis of a design object is explained as the movement in the dimensions of abstract-concrete, undetailed-detailed, and the shift between the three domains.

- *Transformation domain*, also referred to as the activity domain, which describes the structure of processes that transform the operand when a product is in use. It describes how the product is used, by modeling the transformation processes (the activities) that a product takes part in, and the state changes it undergoes during the technical process (Hansen and Andreasen 2002).

- *Organ domain,* which describes the system that realizes a given internal function of the product (Hubka and Eder 1988) and describes what the product does and how the product works, i.e. the intended behavior, functions and mode of action (Andreasen et al. 2015). The organ domain provides an abstract representation of the product and does not capture the material and physical embodiment of the organs (Mortensen 1999).

- *Part domain,* which describes the structure of physical components and sub-assemblies of components that together constitute the embodiment (physical realization) of the product, and thus describes how the product is built or the way by which the organs are realized – it describes what the product is (Hubka and Eder 1988). Parts are building elements of organs, realizing the organs by their structural characteristics and interfaces (Chakrabarti and Blessing 2014), which thereby shape the functionality of the organs.

A causal coherence between the domains exists, which can explain the interplay between the purpose of the product and the tasks realized by its parts (Andreasen et al. 1996). The coherence between domains enables reasoning from "the purpose" of the product to the physical realization of the product (Harlou 2006). Such coherence can ease decision making about the necessary variety within the product family (Haudrum 1994) and can increase the degree of how system components can be may be separated and recombined for different market needs.

The theory of domains provides a framework for reasoning about the product from different viewpoints and helps recognizing the elements of the technical system and the way in which the different elements interact with each other. Thus, the theory of domains is relevant to this research as it establishes a foundation for reading a product from different viewpoints while it forms the basis for understanding coherence between multiple domains that can improve decision making during the development of products, which is important to this research study. The ability reason from purpose of the product to the physical realization is a core contribution of this theory to the research of this thesis.

3.2.4 THEORY OF STRUCTURING

When developing a product, different stakeholders need to "read" the same information in different contexts (Mortensen and Hansen 1999). To get a complete overview of the product information, it therefore needs to be communicated from different viewpoints.

Structure is one of few characteristics that the designer can manipulate and determine directly during the development of a product, which implicates e.g. performance, change, variety, component standardization, manufacturability, and project management (Ulrich and Eppinger 1995).

Manipulating the design characteristics at the design stage influences the future product life condition, often made visible for the designer by a model of the "meeting", which is the meeting between the product and its life-phase systems (Andreasen and Mortensen 1997). The theory of structuring thus extends the theory of domains to include views on multiple products and the life of products. A system, may according to the theory of structuring, be structured from four viewpoints (Andreasen et al. 1997), i.e. system aspect structures, life-phase structures, family structures, and genetic structures (Fig. 3.7).

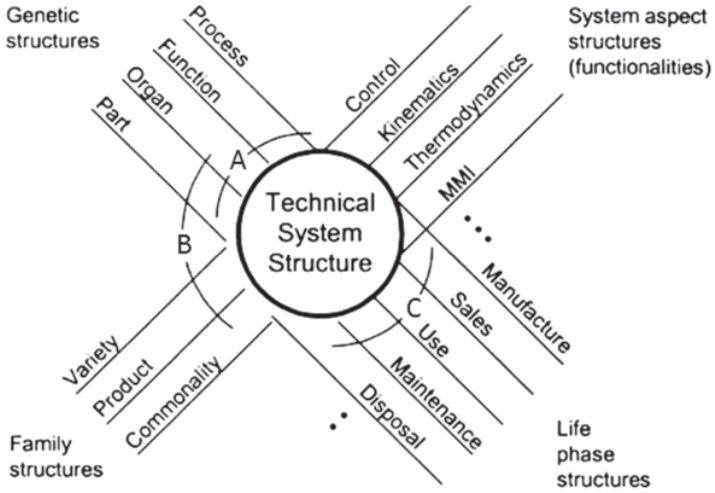


Fig. 3.7: An overview of the four classes of structures of a product: A system may reveal several superimposed structuring principles as categorized in four dimensions (Andreasen et al. 1995)

Andreasen et al. (1995) state that *"the structure of a product is the way in which its elements are interrelated in a model, based on a specific viewpoint"*. Thus, the structure depends on the viewpoint of the stakeholder. A system may reveal several superimposed structuring principles, but can be separated into four classes of structures:

- *System aspect structures*, or the functional view on structures, represent the performance of the product in its primary use situation, i.e. it must possess the right functionality, which is the viewpoint of traditional engineering disciplines. These disciplines often require different modelling methods to capture and communicate information that have been created in the specific field.

- The *life-phase structures* represent the life-phases that a product will undergo throughout its lifetime e.g. production, transportation, delivery, etc. The life phase structures describe the meetings between product and its life-phases its journey, i.e. design for manufacturability, reliability, quality, serviceability, etc.

- The *family structures*, or the product assortment view on structures, represent the family or assortment by which a product is a part of. It encompasses an overview of the family, which shows all the variants that are offered to the market and the commonality that exists between products and product families.

- The *genetic structures*, or the syntheses-oriented view on structures, represent the fundamental ways of describing a technical system, as suggested in the theory of domains (Andreasen 1980). Thus, it addresses the modeling of the technical system itself using the parameters of abstracting and detailing, while being explored and described from different domains.

The theory of structuring provides an extended view on product modelling and therefore is relevant to this research as it provides a framework for keeping track on the consequences of changes a design. It is also relevant when analyzing a larger group of products as the different viewpoints will help address different aspects of the performance of that group and help identify improvement and optimization potentials. Further, it provides a framework for capturing information across multiple structures from different viewpoints and is of great contribution to this research establishing a compliance view to the modelling of a product programs.

3.2.5 THEORY OF PROPERTIES

The theory of properties is based on the idea that a set of properties, where a property can be defined as any characteristic of an object that belongs to and characterize it (Hubka and Eder 1988), i.e. costs, function, lifetime, robustness etc., can be identified and designed into a technical system (Fig. 3.8).

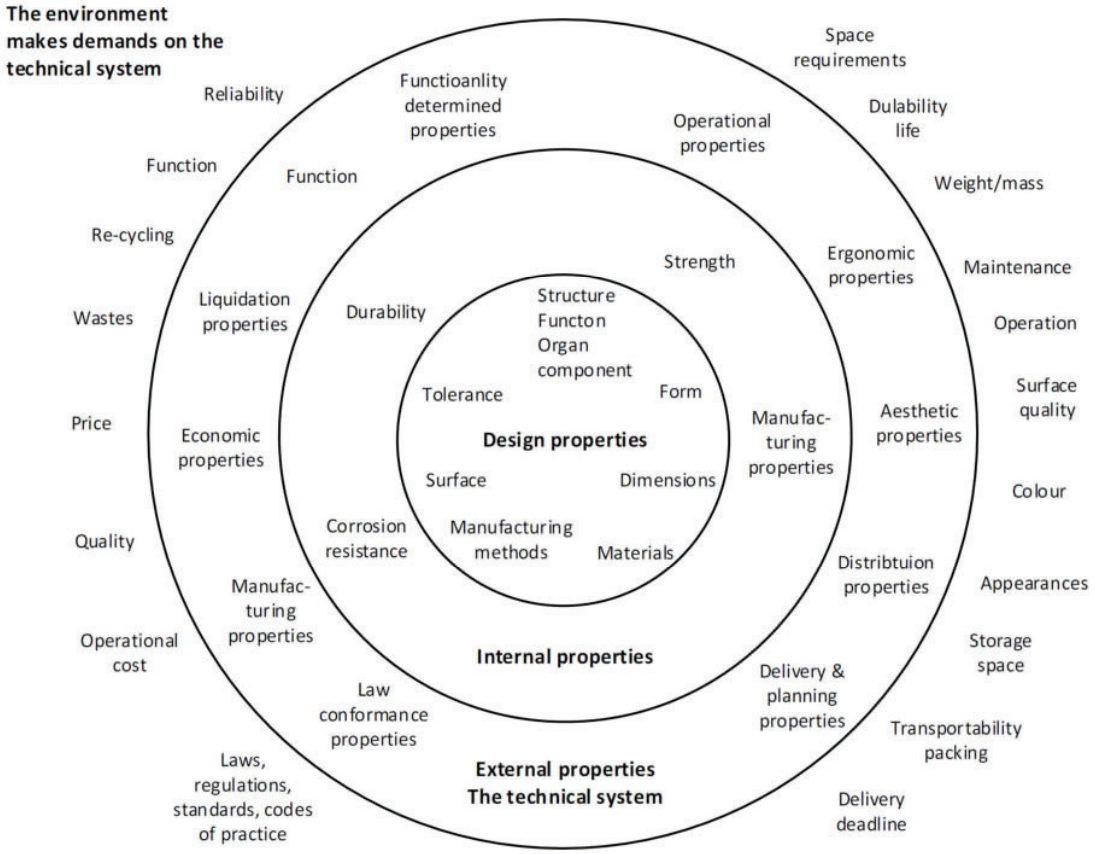


Fig. 3.8: Classes of properties (Hubka and Eder 1988)

Hubka and Eder (1988) distinguishes between three classes of properties: External properties, internal properties, and design properties. Internal properties are of direct interest for the manufacturer and designer, since they serve as a means for the designer to create the desired external properties. External properties are primarily of interest for the user of the technical system and are divided into eleven classes. Finally, the design properties are the means by which the designer achieves all other properties (Hubka and Eder 1988).

According to Hubka and Eder (1988), functions is a superior property to other external properties. There exist a limited number of properties that the designer can determine directly, i.e. the structure, hence the elements, namely the form, material, dimensions, and surface quality, the way by which the elements are arranged. Andreasen et al. (2015) argue that product attributes can be classified into characteristics and properties (Fig. 3.9).

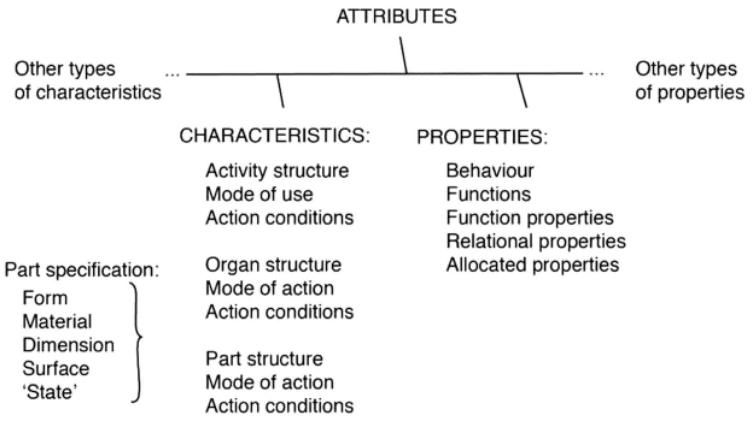


Fig. 3.9: Classification of a product's attributes (Andreasen et al. 2015)

Andreasen et al. (2015) and Weber (2014) propose quite harmonious definitions, identifying two classes of product attributes, namely characteristics and properties:

- *Characteristics* can be defined as *"a class of structural attributes of products and activities determined by the synthesis of the design"* (Andreasen et al. 2015). This is in accordance with Weber (2014) who defines a product's characteristics as the part structure, shape, dimensions, materials and surfaces. Thus, characteristics are the attributes that the designer can directly influence or determine during the development.

- *Properties* can be defined as *"a behavioral class of devices' and activities' attributes, by which they show their appearance in the widest sense and create their relation to the surroundings"* (Andreasen et al. 2015). Weber (2014) defines properties as describing the product's behavior, e.g. function, weight, safety, and manufacturability, testability, serviceability, etc. Thus, properties are attributes that are observable to stakeholders and notable when the product interacts with operands and life phase systems during meetings.

Andreasen et al. (2015) states that the realization of these properties is a process of reasoning from issues, to requirements, to properties, and to design entities, the characteristics of activity, organ, and part (Fig. 3.10).

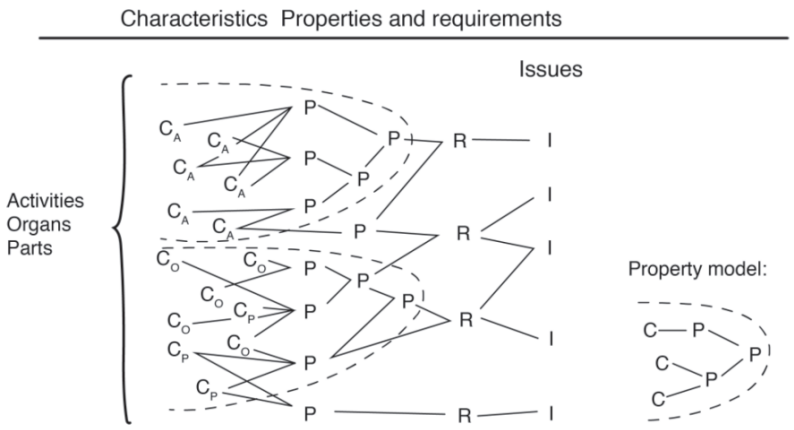


Fig. 3.10: The link model: Issues (I) are linked to requirements (R), to properties (P) and design entities, characteristics ($C_{Activity}$, C_{Organ}, C_{Part}) relating to the three domains (Andreasen et al. 2015)

The composition of a product's deployment (activities, organs, and parts) on the left can be linked to certain issues of interest on the right. Requirements are linked to characteristics via the properties, where the requirements describe what the product should do, and therefore closely related to the properties of the system. While the requirements should be solution neutral, the characteristics of the system describes the solution, where the specification contains characteristics of the solution.

The theory of properties provides the basis for systematical reasoning from external issues, setting requirements, defining the properties and conceptualizing a solution with certain characteristics. The theory of properties is namely relevant to this research as it offers an understanding of what is meant by properties and characteristics, requirements and specifications as well as it provides a general reasoning pattern for the synthesis of products. It is directly related to the research presented in this thesis as the requirements to the product in general express the value of the external properties (from the viewpoint of the customer and other external stakeholders) and the value of the internal properties (from the viewpoint of the designers) as established in the theory of properties.

3.2.6 GENETIC DESIGN MODEL SYSTEM

The genetic design model system (Mortensen 1999) elaborates on the theory of technical systems, the theory of domains, and shares the life phase aspects with the thory of dispositions (Fig. 3.11). The genetic design model system builds heavily upon the theory of domains and its application is shown in the chromosone model (Ferreirinha et al. 1990), where the structure of the product model is derived by the theory of domains with causul relations between the domains. The chromosome model is a genetic model that carrry the design history by linking the purpose of the product to its components (Andreasen 1992b). Mortensen (1999) suggests that

the viewpoints of the theory of domains should relalate to both the meeting (the process) and the technical system (the design) itself. Thus, the modeling of such systems must encompass both constitutive and behavioral models.

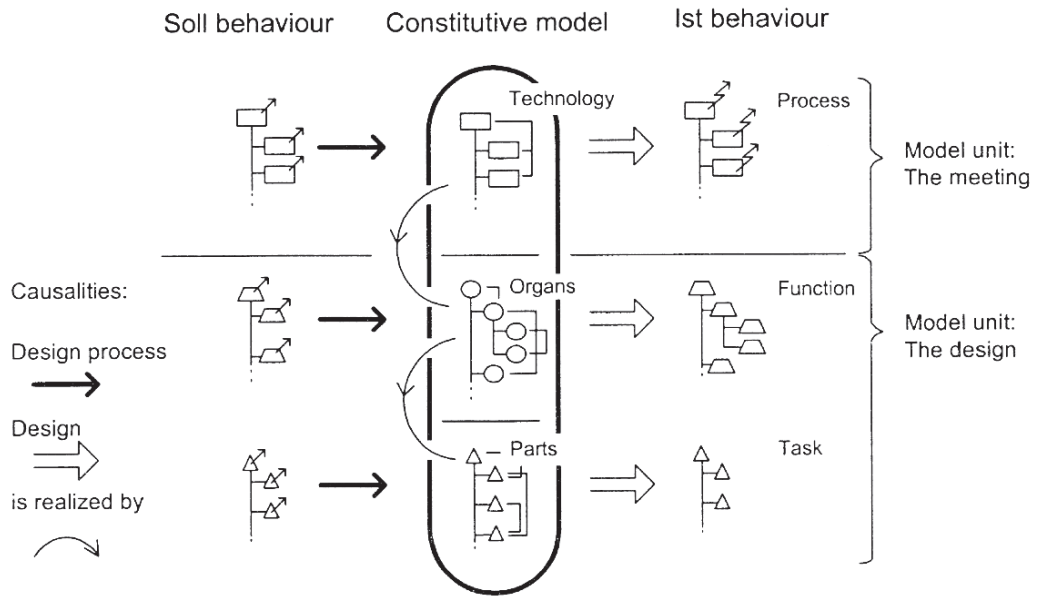


Fig. 3.11: The genetic design model system capturing the meeting and the design (Mortensen 1999), it is based on the chromosome model that clarifies the causality between the domains in the theory of domains (Andreasen 1992b).

The term task adds to the function-physical split in the theory of domains, where a task is the purposeful job done by a part in the part domain. The parts accommodate organs that again carry functions. The functions belong to the class of behaviors. The functions (i.e. the constitutive model) is divided into "*soll* behavior", which describes the intended behavior of the system, and "*ist* behavior", which describes the resulting behavior derived from the realized constitutive model (Fig. 3.11).

- *Modelling the meeting (the process)* – During the design activities, the meeting between the design itself and the life-phase systems are developed. A process plan may for instance be seen as a constitutive description of the meeting between a design and a production system. Behavior of the meeting can be seen as processes in the theory of domains, denoted technology (Mortensen 1999). In the case of a transformation (the top-level effect carrying out the activities of the product), the modelling unit is the meeting, as described in the theory of dispositions (Olesen 1990).

- *Modelling the technical system (the design)* – A technical system (a design) can be modeled from two constitutive (defining) viewpoints, i.e. organs and parts (Hubka and

Eder 1988; Andreasen 1980). The two constitutive viewpoints are necessary for explaining the behavior of a design and its physical realization. The organ models describe the units, which possess functions, and the parts model describes the units, which are realized in a sequence of production processes. The purposeful organ behaviors are called functions (Mortensen 1999).

The genetic design model system provides a basis for two kinds of attributes when describing the nature of a design: The constitutive/structural attributes (the characteristics), which describes what the product is, and the behavioral attributes (the properties), which is basic to systems theory and systems engineering disciplines (Klir and Valach 1965; Chestnut 1967), which describes what the product does. The properties are divided into inherent properties and relational properties. Inherent properties are design attributes that are possessed by the design itself. The inherent properties are causally determined based on the design characteristics and the environment. Relational properties are design attributes, which describe the behavior of the meetings between the design and the life phase system. Relational properties are causally determined based on the characteristics of the design, the life phase system and the meeting.

The contributions of the genetic design model system are important to this research as it provides a clear distinction between behavioral and constitutional models as well as it distinguishes between the meeting (the process) and the technical system (the design) itself, which is relevant when defining the constitutive and behavioral parts of a platform architectures, which is key to this research. Meanwhile, this theoretical contribution is relevant to this research, as it helps understanding whether a given state has to do which the product design, a behavioral characteristic, or an effect arising from a meeting in one of the life-phase systems, which has to do with the state of alignment (i.e. the process in which a company through a purposeful process is trying to create a fit between the product and one or more life-phases), which is an important subject in this research study. Namely, this contributes to the understanding of compliance aspect of the meeting between the product design and regulatory environment by means of the internal compliance capabilities of a company – the purposeful process of proving compliance bringing new products to the marketplace.

3.2.7 AXIOMATIC DESIGN

Axiomatic design (Suh 1990) is rooted in optimization theory and aim at modelling the design process in engineering design (Fig. 3.12). According to axiomatic design, the world is made up of four domains: (1) the *customer domain*, which is characterized by the customer attributes (CA) that the costumer is looking for in a product, (2) the *functional domain* where the costumer attributes are specified in terms of functional requirements (FR), (3) the *physical domain*, where the design parameters (DP) are to be determined in order to satisfy the functional requirements,

and finally (4) the *process domain*, where the process variables (PV) are to be determined in order to produce or realized the product (Suh 1990).

- *Costumer attributes (CA)* are variables that characterize the design in the costumer domain. Consumer attributes are the customer needs and wants that the completed design must fulfill, and thus are the external requirements of the product to be designed.

- *Functional requirements (FR)* are variables that characterize the design in the functional space. These are the variables that describe the intended behavior of the device. They are a minimum set of independent requirements that completely characterize the functional needs of the product in the functional domain.

- *Design parameters (DP)* are variables that describe the design in the physical solution space. Design parameters are the physical characteristics of a particular design that has been specified through the design process. They are the key physical (or other equivalent terms in the case of software design, etc.) variables in the physical domain that characterize the design that satisfies the specified functional requirements.

- *Process variables (PV)* are variables that characterize the design in the process (manufacturing) domain. Process variables are the variables of the processes that will result in the physical design described by the set of Design parameters. They are the key variables (or other equivalent term in the case of software design, etc.) in the process domain that characterizes the process that can generate the specified design parameters.

- *Constraints (C)* are bounds on acceptable solutions. There are two kinds of constraints: input constraints and system constraints. Input constraints are imposed as part of the design specifications. System constraints are constraints imposed by the system in which the design solution must function.

Between the domains, there exist causality, with the left side representing what is intended, whereas the right represents how it is to be achieved. Axiomatic design rests upon the hypothesis that there exist a small set of global principles, or axioms, which are fundamental truths, which can be applied to decisions, made throughout the synthesis of design and manufacturing systems (Suh 1978).

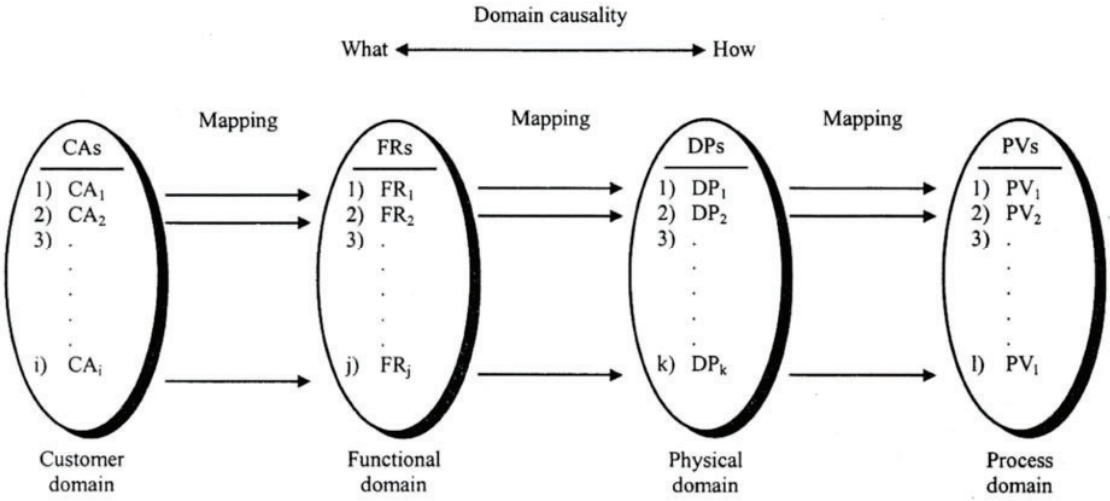


Fig. 3.12: Four domains of the design process: Design as a mapping process between the domains (Suh 1990)

Suh (1990) views the engineering design process as a constant interplay between the desired goal and how this is to be achieved. Objectives are always stated in the functional domain, while the solution is generated in the physical domain. Functional requirements (FR) and design parameters (DP) can be decomposed into hierarchies (Fig. 3.13). As the illustration shows, the design process is an alternation between the functional and physical domain (Suh 1990), which is in accordance with the function-means law, where a technical system cannot be decomposed into sub-functions, before the means realizing the function is found (Andreasen 1992a; Andreasen 1998b).

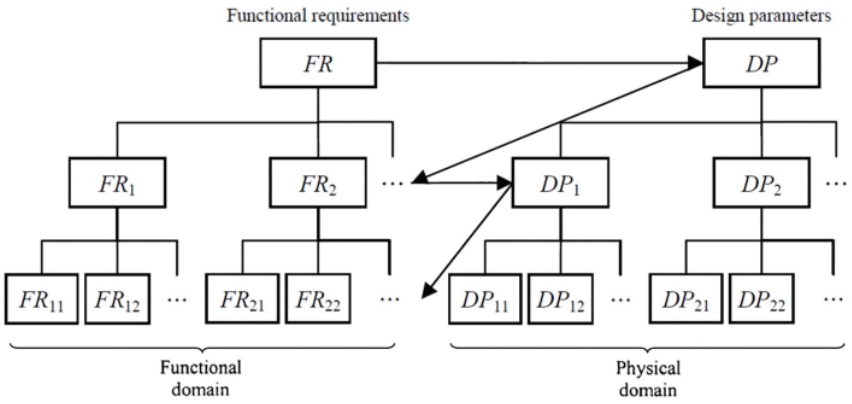


Fig. 3.13: Zigzagging process between domains: Decomposition of the functional and the physical domains in order to create the functional requirement and design parameter hierarchies (Suh 1990)

Suh (1990) elaborates on two types of design: Equivalent design, which is two different designs satisfying the same set of the highest-level functional requirements, but have different hierarchical architecture, and identical designs, which are two different designs that satisfy the same set of functional requirements and have the identical design architecture, the designs are defined to be identical designs.

Axiomatic design introduces parametric variables for establishing the design of objects, while it provides the foundation for evaluating conceptual designs based on quantitative entities across the life-phase system. It seeks to quantify the causality between domains, while it provides the foundation for measure the meeting between the design object and life-phase systems.

The theory of axiomatic design is relevant to this research as it provides a framework for evaluating the development of products with specific focus on conceptualization, i.e. it provides the foundation for conceptual design explorations, from external influencing factors such as customer needs, over internal requirements, to the materialization of the design, which is of highly importance to this research. Meanwhile, the axiomatic design theory contributes to this research with the insight into matrix-based modelling of design objects as a means of quantifying intra- and inter-relations between domains.

3.3 PRODUCT DEVELOPMENT THEORY

The product development theory, or theory of design processes, aims at explaining and supporting the process of product design by providing descriptive and prescriptive models and procedures for its management (Hansen 1974; Hubka 1976; Cooper 2001; Wheelwright and Clark 1992; Ulrich and Eppinger 2004). There are strong indications that structured and systematic design processes for product development can improve the probability of technical success (Pahl and Beitz 1996).

3.3.1 INTEGRATED PRODUCT DEVELOPMENT

According to Andreasen and Hein (1987) the development process is too complex to be described in a one-dimensional advancing process starting with a need and ending up with a complete product and should rather be described in terms different levels (Fig. 3.14). Product development may be regarded from many different points of view, e.g. planning, organization, creativity, methodology, task assignments, etc. From a design methods point of view, it is expedient to describe product development on different levels of resolution.

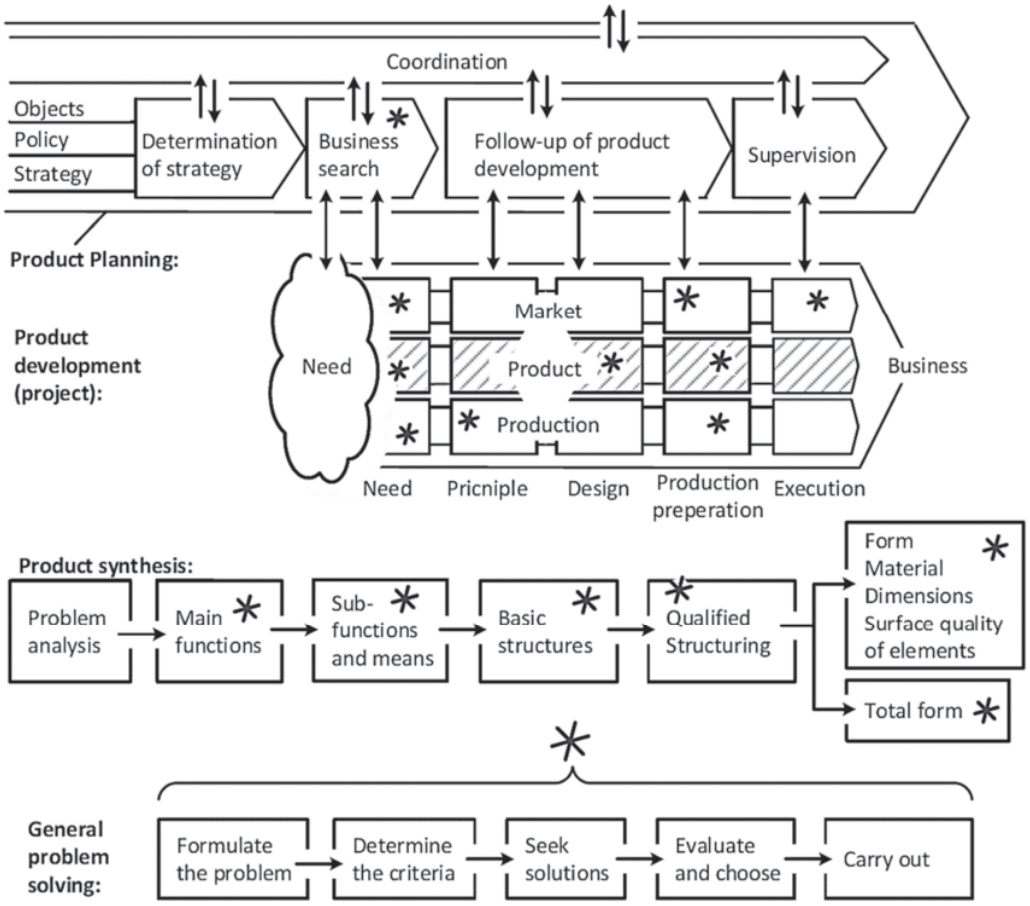


Fig. 3.14: The design methodology on four levels (Andreasen and Hein 1987)

Andreasen and Hein (1987) present a single model including four levels of product development, i.e. product planning, product development, product synthesis, and problem solving. The activities on each level may be divided into phases, and design methods can be attached to each phase. The four levels are:

- *Product planning* is related to activities where decisions regarding introduction of new products and discontinuation of existing products are made (Harlou 2006). It deals with the initiation of product development projects based on indications and is about identifying the portfolio of products that the company intends to develop and the timing of their market introduction while continuously evaluating these based on the business circumstances wherein the company operates (Ulrich and Eppinger 2004).

- *Product development* takes its starting point by the recognition of an identified need and results in the creation of a new product and thereby is about generating successful business. Andreasen and Hein (1987) pursue to capture this in the integrated product development process model (Fig. 3.15). The model suggests an interplay among three

classes of activities; activities related to market, product and production, which should be performed simultaneously to ensure successful product development.

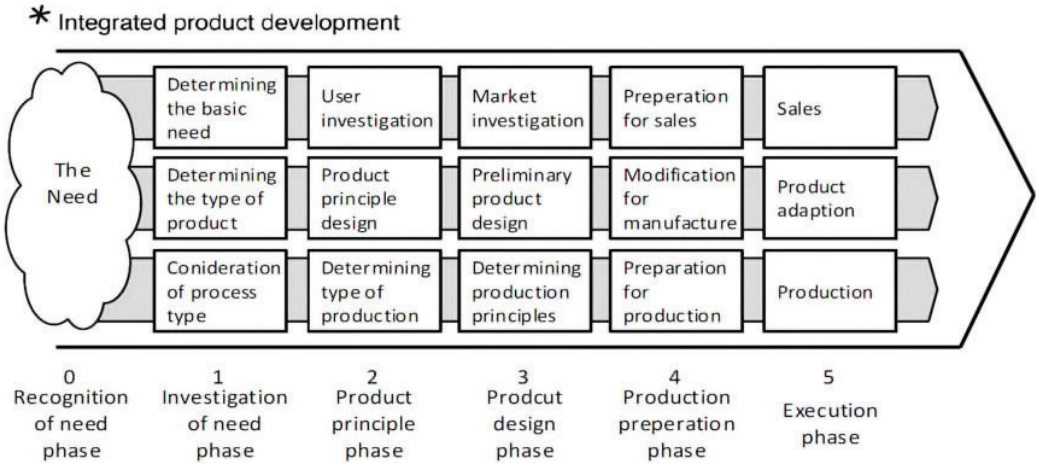


Fig. 3.15: Integrated design process: An ideal design model showing integration of market and production activities for creating new business (Andreasen and Hein 2002)

The integrated product development provides a systematic view of the activities of product development an elaborates on some of the key characteristics of design such as the advantage of dividing the project into phases, decision gates, planning and collaboration across functional units of the company, etc.

- *Product synthesis* focuses on the process of designing the product itself. Tjalve (1976) suggests the model of product synthesis consisting of a sequence of stages to structure the design work (Fig. 3.14). The model takes its point of departure in the decomposition of the functions of the products. Hereafter, solutions are found by means of principle and quantified structures (Harlou 2006).

- *Problem solving* may be regarded as an elementary activity to be applied to sub-problems of design work (Mørup 1993). Tjalve (1979) emphasizes that understanding and framing criteria for a problem before identifying a solution will yield a better result, which reflects the importance of doing adequate problem analysis and defining verifiable requirements before identifying design solutions.

The four-level integrated product development approach shows a coherence and completeness in describing the design process (Buur 1990), while it allows for identification of activities on each level. It acknowledges the necessity of linking and coordinating individual product projects in accordance with the overall business objectives and strategy, while it provides a basic understanding of how product development is ideally conducted in industry and the division of tasks between various functions in a company, which is of relevance to this research study.

3.3.2 SYSTEMS ENGINEERING PROCESS

Systems engineering is a multi-disciplinary field of research that treats systems development, where a system is seen as an integrated composite of people, products, and process that aim at satisfying a given need or objective (DAU 2001). Generally, the process focuses on ensuring that the needs of customers and stakeholders are satisfied in a compliant manner throughout the system's entire life cycle. (INCOSE 2007) and is based on systems thinking, which enforces the designers' awareness of the entirety and how the composite elements of the system interrelate (Haskins et al. 2006).

Systems engineering is thus concerned with holistic designing of systems and encompasses a systematic top-down approach to the development of systems (Fig. 3.16). The Vee-model represents an overview of the sequential steps taken during the development life cycle and emphasizes the results that must be produced during the development (Munk 2011). Whilst the left side of the Vee-model represents the decomposition of requirements, and creation of system specifications, the right side represents the integration and verification testing of design elements and their integration (INCOSE 2007).

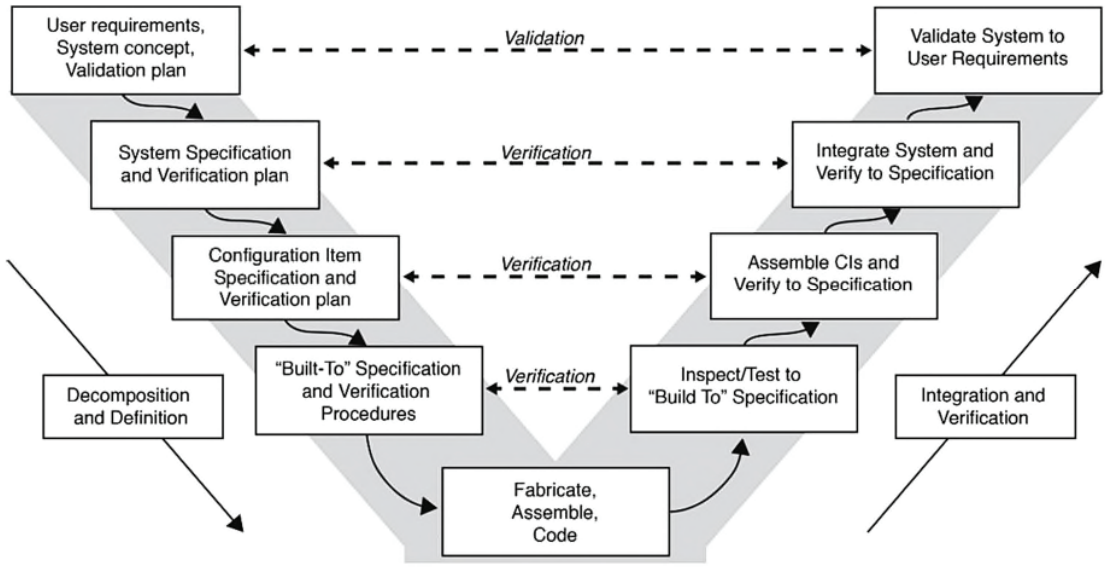


Fig. 3.16: The systems engineering process model (Dickerson and Mavris 2010)

In more detail, the left side of the Vee is concerned with identifying and defining what the system should be able to do and translating this into a systems description and model. The system is first modeled from a functional perspective and then conceptualized into physical form and gradually decomposed into an appropriate level. Detailed design then materializes the components and parts, which are then realized through manufacturing processes. The right side

of the Vee is concerned with testing that the designed elements of the system comply with the specifications (i.e. are we building the product right?) and that the behavior of the manufacturer's products comply with the intended use of the product (i.e. are we building the right product?) (Dickerson and Mavris 2010). Whilst the Vee model is depicted in a sequential order, the reality is that such process is iterative with a constant shifting between synthesizing the solution and analyzing the result. The heart of the model is the generated deliverables and the dependencies and traceability of the information captured in the deliverables.

The model is a helpful presentation to enable discussions about the design of the structure, content and relationship between specifications and information produced in the development process. The Vee-model is relevant to this research as it captures requirements across systems levels while it enables understanding and communicating different levels of requirements and their alignment with system design- and, what in this research what in this thesis is referred to, compliance testing and documentation. It helps capturing relevant information that should be tested and documented throughout the process while it helps constitute the mental mindset about establishing alignment and traceability between the product and compliance view, which is a core contribution of this research.

3.3.3 TRANSDISCIPLINARY PRODUCT DEVELOPMENT LIFECYCLE

The transdisciplinary product development lifecycle, also known as the axiomatic product development lifecycle, is a systems engineering product development model proposed by Gumus (2005), which extends the axiomatic design method by Suh (1990).

The transdisciplinary product development lifecycle covers the whole product lifecycle including early factors that affect the entire cycle such as development testing, input constraints and system components. The framework provides an iterative and incremental way for a team of transdisciplinary members to approach holistic product development. A practical outcome includes capturing and managing product design knowledge.

The model addresses explicitly quality of the design, requirements management, change management, project management, and communication between stakeholders. By adding one new domain, i.e. the test domain, and four new characteristic vectors, the whole development lifecycle knowledge starting from the customer needs to the testing can be captured and managed (Fig. 3.17).

The transdisciplinary product development lifecycle model can be used in project management models such as waterfall, spiral, and iterative-incremental to manage the data produced for each domain as well as the relationships between the domains (Gumus 2005).

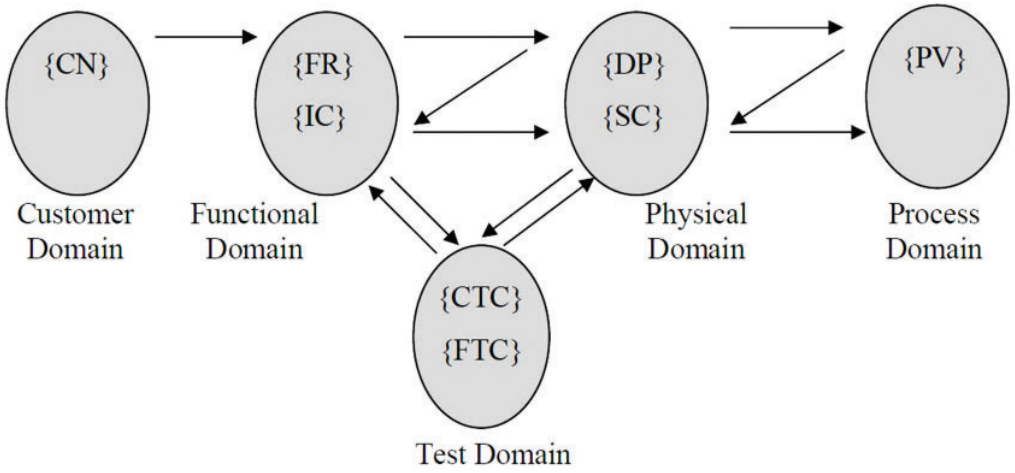


Fig. 3.17: The transdisciplinary product development lifecycle domains and characteristic vectors including a new additional test domain (Gumus 2005)

In the case of adding a test domain to the model, Gumus (2005) claims that testing can be managed using the model. As the illustration shows, adding a test domain to the model implies the introduction of four new vectors (Fig. 3.17), i.e. functional test cases (FTC), component test cases (CTC), input constraints (IC), and system components (SC). A functional test in the test domain consists of a set of functional test cases. By extension, the functional test cases consider system tests that are to be applied verifying that functional requirements are satisfied by the system, which is also referred to black-box testing. The component test cases are equivalent to white box testing and drives the verification ensuring that the system components satisfy the allocated functional requirements and input constraints. Each system component is tested before it is integrated into the system to make sure that the requirements set put on that component are all satisfied.

The transdisciplinary product development lifecycle model utilizes the systematic nature of axiomatic design in order to provide a systematic approach for product development lifecycle activities and management. The model seeks to improves the axiomatic design in the area of domain entity description and management and takes the axiomatic design method one step further to support the test domain of the product development lifecycle, with is of specific interest in this research study. Thus, the model is relevant as it helps develop, capture, and present both the big-picture and a detailed view of the product development knowledge, including design, requirement and finally the testing traceability knowledge, which is of great interest to this research.

3.3.4 THEORY OF DISPOSITIONS

In theory of dispositions, Andreasen and Olesen (1990) seeks to clarify the complex effects of decisions taken in product development and finds that decision making involves a dispositional mechanism. Olesen (1992) defines a disposition as *"... the part of a decision taken within one functional area that affects the type, content, efficiency or progress of activities within other functional units"*. A functional area can be considered as a functional unit or product life activity as proposed by Andreasen (2007). The impact of the dispositions on activities will be effectuated in the so-called meetings between the product and its life phase systems (Fig. 3.18, a). Foreseeing or accounting for such meetings will make it possible to establish rules that can be utilized in the design process to increase the product's expected performance, which is often related to design for X. In accordance with Olesen (1992), Andreasen (2007) finds that there exist dispositional effects of decisions taken in the development of the product, affected by life-phase activities and that these are based on rules, and lastly affect the life of the product (Fig. 3.18, b).

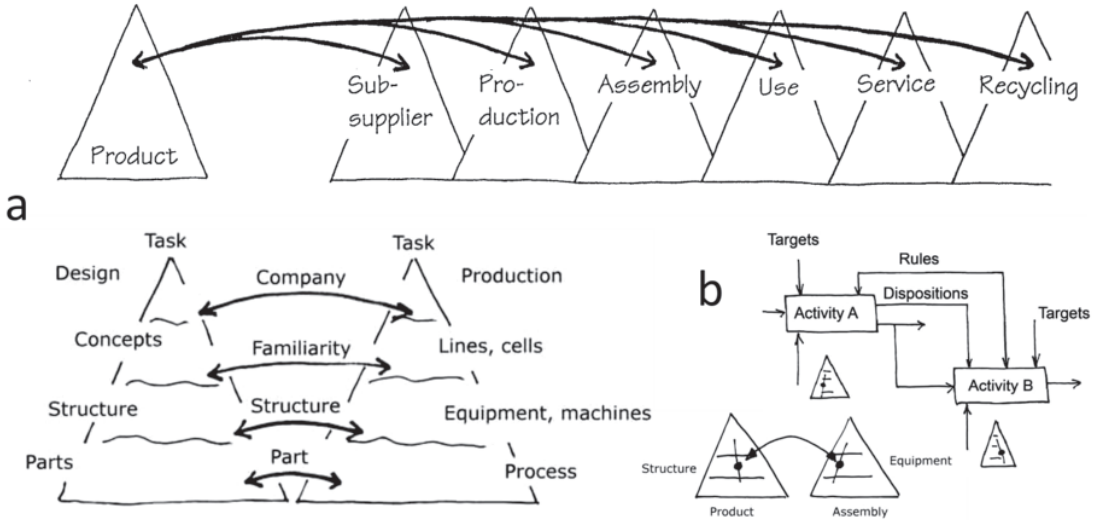


Fig. 3.18: The meeting and its effects: (a) The fitting of the product and the life phase systems are made on four levels (Andreasen et al. 1996), and (b) A general model of a disposition between two functional areas A and B (Olesen 1992)

Forseeing the dispositional effects, the meeting between the product and its life-phase systems have to be considered during the design process. The theory of dispositions and its models make it possible to classify and map principal dispositions mechanisms between design and the life-phase systems, e.g. production, sales, transport, service, maintenace and delivery systems. One implication of the theory is that the life-phase systems and the design have to be fitted and renewed concurrently to obtain optimal product performance throughout the product's life (Fig. 3.19). The meetings are of importance because it is during these that the performance of a

product can be evaluated. In continoation hereof, Olesen (1992) proposes that performance can be measured by means of so-called universal virtues, e.g. costs, quality, flexibility, effeciency, time, risk and environmental effects that all can be quantified during the product's meetings with its life-phase systems.

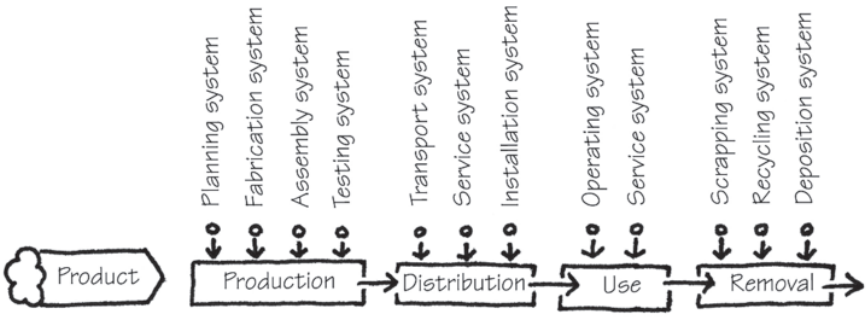


Fig. 3.19: A life cycle model of a product's meetings: The design and some of the life phase systems may be completely renewed while other life phase systems are reused (Olesen 1992)

Further, Olesen (1992) introduces a product life score model, which illustrates that as the product is designed and live its life, it meets with many different systems that also is designed or disposed for (Fig. 3.20).

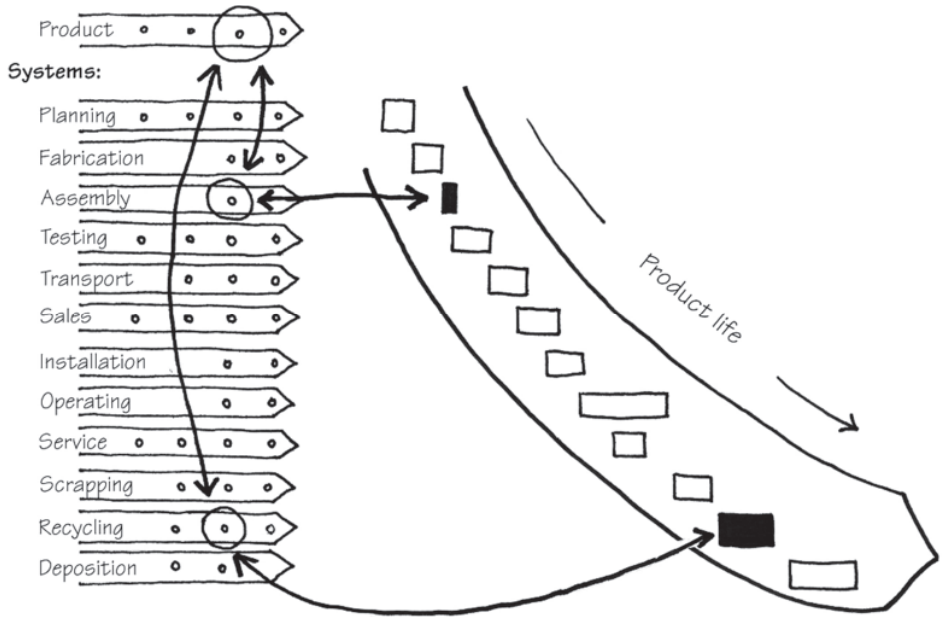


Fig. 3.20: The score model: Provides an overview of the systems that the dispositions affect when a product is developed (olesen 1992)

The theory of dispositions suggests several dispositional mechanisms or systems that cover different types of dispositional effects, i.e. strategical, modularization, standardization, optimization, resource, robustness, etc. It is during the meetings that the dispositional effects should be obtained, and theory of dispositions accordingly suggests several dispositional areas serving to classify at which areas these effects typically arise, the ones that designer must consider and control during the development process, i.e. costs, process and equipment, assembly, quality, etc.

The central concept of this theory, that effects are realized at the meetings between the product and its life-phases is of critical importance to this research. Thus, the theory of dispositions fundamentally contributes to the research of this thesis as it introduces dispositional meetings and effects. This contributes to the understanding of extending today's view on product development adding a compliance view to product design, which is a core contribution of this research. The theory of dispositions is relevant because it describes principal relations between structural aspects of the design and the life-phase systems and thereby creates a basic understanding of establishing a thorough decision basis during new product development. Meanwhile, the theory is important as reveals that there will be an effect on decisions taken early in the design process. This is important when modelling compliance testing and documentation as a means to meet regulatory requirements. Both the dispositional areas and the effects are considered a vital basis for the research presented here, as the identification of a modular platform architecture can be seen as an activity of identifying, balancing and prioritizing dispositional areas and effects for a product program, while architecting modular platforms, according to this theory, can be seen as dispositional mechanism providing some desired effects during the product programs life.

3.4 Closing the Theoretical Basis

In this chapter, an overview has been provided describing the engineering design and product development theories considered relevant for this research. The collective theory base is rooted in theories of the "Copenhagen School" or theories to which the school has contributed, but also other theories have been included to sufficiently found the theoretical basis on which this research build. The engineering design theories form an important basis for understanding design of objects, while the theories related to product development are all needed to understand the context and processes for designing the object and are relevant to this research as it provides insight into design processes that support the act of designing products. The theories introduced in this chapter all are considered as a necessary foundation for this thesis containing research that have been conducted at the Section of Engineering Design and Product Development, Department of Mechanical Engineering, the Technical University of Denmark.

"If you think compliance is expensive – try non-compliance."
Paul McNulty

Chapter 4

Frame of Reference: A Clarification of the Research Phenomena under Investigations

The objective of this chapter is to establish the frame of reference for the research study by providing insight into: (1) the medical domain, its establishment and development and (2) how medical manufacturers develop devices for the marketplace. Meanwhile, this chapter provides an overview of (3) the complexity drivers that challenge the industry, hereunder (a) market, (b) product, (c) process, and (d) organizational complexities. Finally, this chapter clarifies (4) the phenomenon of developing product programs in heavy-regulated industries and how this transmits to the well-established theories of modular platform architecture design. The aim of this chapter is exclusively to clarify the phenomenon under investigation establishing the frame of reference for the research study of this thesis.

4.1 Understanding the Industry and its Complexities

As a result of intense global competition, medical manufacturers are facing the challenge that while they must continue innovating their medical device program under new and highly complex settings, including global product development, outsourcing of design and manufacturing, and the need to incorporate new technologies, they must continuously comply with strict regulatory requirements imposed by governing agencies. The medical manufacturing area is one of the most regulated in which significant quality systems and product requirements must be satisfied. The regulatory requirements are intended to ensure that manufacturers

continuously design, produce, and launch, medical devices that are safe and align with their intended purpose.

A medical device manufacturer's quality management system (QMS) is the creates the basis for maintaining regulatory compliance, continuous improvement, effectiveness and attaining stakeholder confidence in the manufacturer and its product offerings. A QMS is a set of procedures, processes and procedures that help a business meet the requirements expected by its stakeholders and is used for the control and continuous improvement of both business processes and products. In the medical devices industry, a QMS is required by public authorities in nearly all countries around the world. In continuation hereof, ISO 13485 enables an organization to provide safe medical devices while fulfilling both customer needs and regulatory requirements. Thus, these matters are key to this research study. Regulations varies greatly across regions. For this reason, ISO 13485 does not set detailed requirements, but demand the medical device manufacturer to identify those regulatory requirements that are relevant and incorporate them into its QMS. This is an important finding, as these regulatory substances, must be incorporated into the support provided as a result of this research study.

Regulatory requirements are stated by public authorities and are referred to as those demands by which medical manufacturers that design and launch medical devices must comply to ensure the human health and safety. The regulatory requirements stated by the public health are enforced by authorities appointed by the government. These authorities, also referred to as notified body, has the authority to act on behalf of the government to ensure that regulatory requirements of the medical device directives are altered into national law. Medical manufacturers are audited by the notified body to ensure that the company applies to the current legislation set by the government. At audits, of executed every one or two years, both processes and products are inspected, and the company must prove compliance with current regulatory requirements. Hence, the company must prove conformity with the directives applied to the different products of the product program. Thus, it is crucial for a medical manufacturing company to have control of documentation, proving that the company has done what is required to ensure the overall human health and safety, as both products and processes must pose or lead to minimum risk towards patients and operators of the products brought to market.

4.1.1 Regulatory Requirements

Regulatory requirements are legal demands enforced by law. These requirements are non-negotiable and must be complied with for a medical company to exist. Failure to comply with a legal requirement may result in a fine or penalty and possibly sentence for the persons or the organization responsible for such failure. For medical devices, the CE mark is a mandatory

conformance mark certifying that the product has met with safety, health and environmental requirements stated by law. Thus, the medical device must conform to the given legislations before market introduction. The conformity means that the company has followed every standard subject to developing and testing the given product.

A variety of assessments to which a medical manufacturer must conform exist. The following descriptions are excerpt from the key standards, directives and legal regulations published by the organizations and authorities setting the legal requirements.

ISO 9001 – Quality Management System, specifies *"requirements for a quality management system when an organization: (a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and (b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. All the requirements of ISO 9001 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides."*

Quality Management System – Requirements (ISO 9001:2015)

FDA 21 CFR 820 – Quality System Regulation, is *"applicable to manufacturers of finished medical devices sold in the United States, including imported products. It sets out the quality systems for medical device manufacturers, current good manufacturing practice (cGMP) regulations that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. These requirements are meant to ensure that medical devices are safe, effective, and in compliance with the Federal Food, Drug, and Cosmetic Act."*

Quality System Regulation – Medical Devices (FDA 21 CFR820)

ISO 13485 – Medical Devices is based on ISO 9001, and is *"an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. It is designed to be used by organizations throughout the life cycle of a medical device, from initial conception to production and post-production, including final decommission and disposal. It also covers aspects such as storage, distribution, installation and servicing, and the provision of associated services. In addition, the standard can be used by other internal and external parties, such as certification bodies, to help them with their certification processes, or by supply chain organizations that are required by contract to conform. ISO 13485 helps an organization design a quality management system that establishes and maintains the effectiveness of its processes.*"

Quality Management Systems – Medical Devices (ISO 13485:2016)

Any medical device placed on the European market must comply with relevant legislation. Manufacturers' products meeting 'harmonized standards' have a presumption of conformity to the directive. Products conforming to the directive must have a CE mark applied. The core legal framework consists of three directives:

- Council Directive 90/385/EEC – Active Implantable Medical Devices Directive (AIMDD), specifies *"the essential requirements that medical device manufacturers must meet to apply the CE mark and legally market or sell products to the European Union. To demonstrate compliance with the requirements of the directive, a manufacturer must develop technical documentation in order to properly evaluate their medical device designs. Manufacturers must also establish a quality management system that complies with the requirements stated in the directives."*

  Active Implantable Medical Device Directive (Council Directive 90/385/EEC)

- Council Directive 93/42/EEC – Medical Device Directive (MDD), is *"intended to harmonize the laws relating to medical devices within the European Union. The directive is a 'new approach' directive, which means that a manufacturer must comply with these requirements in order to legally launched products to the EU market. Thus, requirements stated in the 93/42/EEC must be met. Manufacturers' products meeting 'harmonized standards' have a presumption of conformity to the directive, but it must be proved at audits carried out by the notified body. Products conforming to the directive must have a CE mark applied."*

  Medical Device Directive (Council Directive 93/42/EEC)

- Council Directive 98/79/EC – In Vitro Diagnostic Directive (IVDD), provides *"regulatory requirements that facilitate the free trade within the European Union and specifically addresses the safety, quality and performance of in vitro diagnostic (IVD) medical devices. The aim of the directive is to ensure that medical devices classified as IVD do not compromise the health and safety of patients, users and third parties and attain the performance levels specified by the manufacturer. The manufacturer is responsible for ensuring that all products comply with the essential requirements of the directive before using the CE mark and legally launch products to the market."*

  In Vitro Diagnostics Directive (Council Directive 98/79/EEC)

The global market for medical devices is, unsurprisingly, an extremely regulated one. Safety for users (operators) and end users (patients) of medical devices is of critical importance, which includes acceptable clinical performance for the intended use.

The challenge for medical device manufacturers is to understand the complex array of regulations for the markets they sell into and how it applies to their specific products. Hence, the subject of this research. Namely to provide better support for systematically evaluate these correlations. By doing this, they can ensure that their products are compliant for efficient entry into that market and to remain on the market, maximizing their commercial potential. Knowledge of the similarities and, sometimes even more importantly, the differences between global regions is crucial to meet regulatory requirements efficiently. As a manufacturer of medical devices, one of the greatest challenges in breaking into, or continuing, success in this market – is navigating the regulatory process efficiently.

4.1.2 Medical Device Diversity and Risk Classification

According to Food and Drug Administration (FDA 2018), a medical device is *"an instrument, apparatus, implement, machine, implant, in vitro reagent, or other similar article, that is intended for use in the diagnosis, prevention and treatment of disease or other medical conditions"*. There exist a huge variety of medical devices at the marketplace, ranging from basic instruments to complex digital machines. Thus, medical devices (MDD) rages from simple devices like wound dressings and scalpels, durable devices like wheelchairs and dentist chairs, implantable devices like cardiac pacemakers and monitors, prosthetic limbs and prosthetic joints life-supporting devices like respirators and lung ventilators, sophisticated, software-controlled devices like CT scanners and MRI machines (ISO 13485 2016). In vitro diagnostics (IVD) medical device is any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, for the purpose of providing information (CD 98/79/EC 1998).

In general, it is seen as economically unfeasible and less justifiable in practice to apply all medical devices to the highest level of conformity assessment procedures available. Therefore, a graduated system of control has been introduced for the medical manufacturers to assess its products according to the level by which the individual device poses risks towards the human health and safety. Thus, by this system, the level of control corresponds to the level of potential hazard inherent in the device that is of concern, which is done through a medical device classification system, so that medical devices can be applied appropriate conformity assessment procedures. It is generally the rule that medical device companies should determine the classification of their products as early as possible during new device development. Therefore, the council decided to establish a system of classification rules within the directives offering the possibility that medical device manufacturers can classify its own products (Meddev 2010).

As indicated above, the classification system for medical devices is a risk-based intended to identify to which degree a certain device is vulnerable acting upon the human body. Thus, the classification system considers the potential risks associated with the device, which can roughly be divided in accordance with its area of application, i.e. medical devices (Fig. 4.1, a) and in vitro diagnostics (Fig. 4.1, b). It is the aim that the risk-based approach allows for using a set of criteria that can be combined in various ways to determine the classification, e.g. duration of contact with the body, if contact is outside or inside the body, the degree of invasiveness, etc. These criteria can then be applied to a range of various medical devices and technologies to set the appropriate classification (Meddev 2010).

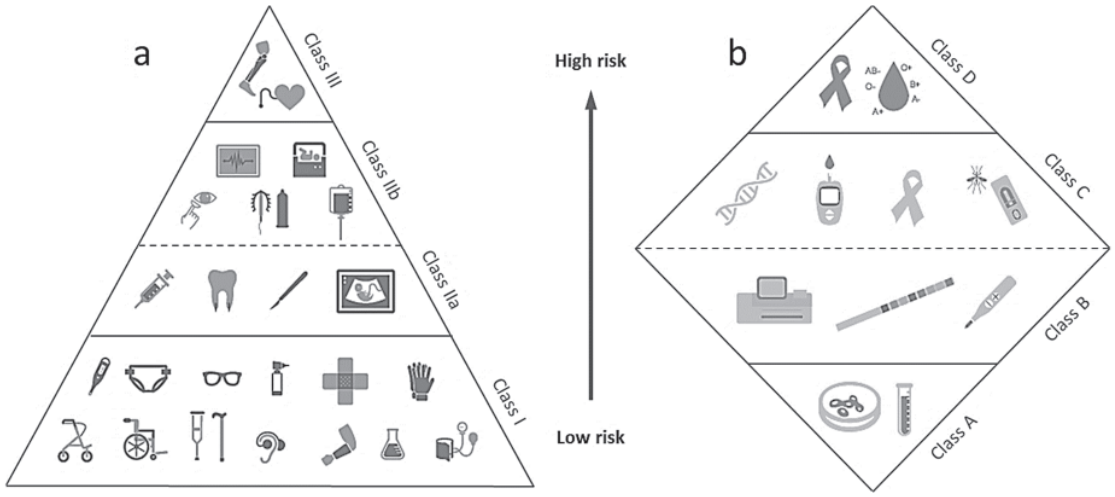


Fig 4.1: General diversity and classification of medical technologies: (a) medical devices and (b) in vitro diagnostics, modified from Gendra (2018).

The class to which a given medical device is assigned determines, among other things, the type of premarketing submission/application required for market approval or clearance. If the device is classified as Class I or II, a 510k will be required prior to market introduction. For Class III devices, a premarket approval application will be required. In this case, a 510k must be established for the market approval prior to launching the product. As described, device classification depends on the intended use of the device and upon indications for use (FDA 2018). A subset of intended use arises when a more specialized device is at hand. It is notable that classification is risk-based, as it means that the risk must be asses to determine in which way the device poses danger towards the patient and/or the user of the device, which is a major factor when assigning a device to a given risk class. Class I includes devices with the lowest risk and Class III includes those with the greatest risk. The anomy of intended use and risk classes is important to this research, as it leads to specific subsets of requirements – the more risk a device poses, the higher class and the more demanding regulation applies to it.

4.2 MEDICAL DEVICE DEVELOPMENT

Medical device development is highly influenced by the concern of verificaiton and validation testing. To understand the affects of verification and validation during the development of medical devices, a waterfall process has been established with a logical sequence of phases with accompanying reviews (Fig. 4.2).

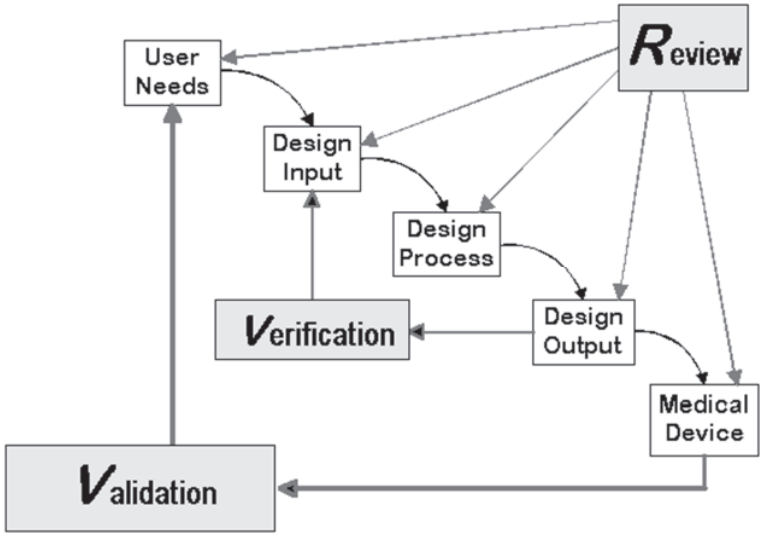


Fig. 4.2: The waterfall model: Application of design controls to waterfall design process (FDA 1997)

Basically, requirements are developed, and the device is designed to work as intended and thereby meet those requirements (Privitera 2015). The design is then assessed, assigned to production, and the device is produced. In practice, feedback routes is required between each phase of the process representing the iterative nature of medical device development process (Jacobson 1997).

Meanwhile, in the waterfall model proposed by the medical authorities, design reviews are performed at certain points in the design process. For example, a verificaiton review, is done to ensure that the input requirements are ample prior to being converted into the design specifications. Others, later in the process, are used to ensure that the device design is ample prior production, often by designing prototypes for the purpose of use testing and clinical evaluation. Last, a validation review, is conducted prior to transfer of the design to production. Generally, they are applied for the ensurance that a stage has been completed in an acceptable manner, and that the next activity or phase can begin. As shown in the illustration, two subjects are important converting design inputs to design outputs, namely the verificaiton of those

requirmeents, while validation is important to ensure that the finalized product meets the user needs defined in the first place.

Design Verification: *"Have we Built the Thing Right?"*

In general, medical devices must be demonstrated to be fit for their intended use or purpose before market clearance can be achieved, which is the purpose of conducting verification tests. As described, verification is an inherent activity of the device design, process design, and production development activities, and generally are to answer the question: *"Have we built the thing right?* The design verification involves comparing design outputs (outcomes of a design stage) against its inputs (the requirements for the design).

The design input and verification of design outputs are very important in medical device development. When the design input has been reviewed and the design input requirements have been determined in accordance with acceptance criteria, these will be translated into design requirements. Here, the first task is to to convert these requirements into system or high-level requirements, which are to be considered the design inputs. These high-level specifications are then verified if they conform to the design input requirements and then become the design inputs for the next step. This process of translating and verifying their input requirements is repeated thorughout the design process. Thus, every design input is tranlated into a new design output, each output is verified if it is conforming to its input, whereby it becomes a design input for the next phase of the design process. By this, design inputs are converted into device design conforming to those requiremnets (FDA 1997).

"The consequences of poor verification of safety-critical products such as medical devices can be disastrous, both commercially and in terms of human life" (Clarkson et al. 1999). This is why all designers, especially those who develop high-risk medical devices, must undertake verification tests in a rigious well-documented way. This process is also refered to as design control and is a mandatory obligation demanded by law. Through thorough design and process control, designers must show evidence, or compliance, with given regulations. This is done by proving that the company has performed verification tests that demonstrate that all design requirements have been met and that the guidelines and legel requirements have been met. Therefore, there is a strong incentive for the designers to have identified legel requirements, followed the verification test procedures and mitigated risk of errors and thereby potential hazards before applying for acceptance of new medical devices. Meanwhile, the company should continously evaluate and potentially update design and document controls as new legel requirements are enfforced by law.

Design Validation: *"Have we Built the Right Thing?"*

Whereas verification ensures that the medical device is design right, the validation ensures that the developed device actually fit is intended purpose, also refered to as its intended use, or just use, accounting for its entire life cycle (Alexander and Clarkson 2010). Validation is concerned with demonstrating consistency and completeness of the design with regards to the original offset of what the product should do. Thus, validation can be seen as the overall process of proving that the device is intended for purpose or a means for answering the question: *"Have we built the right thing?"* Although current literature treats the subject of medical device design validation, only little research has been carried out in respect to actually mapping the validation domain. Previous work has identified the need for an approach to medical device design that incorporates design and validation principals (Clarkson et al. 1999). Based on interviews carried out with designers and managers within the medical device industry, along with the review of design case studies, Alexander (1999) finds that while validation philosophies for the development of medical equipment have been in place for some time, current methods for device validation is relatively difficult to use in practice. Validation of medical devices, namely to prove that the device is fit for purpose involves an evidence building process, as well as proving that the product meets the original user needs and intended uses (Alexander and Clarkson 2010). Good design practice techniques and rgious design methods, should be considered when planning for proper verification and validation activities, but those available are diffcult to implement in practice (Wiklund 1995).

4.3 Complexity Drivers in Medical Industry

The complexity drivers in medical industry can be summarized within four specific domains, i.e. market complexity, product complexity, process complexity and business complexity. The market complexities relate to those influencers that are largely external to a medical manufacturing business, while product and process complexity relate to the internal ability to streamline the development of new products while maintaining products already brought to market. Lastly, the business complexity relates to a company's ability to develop its business based on the external and internal drivers for complexity, as it is influenced by the driving market forces and the company's fitness to meet the external challenges straining the business.

4.3.1 Market Complexity: Technology Evolution, Customer Needs and Regulatory Requirements

Medical companies are faced with the fact that they operate within an industry that are to fulfill a two-faced market setting – on one hand they must meet ever growing customers' needs while on the other they must comply with restrictive regulatory requirements set by the public

authorities. High consumer expectations for better healthcare and technology advances that improve quality of life are creating favorable market conditions. Yet, rising costs and especially compliance concerns are forcing medical device companies retain its progress. Companies must balance the competitive drive for new product launches while consumers need to be ensured that what they buy safe and well-priced. Medical companies must cope with the following market complexities:

- Growing competition due to a more globalized marketplace has increased the customer's expectations to have products tailored to fit their exact needs (Pine 1993). The era of 'one size fits all' medical products with numerous drugs and devices not working on 50% or more of the population is at change (Taylor et al. 2014). Patients, doctors, surgeons, physicians, laboratory technicians, etc., after all, are like any other consumers: They want not only a good product – quality care at a good price – but also ease of use of products that fit their exact needs (Herzlinger 2006). This leads to an increasing number of product variants to be brought to market. Consequently, companies must speed up the pace while being vigilant towards changes to specific customer needs.

- Technology evolution is at its pace, new IOT technologies, wearable technologies, data sourcing systems, additive manufacturing, biomaterial printing technologies etc., provides a foundation for new products and may provide competitive advantage for the firms that are able to utilize its probabilities (Walsh 2004). Though, these new technologies generally pose more risks and unknowns to a company (Cooper 2006). Especially the fact that regulatory frameworks for such technologies are not yet in place, thus on one side a company should seek to innovate its products incorporating new technologies, meanwhile its very uncertain whether such products are to be approved by the authorities.

- Where customers influence a company's selling figures, regulatory authorities decide whether a company can sell its products. These regulatory frameworks that companies are to follow, leads to comprehensive approval processes that hugely affect time-to-approval for new medical products (Pietzsch et al. 2009). Numerous regulatory frameworks exist around the globe while these are at constant change, which hugely affect medical companies' ability to show compliance when bringing new products to market.

- Not only do the regulatory frameworks apply to new product development projects, they also apply to products already launched to the marketplace. Companies face the challenge that changing regulatory requirements affect the current product portfolio. Companies must at any time be ready to reach compliance at any new level set by the public authorities, which also requires full overview of the product portfolio as well as

control of the test documentation related to the products. Companies are often given a limited time to reach compliance with the newly established requirements, i.e. time-to-compliance.

The market complexity sets an enormous pressure on medical manufacturers, as not only must these companies cope with ever growing competition, developing innovative solutions to meet new customer needs, medical manufacturers must also constantly be surveilling towards new regulatory requirements, which hugely affects a company's ability to bring new products to market.

4.3.2 Product Complexity: Product Design, Engineering Requirements and Data Management

The slowly but steady increase of product variants leads to an increasing pool of design concepts, subsystems, components, manufacturing processes, and finally control processes, which drives the internal complexity of the medical companies. The following key developments are found to drive product complexity:

- Medical products have shifted from mono to being more multi-disciplinary – mechatronics have taken over – and tomorrow it will be the intelligent or even cyber-physical systems that dominate the market (Dumitrescu et al. 2015). Meanwhile, product functionality has transitioned from the user to the machines, thus requiring training of users to operate them safely. These complex systems require extensive technology- and user-oriented risk mitigation, which raises the product to documentation process complexity of medical companies.

- In order to meet the customer demands, companies tent to compete on superior product functionality and performance, while they seek to integrate multiple technologies, which often are multi-disciplinary, causing product complexity to rise (de Weck et al. 2014).

- Increasing product complexity challenges the understanding of how properties are realized in the product, which requires companies to produce radically more documentation (Jensen et al. 2015). Meanwhile, designers seem to sort and structure their data using the same approach as they apply when compiling a pile of laundry at home (Harlou 2006). Product data and documentation is still not systematically stored documenting the product data outcome (Kvist 2010), which considerably affects the ability to reach regulatory approval.

- The increase in medical device complexity combined with the expansion of user environments is increasing the chances for significant quality issues. Increasingly when

quality problems do occur, legal, regulatory, media and social media attention increases, magnifying and focusing attention on the issue (Fuhr et al. 2013).

What is more to the above mentioned, is that at a time where multi-product development seems to be the answer to the growing market challenges, the rise of product complexity is an imminent obstacle to successive achievement of the competitive advantages that portfolio thinking can bring to a company

4.3.3 Process Complexity: Compliance Activities, Operating Procedures and Practices

Processes and activities of medical manufacturers are hugely affected by regulation. Processes must be established in accordance with given regulation in order for a company to uphold their certification required to stay at market showing constant conformance with statutory and regulatory requirements. The following key developments are found to drive process complexity:

- Tightening statuary and regulatory requirements demands medical device companies to have increasingly extensive documentation processes in place, which conflicts with the fact that product complexity rises due to the expansion of the product portfolios and the intermediate lack of the required data and documentation managing discipline (Meyer and Lehnerd 1997; Hvam et al. 2007; Ericsson and Erixon 1999; Anderson and Pine 1998).
- Product-centric documentation is required for staying in compliance with given regulations, which drives process complexity as it forces companies to structure the entire product life-cycle while tracing everything from the patient, to requirements, design, test, manufacturing, and servicing of the device, which require information rich product-to-documentation traceability methods that are currently not at hand (Boucher 2015).

Regulatory requirements significantly shape a medical manufacturing business. It is a constant and ever-growing challenge to upkeep process conformities, which is required to stay at market. Proving compliance with current legislation is a multidimensional task. Medical manufacturers must show full compliance with the quality management system dictated by the governing agencies, which requires continuous improvement. One thing is to establish the system, another is to follow it. Documentation of tests plays an central role in the medical device industry as this a mirror of the given processes that a company has established and is obliged to follow, thus if the documentation pose nonconformity, so do the processes by which the activities of a company is executed.

4.3.4 Organizational / Business Complexities: Time-to-Money and Reimbursement Strategies

The medical industry deviates from others in the sense that profitability of new product launches depends on third-party payments, the reimbursement of the medical product. The following key developments are found to drive business and organizational complexity:

- Reimbursement to large extend influence companies strategy for market launches, as medical companies face long investment time for new drugs or therapies that require FDA approval, e.g. a biotech firm have to wait ten years even to find out whether a product will be approved for use (Herzlinger 2006). From medical approval to reimbursement, companies face rising costs of regulatory compliance (Taylor et al. 2014).

- Increasingly empowered costumers and cost-pressured payers are demanding accountability for new product innovations demanding a medical company to show cost-effectiveness and long-term safety, in addition to fulfilling the sorter-term efficacy and safety requirements of regulatory authorities (Herzlinger 2006). Thus, one thing is the time it takes for a company to reach approval of products, another is the time spend from approval to reimbursement (time-to-money), and the cost associated with this time is tremendously high compared to other industries.

These conditions naturally hugely affect the strategic decisions, as well as the business and economic models of a medical company. This highly complex situation raises a profound need for research that aims at supporting these companies in overcoming the challenges of executing sufficient design controls during new healthcare product development and general management of products already at market for the satisfactory of the regulatory requirements enforced by public authorities.

4.4 Summary of the Phenomena under Investigation

Based on the discussed elements affecting and driving the complexity of new medical device development, a meta model illustrating the comprised phenomena to be investigated is established (Fig. 4.3). The situation is that the market is globalizing, which drives the diversity of regulatory substances and drives companies to compete on superior product functionality and product variety. Meanwhile, the increase functionality increases the complexity of products being developed within the medical device domain. The growing complexity of product variants and the increasing product variety changes the state of the medical manufacturer's product program, going from lower to higher complexity. Further, as it has been described, the regulatory framework is changing from setting light-weight requirements to more tightened

requirements, which affect the control of documents within the company – going from low to high complexity.

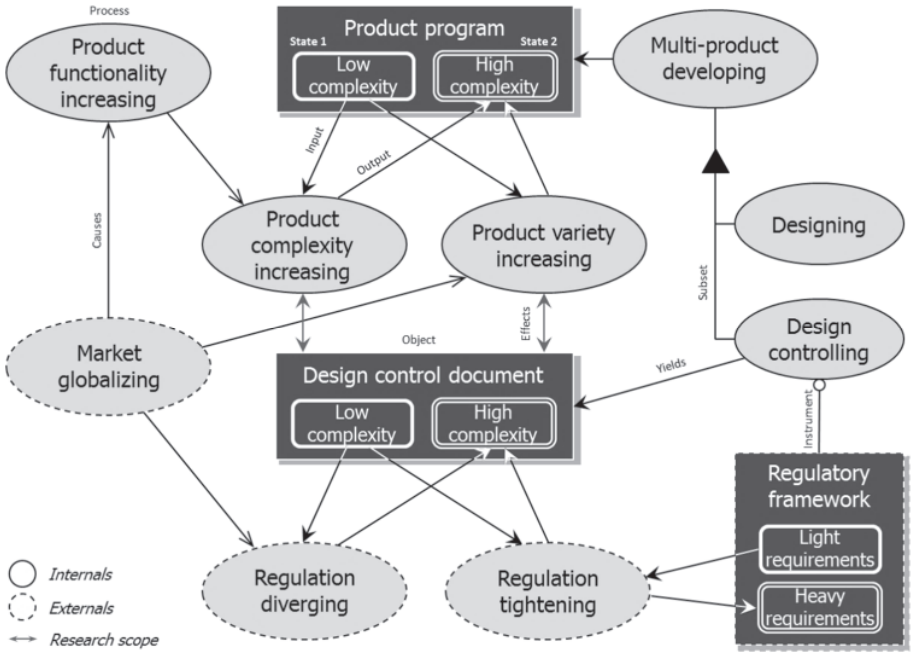


Fig. 4.3: Meta-model illustrating the phenomena under investigation, conceptual modelling language inspired by the Object-Process Methodology developed by Dori (2002)

This phenomenon, growing market complexity driven by customers and governing agencies, challenges medical device manufacturer's ability to bring new products to market and maintain the program of products already at market staying in compliance with the diverse and highly complex regulatory frameworks. Thus, the aim of this research is to support manufacturing business within the medical device domain to overcome the challenges of increasing complexity forces straining the business. The research scope is centered around the increasing product complexity and the increasing product variety which hugely affect the design control of the business. Thus, the aim is to develop support for the medical manufacturing companies so that they can better cope with these challenges while taking into account the influence of regulation.

"All theories are legitimate, no matter. What matters is what you do with them."
– Jorge Luis Borges

Chapter 5

Clarifying the Current Solution Space: A State-of-the-Art Literature Study on Modular Platform Architecture Design

The aim of this chapter is to introduce the theoretical state-of-the-art literature about modular platform architecture design. First, an introduction to the review is given, including the outline and scoping of the literature study. Next, the terms and concepts of family, architecture, platform, and module are provided as these three elements form the cornerstones based on which the definitions used in this thesis is provided. Hereafter, relevant state-of-the-art tools and methods that support modular platform architecture design is described and discussed, i.e. how these contribute to this research. Finally, the entire review is discussed, and shortages are identified based on the scope of the research study outlining the current solution space.

5.1 Introduction to the Literature Study

Continuous development of multiple products, often referred to as the development of product families, based on modular platform architectures has gained significant attention in industry and academia. Numerous publications of papers, journals and books on the subject indicate this growing interest, and many methodologies exist for the development of modular platform architecture designs. The objective of this chapter is to provide an overview of relevant research contributions within this field of research. The chapter will not provide exhaustive descriptions of all theory areas utilized but will focus on the main contributions on which this research builds. Thus, the focus of this state-of-the-art literature study is primarily on the front-end engineering

part, or early stage development, of modular platform architecture designs, i.e. market segmentation, customer needs gathering, system requirements and concept design, component/module selection, and last but not least methodologies for modular platform architecture concept layout. The chapter aims at providing an overview of the current solution space for overcoming the challenges identified earlier in the thesis. Hence, this chapter seeks to clarify the basis for the theoretical contributions within the research area of interest and clarifies some of the open areas that have not been fully investigated yet. Thus, this section seeks to bring answers to the following questions:

- What are the main perceptions of family, platform, architecture, and module?
- What are the main methodical contributions within this field of research?
- To what extent do the current contributions address the identified challenges?

The chapter is structured so that it treats each of the main research contributions one by one describing the point of views on developing modular platform architectures. First, the terminology and concepts of product family, product architecture, product platform, and module are introduced based on the last decades of research within the design community. Second, the predominant tools and methods are introduced, from which specifics are described in detail. These tools and methods are chosen based on their perceived relevance to the topic of developing modular platform architectures under restrictive regulatory business constraints. At last, the state-of-the-art contributions are discussed and reviewed based on this objective, and the section ends with gap identification and concluding remarks on the theoretical state-of-the-art review.

5.1.1 Outline for Investigating the Phenomena

Many topics are relevant to the development of modular platform architectures and therefore such development is a multifaceted subject to study. From a large pool of topics a few have been selected based on their critical relevance to the development of multiple medical devices under restrictive regulatory business constraints. The key topics are applied in the evaluation of state-of-the-art review of methods and tools at hand when developing modular platform architectures. The three topics of critical relevance to the research subject of interest are:

Scope – The level of abstraction is fundamental to the type of manipulation carried out and the competitive advantages reached by a company. Top-level manipulation is about changing the program of products, while the lower level is about manipulating the product family, and finally the manipulation of single products is the lowest level of manipulation. In the epoch of multi product development accommodating a growing multitude of market requirements, it is essential that companies undertake high level manipulation. Manipulating programs or large

portfolios dissecting families of products is a necessity to companies working within the medical domain.

Aspect – The aspects considered is important when developing new products and is fundamental to the maintenance of medical devices already brought to market. Early stage aspects include market segmentation, customer needs gathering, and engineering design and back-stream testing. When continuously developing multiple medical devices, the aspect of regulation, testing, and the documentation hereof plays a crucial role for the market introduction of new products and is also essential to the ability to stay at market with products that have already been brought to market. Hence, as compliance forms the basis for medical companies' existence, the inclusion and alignment of these related aspects are of imminent importance to medical device manufacturers.

Purpose – Methods and tools for the development of modular platform architectures fundamentally aims at either analysis for rationalization or synthesis for new product development. The method chosen by a company has great impact on the benefits that a given company is to harvest pursuing modular platform architecture development. Within the medical device domain, manufacturers are continuously challenged with the ability to bring new products to market while staying in compliance with products already at market. Hence, the scope, i.e. synthesis for new development and analysis for rationalization, both plays a critical role for medical manufacturers – continuity between analysis and rationalization of a given method should be aligned in order to establish holistic control proving full compliance traceability of the method used with given regulatory requirements.

The following investigates the state-of-the-art literature on developing modular platform architectures within the design science community – based on the above topics, the fundamental concepts, terms and definitions, and the predominant methods and tools currently available will be presented.

5.2 Fundamental Concepts, Terms and Definitions

In this section an array of terms and definitions is introduced to provide insight to the literary subject of modular platform architectures. The section is divided into the subjects: Product family, product architecture, product platform, and module, modularity and modularization, while it provides insights into the coherences between the subjects. The conceptual descriptions are based on engineering design literature and thus describe the phenomena from an engineering design and product development perspective, the research community from which this research study originates.

5.2.1 PRODUCT FAMILY

A product family can be seen as a group of related products based on a product platform, facilitating mass customization by providing a variety of products for different market segments cost-effectively (Simpson et al. 2005). Simpson et al. (2006) argue that a product family should ideally be built not only on elements of the product architecture (components and interfaces) but on a multidimensional core of assets which includes also processes along the whole value chain, customer segmentation, brand positioning, and global supply and distribution. Thus, a product family can be defined as *"…a group of related products that share common features, components and subsystems remaining constant from product to product and differ in others varying from product to product.*" (Messac, et al., 2002). A product family represents a set of similar products derived from a common platform and yet possesses specific features/functionalities to meet customer requirements. Each individual product within a product family is called a product variant, and while a product family targets a certain market segment, the product variants address a specific subset of customer needs within the market segment (Meyer and Lehnerd 1997). All product variants share certain mutual structures and technologies, which form the product platform and according to Erens and Verhulst (1997) a product family can be defined as: *"…a product with identical internal interfaces i.e. interfaces between the product's components, for all variants in each domain. Interfaces must be standardized in each of the functional, technology and physical domains to allow the full exchange of components"*. Supplementary, a component may be defined as any distinct region of a product, a discrete physical part or sub-assembly of a product (Ulrich 1995). Streams of individual products generated by firms may be thought of as evolving families of products (Meyer and Utterback 1993). The interpretation of product families depends on different perspectives. From the marketing and sales perspective, the functional structure of product families exhibits a firm's product line or product portfolio and thus is characterized by various sets of functional features for different customer groups (Agard and Kusiak 2004). The engineering view of product families embodies different product technologies and the associated manufacturability and thereby is characterized by various design parameters, components, and assembly structures (Simpson 2004). The aim of developing product families is to create a certain synergy for the purpose of managing a high product density. The product families can be seen as the means to improve the commercial variety whilst limiting development, manufacturing and servicing efforts. Jiao et al. (2007) states that product families can offer a multitude of benefits, i.e. cut in risks and system complexity, better ability to upgrade products, and improved flexibility and responsiveness of manufacturing processes.

In this thesis, to summarize, a product family is a group of related products that share common features, parts, and subsystems; yet satisfy a variety of markets. Here, form features refer generally to the shape and characterizing features of a product; function refers generally to the

utilization intent of a product. A family is a larger number of products derived from a smaller number of subcomponents, whilst sharing some common structures constituting the product platform. Within the product family, each product variant shares interfaces between the product's components allowing full exchange. Hence, a high level of component reuse is found across the product variants in order to reach internal commonality whilst providing commercial variety.

5.2.2 PRODUCT ARCHITECTURE

All products have architecture, even if it has not been considered during the design phase (Lanner and Malmqvist 1996). The choice of architecture has broad implications for product performance, product change, product variety, and manufacturability (Ulrich 1995) while it is strongly coupled to the firm's development capability, manufacturing specialties, and finally the product strategy (Pimmler and Eppinger 1994). The concept of architecture, with respect to product design, is synonymous with the layout and configuration, or functions and their embodiment. Thus, product architecture can be defined as the way in which the functional elements of a product are arranged into physical units and the way in which these units interact (Ulrich and Eppinger 1995). Fujita and Yoshida (2004) point out one important characteristic to discern the architecture of a family of products from that of a single product – the simultaneous handling of multiple products. Erens & Verhulst (1997) consider the functional and physical architectures for product families and describe them using a package of single product models.

Ulrich (1995) discusses the relationship between product architectures and managerial problems related to product strategies. Ulrich (1995) defines a product architecture as the allocation of functions to physical entities of a product, or more precisely*: "…the arrangement of functional elements, the mapping from functional elements to physical components, and the specification of the interfaces among interacting physical components"*. A product architecture is classified as either modular, if there is a one-to-one or many-to-one mapping of functional elements to physical structures, or integral, if a complex or coupled mapping of functional elements to physical structures and/or interfaces exists. According to de Weck (2006) the embodiment of concept and the allocation of physical/informational function (process) to elements of form (objects) and definition of structural interfaces among the objects represent a product architecture. Moreover, it is emphasized that the value-generating functions of the product and mapping to the physical components and modules represents a well-situated architecture, where parts are the atomic units of the product, which cannot be further taken apart before they lose their functionality and integrity, and can be hardware or software. In continuation, Crawley et al (2004) have a systems approach to their definition and talk about system architecture rather than product architecture; thus, instead of physical components they refer to entities that could be functions, physical or non-physical elements. Thus, according to

Crawley et al (2004) a *"… system architecture is an abstract description of the entities of a system and the relationships between those entities"*.

The definitions found in literature deal either with the physical structure of a product, the abstract representation of the system components, or the mapping between the two. The common theme in all these definitions is the arrangement of elements of a product. The last definition is the most abstract and therefore also less restrictive than the other definitions. In this thesis the definition of an architecture is adapted from the definition by Crawley et al. (2004) while recognizing the existence of alternative architectures of a product as in Ulrich's (1995) definition, so: A product architecture is an abstract description of the entities of a system and the relationships between those entities and the scheme by which these entities are mapped to larger physical or non-physical sub-systems of a system.

5.2.3 PRODUCT PLATFORM

Platform-based product design is according to literature (McGrath 1995, Sanderson and Uzumeri 1995, Meyer 1997, Meyer and Lehnerd 1997, Robertson and Ulrich 1998, Simpson 2006, Gershenson et al. 2006) a multi-dimensional subject and thus can in accordance with the literature be related to multiple domains, i.e. market, products, technologies, sourcing, manufacturing and supply processes, customer segmentation, brand positioning, and even people and relationships (Jiao et al. 2007). For the purpose of aligning the definitions and understanding of the term platform, Kristjansson et al. (2004) suggested a common definition as *"a collection of core assets that are reused to achieve a competitive advantage"* and Shapiro (2006) states that *"what these notions have in common, is a sense of platforms as foundations to build upon"*.

Though, while looking into the definitions stated in literature, Meyer and Lehnerd (1997) focus on the basic architectures that comprise subsystems or modules with interfaces between them. Here the need for interfaces between interacting systems is emphasized. Concretely, Meyer and Lehnerd (1997) define a product platform as: *"a set of common components, modules, or parts from which a stream of derivative products can be efficiently developed and launched"*. One possibility to build a platform, is to define it by means of the product architecture. This way of looking at product platforms has been defined by McGrath (1995) as a set of subsystems and interfaces that form a common structure from which a stream of related products can be efficiently developed and produced. More precisely, McGrath (1995) defines a product platform as *"…a collection of the common elements, especially the underlying core technology, implemented across a range of products"*. In continuation, Robertson and Ulrich (1998) describe a platform as a collection of assets, components, processes, knowledge people, and relationships that are shared by a set of products. The meaning of platform differs in scope: some definitions and

descriptions focus primarily on the product/artifact itself (Meyer and Utterack 1993) while others try to explore the platform concept in terms of a firm's value chain (Sawhney 1998). Simpson et al. (2001) define product platforms as a set of parameters, features, and/or components which remain constant for several products within a given product family. In this definition, product families are described as groups of related products that share common features, components, and subsystems, all of which can be combined to satisfy various market niches. Variants are configured by combining common components with variant-specific ones. Gershenson et al. (2006) look at platforms as architectures controlled by design, characterized by common structures, scaled variables, and variable structures, which can support more than one product. This view expresses the need to exchange parts or components and to scale products to suit certain customer segments. Platforms are, according to Jiao et al. (2006), designed for either functional variety or technical variety. The first aims to satisfy diverse customer needs, while the second aims to reduce the in-house variety. Many companies define a product platform as the common resources within a single product family.

Baldwin and Clark (2000) define three aspects of the underlying logic of a product platform: (1) its modular architecture; (2) the interfaces (the scheme by which the modules interact and communicate); and (3) the standards (the design rules that the modules conform to). The main requirements for building a product family based on a product platform are (a) a certain degree of modularity to allow for the decoupling of elements and (b) the standardizing of a part of the product architecture (i.e., subsystems and/or interfaces). Product platforms may be distinguished in three categories, i.e. modular platforms, scalable platforms and generational platforms (Jiao et al. 2007). A modular product architecture is thus characterized by a high degree of independence between elements (modules) and their interfaces. No matter, the architecture seems to play a crucial role in the definitions of a platform, and thus lays the predominant basis for identifying platform potentials (Simpson et al. 2006). Product platform concepts can be classified into two types: module-based product platform and scale-based product platform. The former, the one in focus in this research study, includes two viewpoints, one is that a product platform is defined as a set of function elements shared in several correlative products and the task of product platform planning is to identify the shared function elements (Ulrich 1995; Jiao and Tseng 2004; Robertson and Ulrich 1998). The other is one where the product platform is defined as a common structure of a group of shared parts, sub systems, accordant interfaces and similar manufacturing process (Meyer and Lehnerd 1997). Module-based product platform mainly focuses on identifying shared modules, which combine as more products as they can. Krisjansson et al. (2004) studied the product platform phenomenon from a strategic view. They define a platform as *"a collection of core assets that are reused to achieve a competitive advantage"*. In this context assets are components, processes, knowledge, people and relationships among people. This definition is derived from literature by finding the lowest common denominator of a series of definitions. In continuation hereof, Kristjansson and Hildre

(2004) define a platform strategy as: *"... the overall elaborate action plans a company has to managing its platforms"*.

In this thesis, a platform is seen as an enabler of multiple product offerings, allowing increased leverage and re-use across the product line. It sets the architectural rules/standards manage how technologies and subsystems can be integrated. It defines the basic value proposition, competitive differentiation, capabilities, cost structure, and life cycle for a set of products. Thus, a platform is a collection of the common elements, especially the underlying core technology, implemented across a range of products. It is the common set of design variables around which a family of products can be developed. In general terms, a product platform is the common technological base from which a product family is derived through modification and instantiation of the product platform to target specific market niches. Individual products are derived from the platform by addition, removal, and/or substitution of one or more modules, hence the definition of module-based product platform.

5.2.4 MODULE, MODULARITY AND MODULARIZATION

Modularity has become very popular in academia in recent years even though it has existed for at least forty years and the idea of hierarchical systems consisting of semi-independent sub-systems was already brought up in the early 1960's by Simon (1962). Several companies have adopted modular thinking in various industries such as Boeing, Chrysler, Ford, Motorola, Swatch, Microsoft, Conti Tires, etc. (O'Grady 1999). When reviewing the literature on modularity, definitions and methods highly depend on the purpose of modularity (Fixson 2003; Gershenson 2003).

Modular product architecture consists of modules, often clusters of physical components or functional building blocks with standardized interfaces (Ericsson and Erixon 1999; Ulrich and Eppinger 2008). These standardized interfaces allow different sizes or versions of a module to be interchanged, resulting in potential benefits of variety. The concept of modules and modularity is central in constructing product architectures (Ulrich 1995) and modularity in product variants design is essential when designing product platforms (AlGeddawy and ElMaraghy 2013). Andreasen et al. (2001) argues that the goal of modularization is to create commercial variety meeting diverse customer needs, whilst simultaneously creating commonality between module variants, and such structural properties, that reduction of complexity is achieved in company operations. Ericsson & Erixon (1999) state that a module is a closure of one or more design units into a grouping and a module must comply with at least one of the module drivers.

Baldwin & Clark (2000) base their definition of modularity on relationships among structures: *"A module is a unit whose structural elements are powerfully connected among themselves and*

relatively weakly connected to elements in other units", but as there are degrees of connections, accordingly there exist graduations of modularity. In alignment, AlGeddawy & ElMaraghy (2013) defines a module as *"a unit which serves identifiable functions, while its structural elements are strongly interconnected, and weakly connected to elements in other units/modules"* and modularity as *"the product design architecture where alternate product variants are created by different modules combinations"*. This is supported by Ulrich (1995) who states that modules are identified by their minimal interaction between each other, whilst interactions may be high within the single modules. Further, Ulrich base his definition of modularity on relationships among functions and defines it as one that *"includes a one-to-one mapping from functional elements in the function structure to the physical components of the product and specifies de-coupled interfaces between components"*. Martin & Ishii (2002) states that full modularization is reached when geometry, energy, material or signal can be changed in order to fulfil a certain customer requirement without requiring other components to be changed

Another common way of defining a module is a more abstract definition such as that of Otto and Wood (2001): *"product modules are defined as integral physical product substructures that have a one-to-one correspondence with a subset of a product's functional model"*. Ericsson and Erixon (1999) add that in addition to the similarity between the physical and functional architecture of a product, a module should have minimal interaction with other modules or the rest of the system. This strong connectivity within a sub-system and loose connectivity between sub-systems was discussed by Simon (1962) quite early. Also, Suh (2001) considers the connectivity of the module to the rest of the system in his definition where a module is a row in his design matrix.

As revealed, there exists a certain consensus about the concepts of modules, modularity and modularization. In this thesis, a module is characterized by its limited connection (de-coupled) to the rest of the system, though the module itself may be strongly interconnected. Modules can be described as the encapsulation of one or more design units and these must comply with at least one of the module drivers in order to be a module. The ability to modularize is closely linked to and thereby depending on the interfaces between components and sub-assemblies. Modularization is only achieved if the interfaces facilitating transactions between two modules are not affected when changing one module in order to upkeep the functionality of the product. Further, the change of one module must not require change in another module.

5.3 STATE-OF-THE-ART: CURRENT TOOLS AND METHODS

Modular product platform architectures have shown to provide substantial cost and time savings while still allowing companies to offer a variety of products. As a result, a multitude of tools and methods have been developed over the last decade within the design research

community: Methods that map requirements of a family to a set of products; methods to define the common and unique platform modules; methods to optimize variety, cost, commonality, and other parameters; methods to evaluate platforms, etc. (Simpson et al. 2007; Jiao et al. 2007; Simpson et al. 2014).

This review of tools and methods is inspired by the systematical requirement flow-down model of the architecting steps introduced by Otto et al. (2016). In the paper, the authors introduce a generic sequence of steps with related modularity methods for platform concept development. The study is based on a sample of ten companies that regularly develop modular product platforms that provides a variety of applications from automotive, industrial, electronics, and software business, i.e. ABB, Airbus, Carrier, Cummins, Danfoss, Ford, IVM, ITT, LG, and Motorola. Otto et al. (2016) find that the transfer of tools and methods to industrial practice currently is inhibited by a seemingly broad array of material.

Therefore, this review of currently available tools and methods published in academic literature has the objective to illustrate how the different areas of focus support the challenges faced by the medical industry developing modular platform architecture concept designs. The scope of the review is to introduce various alternative tools and methods to which these contribute to the overall goal of developing a portfolio of medical devices. The aim is to review the array of tools and methods from a compliance-driven perspective. Thus, this section is to provide insight into how the currently available tools and methods support the identified situation.

5.3.1 Strategic Modularization

Modular product platforms allow for development of multiple products for multiple markets. Thus, the platform development effort includes the defining customer characteristics and product applications. Typically, this starts with an observation of a perceived need in an application domain and extension into exploring the range of different geographies and demographics that may have similar needs. The market segmentation methods help in identifying potential clusters of customers with similar needs. This, in turn, enables designing a product variant on a per-market segment basis, rather than a product that is trying to meet all the vastly different needs.

The widespread use of market segmentation is the inevitable consequence of the increase in competition and the global nature of today's marketplace. The umbrella of methods entitled "Strategic Modularization" includes the power tower and leverage strategies, platform planning approaches, factors that influence platform strategy, and strategic modularization based on platform architectures. Common to these methods is their largely market oriented view and strategic perspective on modular platform architecture design and development.

Power Tower and Leveraging Strategies

Successful application of architectures, platforms, and modules often implies strategic management attention. Meyer and Lehnerd (1997) propose the so-called power tower that describes the application of platforms in the marketplaces and some of the strategic options available (Fig. 5.1). The power tower consists of three elements: common building blocks, product platforms and market applications.

The common building blocks are the assets that a company builds its business upon, i.e. customer insights, product technologies, manufacturing technologies and organizational capabilities. The product platform is defined as: *"A product platform is a set of subsystems and interfaces that form a common structure from which a stream of derivative products can be efficiently developed and produced"* (Meyer and Lehnerd 1997).

Market applications relate to segmentation of the market and application of platforms on the market. In the power tower the market is segmented according to user groups and product price and/or performance characteristics. Together the common building blocks, the product platform and market applications illustrate how platforms should meet with the market segments.

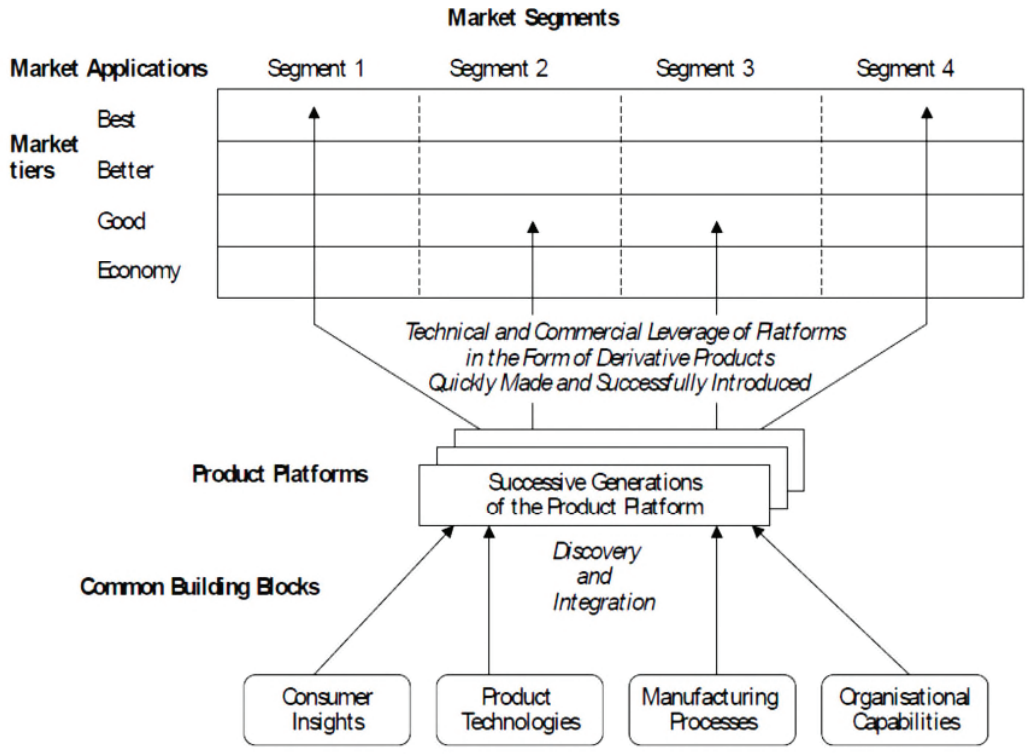


Fig. 5.1: The power tower is constituted by common building blocks. These form the basis for the platforms. The platforms then must be assigned certain market applications (Meyer and Lehnerd 1997)

Meyer and Lehnerd (1997) propose leveraging strategies for introduction of platforms in the marketplace using a market segmentation grid (Fig. 5.2). In a market segmentation grid, the total market for a product family is defined through a matrix of market niches that identify particular user groups and price/performance tiers. Market segments are plotted horizontally in the grid while price/performance tiers are plotted vertically – the intersection of each price/performance tier with each market segment defines a specific market niche.

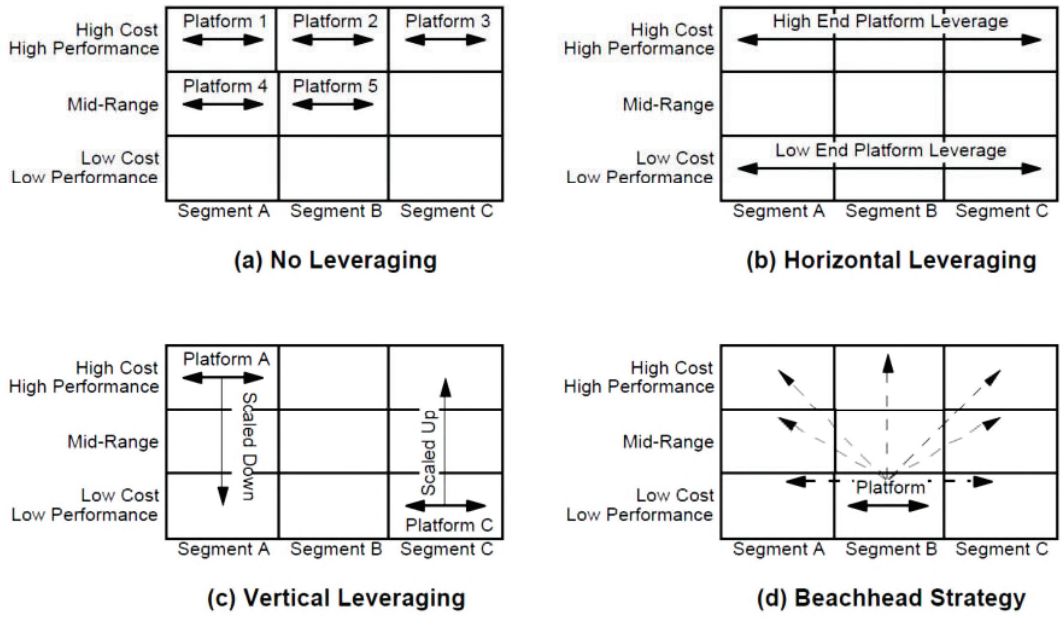


Fig. 5.2: Platform leveraging strategies illustrated using the market segmentation grid (Meyer and Lehnerd 1997)

Based on the segmentation grids several leveraging strategies can be defined.

Niche-specific – The niche-specific platforms have little sharing of subsystems and manufacturing processes and is a strategy that provides no leverage across market segments. Here, platforms are dedicated to each individual market niche (Fig. 5.2, a). The result is numerous platforms with little sharing of subsystems and manufacturing processes.

Horizontal – The horizontal leveraging strategy (Fig. 5.2, b) is one in which subsystems and/or manufacturing processes are leveraged across different market segments within the same price or performance tier – a platform strategy is to have a platform that is leveraged from one market niche to the next within a given tier of price-performance.

Vertical – The vertical leveraging strategy (Fig. 5.2, c), scales key platform subsystems and/or the capability of the company to leverage its knowledge about a particular market segment without having to develop a new platform for each price/performance tier. The company seeks

to address a range of price/performance tiers within a market segment with a common product platform. Two variants of this strategy exist, where the initial platform is either scaled up or down to another tier of price-performance.

Beachhead – The beachhead approach (Fig. 5.2, d) combines horizontal leveraging with vertical leveraging to develop an effective, low-cost platform with efficient processes. This strategy takes its starting point in a market segment with low cost/performance. Hereafter the platform is scaled to other segments and price/performance markets. It can scale up the performance characteristics of the platform for low-end users to the mid-end and high-end users, as well as be applied to different market segments.

Notice that horizontal leveraging (Fig. 5.2, a) can generally be associated with swappable modules where a common subset of core modules are used across different products, while vertical leveraging (Fig. 5.2, b) can be associated with scalable platforms where different sizes of the same modules and components are used. Successful platforms often utilize a combination of scaling and modularity to attack the market in a strategic and cost-effective manner (Kumar et al. 2009).

Product Platform Planning

As Robertson and Ulrich (1998) states, planning for successful platforms is a cross-functional activity involving both marketing, product design, and manufacturing teams. They support the viewpoint of Meyer and Lehnerd (1997), that coordination between customer-perceived differentiations on the one hand and component and process communality on the other is key to success, and advocate a three-step approach to planning of product platforms (Fig. 5.3):

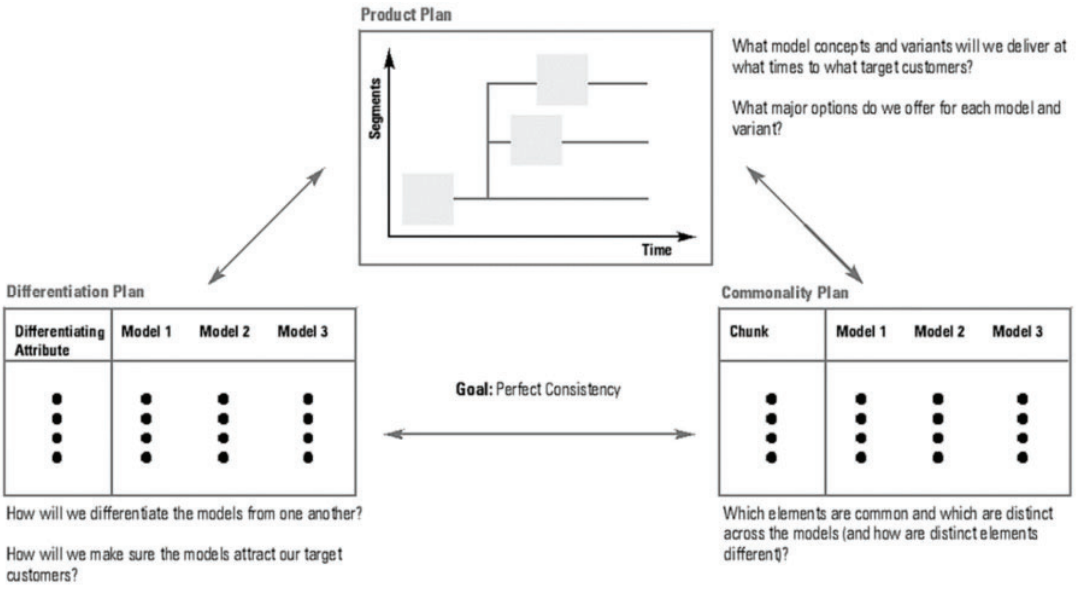


Fig. 5.3: The platform-planning process (Robertson and Ulrich 1998)

- The product plan, which describes the products that are to be offered at a certain point in time. The product variants are assigned to their target market segments and drawn according to their planned market entry. It thus reflects the product strategy of the company.
- The differentiation plan, which describes how products are to be differentiated. The relevant differentiated attributes as well as their characteristics for the individual product variants are entered. In addition, the relative importance of the differentiator is evaluated from the customer's point of view.
- The commonality plan, which describe the components/modules that are to be shared. It shows the estimated development, tooling and production costs for the derivation of the individual product variants.

Note that the planning process is iterative, and each plan must be refined by core representatives from the different functional units of a company.

In the platform-planning process, balancing between broad market coverage, a clear differentiation of the individual product variants, and a reduction in development and production costs is key as making complex trade-offs in making good platforms decisions.

Factors Influencing Modular Product Platform Strategy

Krisjansson et al. (2004) have studied what factors that influence the platform strategy and find that a platform strategy should elaborate and systemically plan action to manage a group of platforms, both individually, as well as group-wise. Further, they argue that the competitive advantage strategy of the company, the industrial situation, the market situation and the internal core competencies of a company have to be studied and understood in order to propose a platform strategy (Tab. 5.1).

Areas	Factors	Suggestions regarding the platform strategy
Core competencies	Identifying present core competency platforms	Core competencies must be used; the competencies of a company should be based on platforms.
Industry situation	Threat of new entrants	A company should strive to use platforms in a way that increases barriers to entry.
	Bargaining power of suppliers	Suppliers should not have too much bargaining power in reference to platforms.
	Bargaining power of buyers	Bargaining power affects the decision of what to include in a platform. If bargaining power is high, platform threshold and performance and focus on excitement add-ons to differentiate.

	Threat of substitute products or services	Substitutes are bought either due to cost or differentiation. Platform is to minimize the threat.
	Rivalry among existing firms	If rivalry is high, platform the commodity part.
	Clock speed / innovation pace	Platform low paced assets. Platform mid- and high paced depending on volume and volatility.
	Proprietary vs. open source	Open source SW platforms might be useful where the need to establish a standard is large.
	Maturity level	Usually a high maturity level indicates a focus on cost rather than innovation and technology. Platform commodity and differentiate
	Disruptive technologies	If threat of disruptive technologies is high, the platform should not contain the as-is technology.
Market situation	Kano's model of customer satisfaction	Depending on volatility, platform threshold and possibly performance.
	High- or low involvement products	Buyers find high involvement products risky. Platforms in high involvement products should decrease the feeling of risk.
	Volatility	High volatility indicates a need for flexibility. Platform accordingly.
Competitive strategy	Differentiation	Platform threshold assets.
	Cost leadership	Platform threshold and performance assets.
	Focus	Knowledge platform of importance.
	Market plan	Does the company have products in different price segments, industry segments

Tab. 5.1: Summarization of the factors that a platform strategy must consider (Krisjansson and Hildre 2004)

Kristjansson and Hildre (2004) find that a platform strategy derives from the core competences of a company, the industry and market situation, and the company's chosen competitive advantage strategy. Further, they argue that by focusing on the areas/factors identified, stakeholders can make better decisions and create better platform strategies, including decisions on platform market plan, platform lifetime, and platform usage.

Thus, competitive advantage strategy of the company, industrial situation, market situation, and internal core competences of a company have to be studied and understood in order to propose a platform strategy.

Strategic Modularization based on Platform Architectures

One of the authors to recognize that platform architectures can be a strategic tool for managing product families is Sanchez (1999a; 1999b) and Sanchez & Collins (2001). Sanchez (1999b)

distinguishes between product and process architectures (Fig. 5.4). The concept of product architecture is in line with Ulrich's (1995) perception of product architecture.

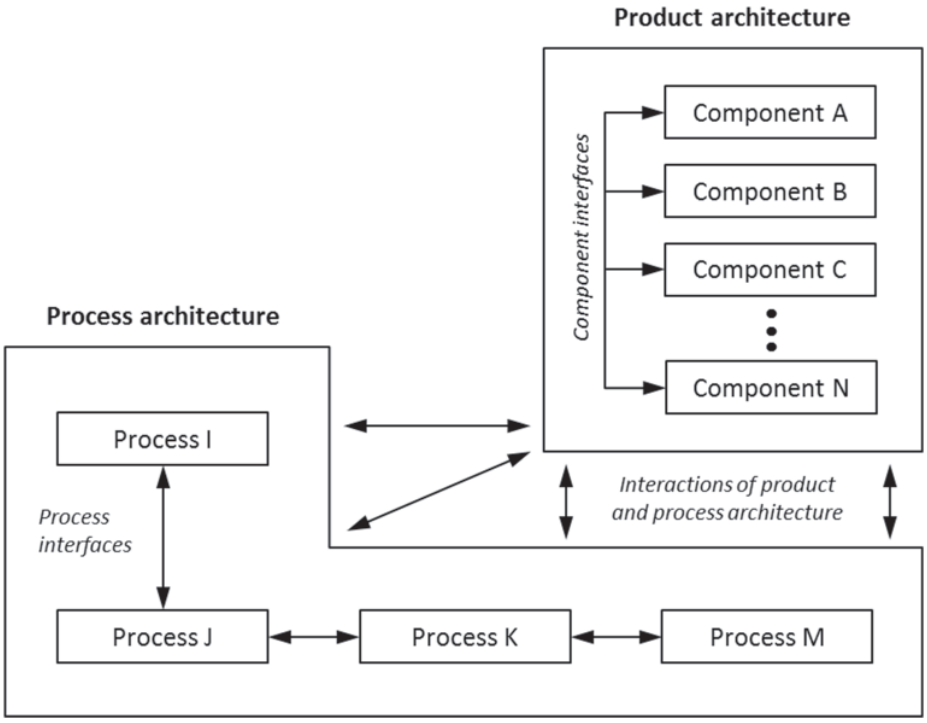


Fig. 5.4: Interactions of product and process architectures (Sanchez 1999b)

According to Sanchez (2000), the essential features of modular strategies and development processes is how the organizational learning about product performance is captured in improved component designs and interface specifications.

Four kinds of knowledge are according to Sanchez (2000) embedded in modular architectures: (1) Knowledge of how a given product functionality may be decomposed into specific functional components in product and process designs, (2) Knowledge of how product and process components function and can be designed, (3) Knowledge of how functional components of various types interact in product architectures and in process architectures, and (4) Knowledge of how each product component interacts with each process component.

Further, Sanchez introduces the Modularity Maturity Model (Tab. 5.2), describing different viewpoints on modularization that companies can apply. He concludes that most companies are located in the lower levels of the scale.

Level	Management Understanding	Design and Development Activities
7	Modularity as framework for identifying and developing new strategic competences	Architectural management function directly involved in identifying goals for strategic competence development
6	Modularity as framework for strategic integration	Architectural management function directly involved in setting market, technology, and business strategies
5	Modularity as framework for knowledge management	New architectural knowledge created in development is captured in improved interface specifications
4	Modularity seen as means to reduce time to market	Modular development process based on "new rules and new roles" enables concurrent component development
3	Modularity Seen as means to increase product variety	Strategic partitioning to decouple stable from variable components to enable configuration of product variants
2A / 2B	Modularity seen as means to reduce product costs	Early form of modular development process seeks to use common components (2A) and reusable components (2B)
1	Modularity seen only as engineering issue	Conventional development process uses technical modularity to reduce design time and cost
0	Unaware of modularity	Conventional development process with no systematic use of modularity

Tab. 5.2: Modularity maturity model (Sanchez 2013)

Sanchez (1999b) recognizes the importance of alignment of the product and process architectures. It is when these two types of architectures are aligned and interacting as intended that the benefit of the architectures can be harvested. A good product architecture is worthless if it is not supported by a good process architecture.

How "Strategic Modularization" Contributes to this Research

While engineers tend to treat modularization and platform development as a technical discipline, the power tower proposed by Meyer and Lehnerd (1997) show how platforms can be applied as a strategic tool for addressing several market and cost/price segments. The coupling of market requirements and platform development adds to this research by providing a methodical approach to alignment of market needs and technical requirements. In continuation

hereof, Robertson and Ulrich (1998) introduce platform-planning as a cross-functional activity and emphasizes that not only engineers should drive the activity, cross-functionality is a necessity achieving the full potential of platforming. This viewpoint add to this research study in the sense that platforming is something that involves multitudes of personnel across functions and levels of a company. Kristjansson et al. (2004) contributes to this research by pointing out the importance of platform strategies and show that platform strategy is a multifaceted task, and it is contextual dependent on the business or industry under investigation. This adds to the research as it focuses on a heavy-regulated industry per se, and the nature of such industry should be considered along the study. Sanchez (2013) recognizes the importance of aligning different types of architectures. It is when the product architecture is combined with e.g. a process and knowledge architecture that the architecture phenomenon makes sense. Further, Sanchez (2013) brings the architecture phenomenon from being a technical engineering discipline to a more strategic tool for managing product families. The recognition of multi architecture alignment and its ability strategically to manage multiple products is of great importance to this research. Thus, the methods under "Strategic Modularization" contributes with the acknowledgement of the strategic intend and alignment of architectures for the successful development and implementation of platform thinking.

5.3.2 Modular Product Design

Modular product design deals with requirements, which are often categorized into functional requirements and constraints (Suh 1990). A functional requirement typically exhibits a certain functional behavior, i.e., to do something. A constraint, on the other hand, is a requirement that cannot be achieved by a single function. Weight and size are typical examples of constraints.

Otto and Wood (2001) provide a process for mapping and defining functions versus constraints. Once the system requirements are set, one can take one of two approaches to develop platform architecture: a function-based approach or a component-based approach. A sequential approach going from function-based methods in the early conceptual phases to more refined component-based methods is also possible, but here a more common alternate approach is described. The function-based approach takes a more general view to define common functions independent of any particular embodiment decisions. On the contrary, the component-based approach makes use of a priori knowledge, however acquired or assumed, of the most relevant components needed. If the function-based approach is used, then that approach is followed by mapping function to form, i.e., defining the components as part of embodiment design.

Many methods under "Modular Product Design" are available. In this section, a number of these are described. These include modular design based on the so-called baukästen system, function-means model, functional structure diagram, and modularity heuristics. These methods all focus

on structuring the products from a modularization perspective and contribute to the modelling of products, which is of great importance when developing modular platform architectures, and this is why they have been depicted for further investigation in this section.

Modular Design based on "Baukästen System"

Pahl and Beitz (1997) define modular products as *"machines, assemblies and components that fulfil various overall functions through the combination of distinct function units (building blocks) or modules"*. In the development of "bäukästen", an establishment of a sufficient functional structure is core, as in a modular system design *"the overall function results from a combination of the building blocks"* (Pahl and Beitz 1997). For this purpose, the functions are classified according to the modular system as basic, auxiliary, special, adaptive, and customer-specific functions (Fig. 5.5). The establishment of function structures is of importance in the development of modular systems. With the function structure – that is, the splitting up of the required overall function into sub-functions – the structure of the system is already laid down, at least in principle. From the outset, designers must try to subdivide the overall function variants into a minimum number of similar and recurring sub-functions.

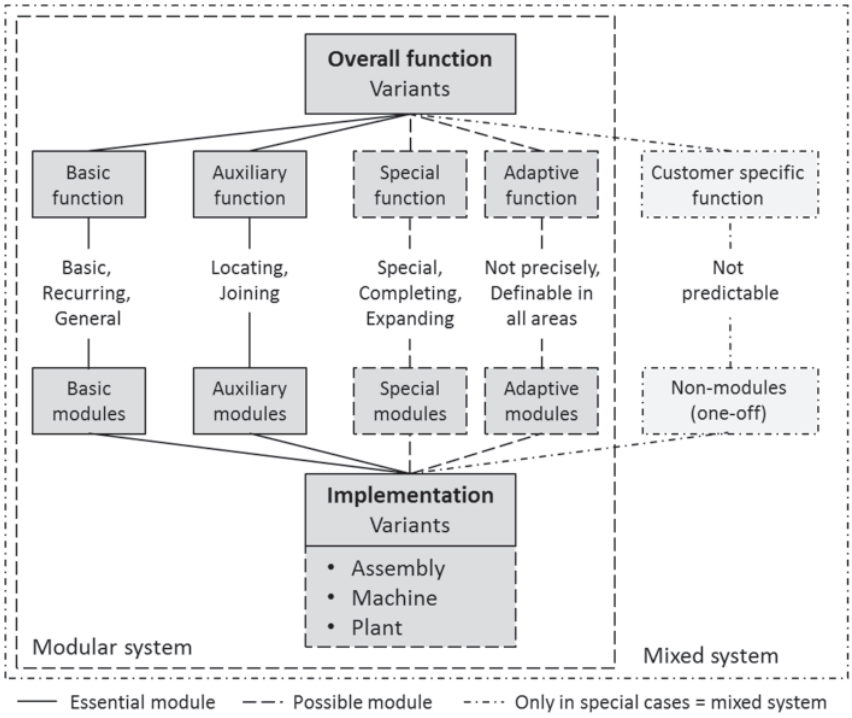


Fig. 5.5: Function and module types in modular and mixed systems (Pahl and Beitz 1997)

The function structures of the overall function variants must be logically and physically compatible, and the sub-functions determined by them must be interchangeable. To that end, it is useful if, depending on the particular task, the overall function can be achieved by essential modules and by additional task-specific possible modules.

Function-Means Model

The concepts of function and behavior are symbiotic; a function is the "what" for a product, and behavior results from how a function is implemented. In terms of modeling or representation, function corresponds to the action of a product on its inputs (materials, energies, or signals) to produce desired outputs (Otto and Wood 2000; Stone and Wood 1999), such as "convert torque" or "transmit electricity." Research in functional modeling has produced formal methods for representing product function as a vocabulary and its corresponding topology of inputs and outputs (McAdams et al. 1999; Stone and Wood 1999; Stone et al. 2000).

Products and platforms can be modelled according to the Function-Means (F-M) model (Andreasen 1980; Pahl and Beitz 2007, Svendsen and Hansen 1993). This is a technique for functional decomposition and concept generation of systems and products. It presents a systematic way of arranging functions and solutions to functions in a hierarchic tree structure (Fig. 5.6).

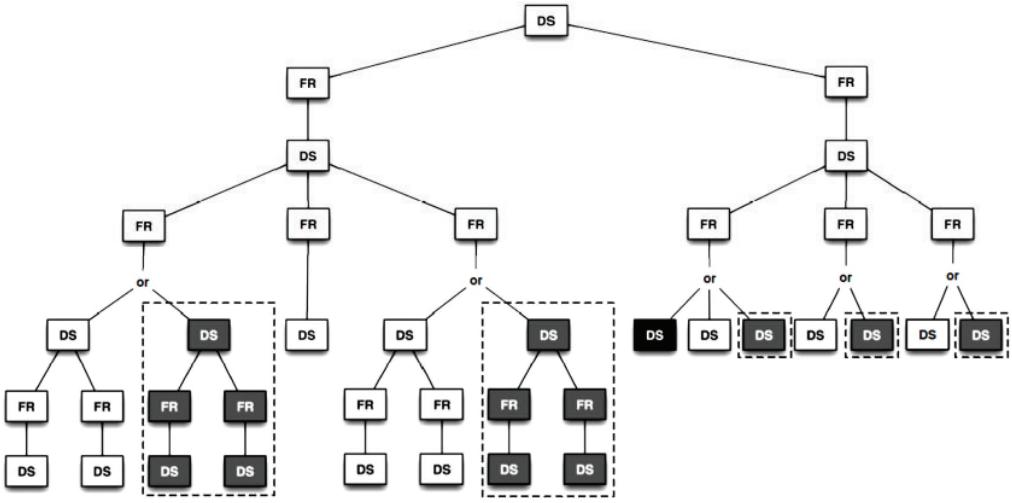


Fig. 5.6: Function-Means Model: The white objects are present in all configurations and the shaded objects are present in some. The dashed branches represent alternative configurations. In order for the Functional Requirements to be fulfilled, all embodying Functional Features must be mapped to components (Raudberget et al. 2014).

It is an object-relational model that describes the functional requirements (FR) for the system and what design solutions (DS) that can be used to meet these requirements. Creating the functional model is a creative work, zigzagging between functional requirements and design

solutions where a chosen technology will render specific sub-requirements. An extension of function-means modelling to support the development of product platforms is the Configurable Component Framework (Johanneson and Claesson 2005) that presents an object-oriented approach of modelling platforms. In this context Levandowski et al. (2014) introduce the concept of components to describe how functions can be allocated to the physical artefacts that realize the desired functionality.

Function Structure Diagram

Function Structure Diagrams (FSD) is a graphical representation of the functions that a product performs on its inputs and outputs (Fig. 5.7). Sudjanto and Otto (2001) uses the functional structures as a basis for identification of modules that can be re-used across different product families. According to Zamirowski and Otto (1999) and Sudjianto & Otto (2001) the function structures explicitly relate the functions through flows. A function structure connects sub functions with flows of energy, material and information. A functional structure can form the basis for modularization to support multiple brand platforms. Each block represents a function. The blocks that are not shaded, are the common functions used in all product families.

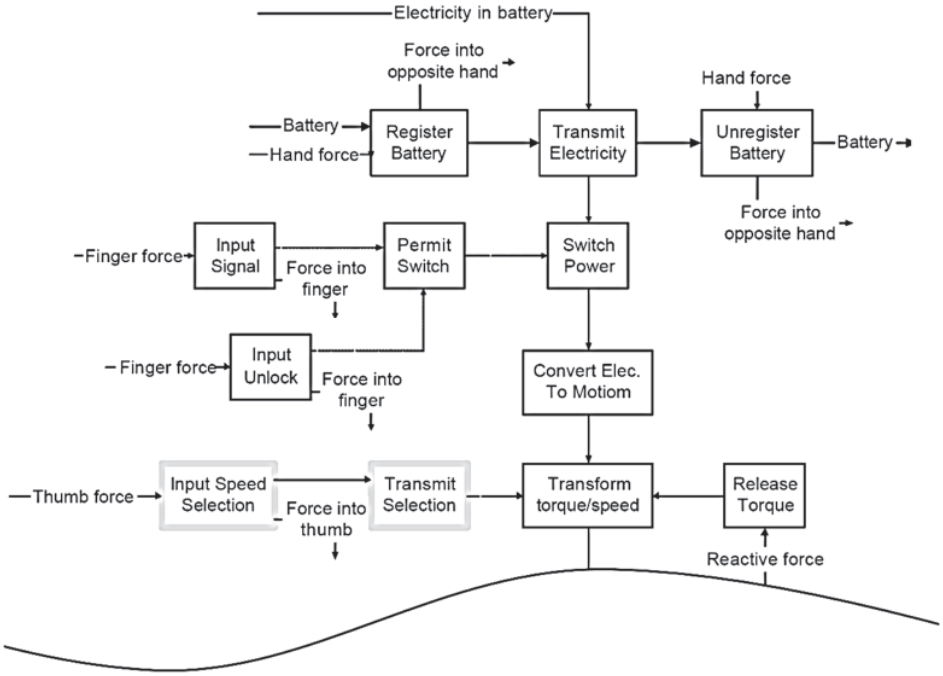


Fig. 5.7: Family function structure of a drill cord (Sudjianto and Otto 2001)

The method places the emphasis on what must be accomplished rather than how. By this method, the overall function is broken down into elemental or atomic sub-functions. Each sub-

function cannot be broken down further and is solution neutral. The sub-functions are connected by "flows" on which they operate. Flows are materials, energy or information that is used by or affects the product. Functional structure diagrams are used for many tasks in the design process. Most importantly they can help break down a complicated design problem into manageable chunks. Solutions for each chunk can be found and then an engineering concept assembled from a group of solutions for each chunk.

Modularity Heuristics

Stone et al. (2000) developed a function structure heuristic method, based on the functional structures introduced by Pahl and Beitz (1999). Stone et al. (2000) separate modules from a single product's function structure by finding the dominant flow, branching flows, or conversion-transmission function pairs (Fig. 5.8). Stone (1997) and Stone et al. (2000) use revenue-oriented functional structures as the basis for product structuring but develop a much more concrete approach. The starting point of the method is the inclusion of customer requirements and their weighting. The function structure is then set up by dividing the overall function of the product into sub-functions. The breakdown is terminated when the overall function of the product can be described by the functions it has specified. The actual modularization takes place with the help of three heuristics, which are applied to the functional structure. In the first step, the heuristic dominant flow is used (Fig. 5.8, a). Due to this heuristic, functions are combined to form a module through which a dominant flow pass. Whether a flow is dominant, results from the previously established order of rivers. The module ends when the flow exits the system, or the flow type is converted. The second step is the heuristic branching. For the purpose of this heuristic, parallel function chains are combined into modules (Fig. 5.8, b). The remaining heuristic conversion and transfer build modules based on functions that transform a flow (Fig. 5.8, c), sub-functions are also included in the module if they refer exclusively to the transformed flow.

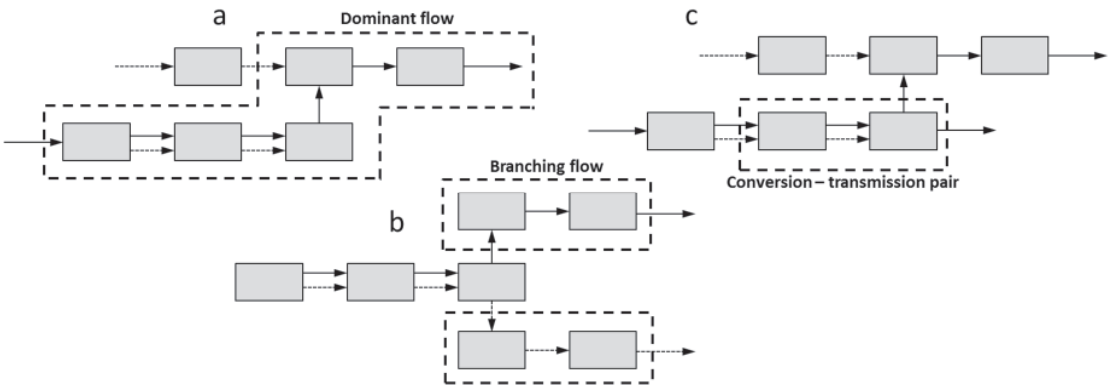


Fig. 5.8: Function structure heuristics (Stone et al. 2000)

The main modularization criteria considered in the function structure heuristic method are functionality and module interfaces. Other criteria such as business or strategy related factors are not represented in the function structure heuristic method but, instead, enter through designer judgment in where the rules get applied. After applying the three heuristics, the proposed modules are combined to form a complete solution.

Zamirowski and Otto (1999) present three additional heuristics to find modules across products in a product family (Fig. 5.9). They find similar and repetitive functions within a single product, common functions across products, and unique functions that are found only in one product within the product family and separate them as modules.

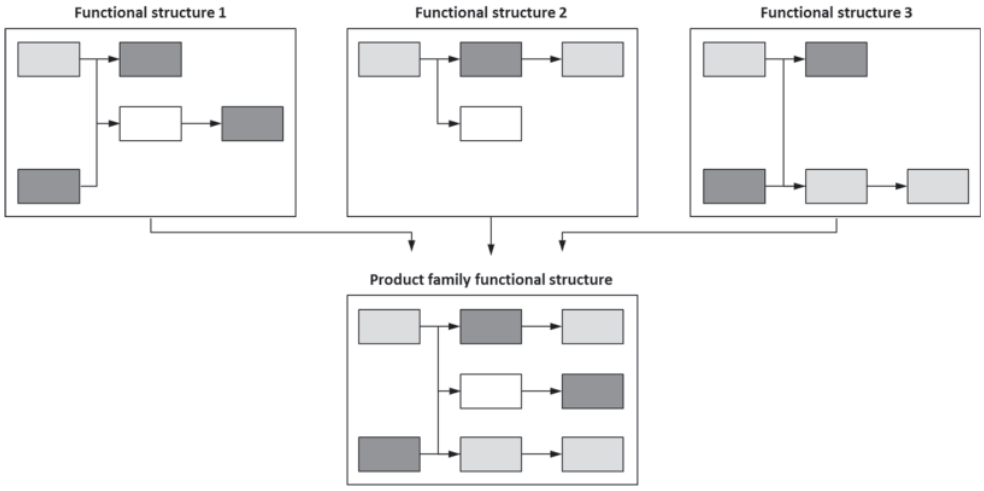


Fig. 5.9: Functional structure of product family using similarity heuristics (Zamirowski and Otto 1999)

These three product family heuristics are similar to the component standardization strategies introduced by Perera et al. (1999). Dahmus et al. (2001) develop a systematic methodology to architecting product portfolio based on function structuring and the three heuristics described: *"A function structure is a set of sub-functions interconnected by flows. Identifying these flows proves effective for helping to partition products into modules"* (Dahmus et al. 2001). They propose to specify a function structure for each product concept and combine these into a large family function structure that indicates the interrelationships of function for all products and thereby establish a comprehensive overview of all functions in the family and make distinction between common and unique functions. Dahmus et al. (2001) supplement the approach with a modularity matrix. In this matrix, the product variants are compared with the functions occurring in a product family, and the respective characteristics of the functions are entered in the matrix fields. Modules are represented in the matrix by the colored background of the corresponding fields. Based on this approach, it is possible to cluster modules and identifying sharing these across families of products and thereby enable modularity of the product families.

Modular Function Deployment

In the Modular Function Deployment (MFD), developed by Erixon (Erixon 1993; Erixon 1998), products are modularized based on product-strategic aspects – the objective of MFD is to identify the modules of a given product. MFD uses three interlinked matrices to integrate the Voice of Customer, the Voice of Engineering, and the Voice of the Company to predict a modular product architecture. In general, the MFD is a systematic method and procedure for company-supportive product modularization that is divided into five steps or tools that are linked together: (1) Clarification of customer requirements, (2) Selection of technical solutions, (3) Concept development, (4) Concept assessment, and finally (5) Improvement of the modules (Fig. 5.10). The starting point of the method is the clarification of customer requirements – define customer requirements. This step is intended to ensure that the customer's requirements are translated into suitable technical requirements. Erixon (1998) uses Quality Function Deployment (QFD) for this. Modular function deployment is also based on functional decomposition, such as functions structure heuristic method, but in this method, modularity drivers other than functionality are considered. MFD is designed to modularize a single product at a time. In order to clarify the extent to which a modular product structure contributes to customer requirements, modularity is entered in the first column of the QFD matrix. In the second step of the method – select technical solutions are developed. For this purpose, the product is broken down into functions and sub-functions, and the functions are assigned technical solutions.

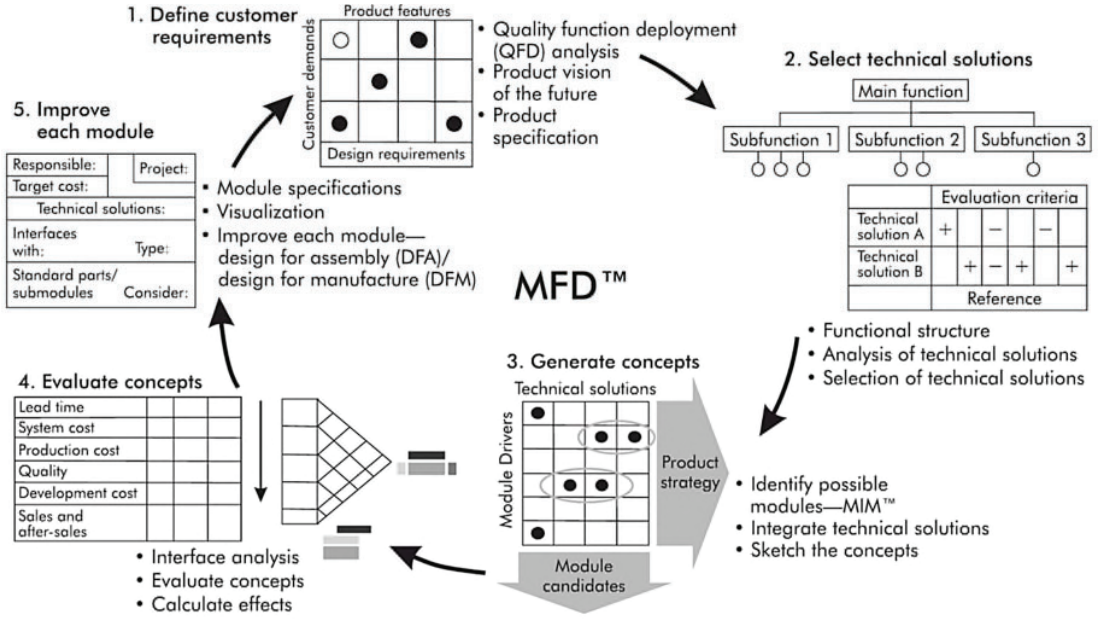


Fig. 5.10: The five steps of Modular Function Deployment (Ericsson and Erixon 1999), originally published in Erixon (1998). The circle illustrates the design work as an iterative process

In order to enable the development of a robust modular product structure, a high degree of independence between the individual functions and function carriers is sought. The actual modularization takes place in the third step – generate concepts. The basis for this is the so-called module drivers (Tab. 5.3). These are product-strategic reasons for the formation of modules identified in case studies (Östgren 1994):

Module driver	Motivating factor
Carryover	A carryover is a part or a subsystem that will not be exposed for changes during the life of the platform. Therefore, if the module continuously carries a function fulfilling customer and corporative requirements, it will be possible to 'carry over' this module from one generational platform to a future one.
Technical evolution	Technical evolution implies parts or subsystem that most likely will undergo changes due to changes in the marketplace and/or emerging technologies. These can with advantage be separated into a module so that changes are assigned specific parts of the product and not the entire product itself.
Planned product changes	Planned product changes refer to parts or subsystem that the company intends to develop or upgrade in the course of future product introductions.
Different specification	Parts or subsystems with a different specification can with advantage be separated into a module, which enable commercial variation without changing the entire product.
Style	Parts or subsystems visually exposed in the product are often subject to changes coursed by changing market trends and tendencies, thus can with advantage be separated into a module.
Common unit	A common unit is a part or a subsystem that carries a function required by all customers and the module can therefore be implemented in the entire product assortment.
Process and/or organization re-use	Parts or subsystem requiring the same production process and/organizational requirements can profitably be clustered together in a module offering the advantage of automation, reduced lead time processes, better controlled ergonomics etc.
Separate testing	Parts can be clustered together and tested at the production line before final assembly. By this, it will be possible to detect product errors earlier at the production line and might improve quality of product, reduce feed-back time and eventually overall costs.

Available from suppliers	Standard modules can with benefit be purchased from vendors. This has the obvious advantage that the vendor takes full responsibility for manufacturing processes, design activities and quality control.
Service and maintenance	Quick service and maintenance in the field is often expressed as an important customer requirement. Parts or subsystems exposed for regular service and maintenance can with advantage be clustered together in a so-called service module, supporting this customer requirement.
Upgrading	Customer requirements changes over time, and therefore designing modules that allows future upgrades and thereby offers customers the possibility to upgrade the product accordingly to changed requirements, might be a great advantage.
Recycling	Because of a growing interest in environmental issues, companies are forced to increase their focus on sustainable design. The separation of parts and subsystems into modules gives the advantage of disassembling the product for more efficient recycling.

Tab. 5.3: Module drivers: 12 motivating factors for executing modularization (Ericsson and Erixon, 1999)

Though, the MFD is similar to QFD, the modularity drivers are mapped against functions instead of customer requirements in a matrix. The grouping into modules is started by the functions receiving the highest summed; and the functions dominated by the same modularity drivers are good candidates for a module according to this method. The number of modules according to MFD is approximately the square root of the number of parts or assembly operations. The estimate is based on optimizing the assembly lead time of the whole product.

Ericsson and Erixon (1999), Stake (2000) and Blackenfelt (2001) show how MFD and DSM can be integrated in the grouping phase. Blackenfelt (2001) builds strategic DSM using simplified modularity drivers from the MFD. He suggests using also a functional DSM in conjunction with the strategic MFD to systematize the grouping phase in the MFD.

In addition, MFD has a step for interface design that considers form, fixation principles, number of contact surfaces and attachments, as well as the number of energy connection points, material flow, and signals. It relies more on the intuition of engineers than presentation of a systematic method to locate and choose cut-off points for modules, which again is either a benefit or a problem, depending upon one's perspective. The module drivers are compared to the components of the product in the so-called Module Indication Matrix (MIM), which is used to identify possible modules by examining the interrelationships between "module drivers" and technical solutions (Fig. 5.11). The meaning of the individual module drivers is evaluated in the

matrix with 1 point (= weak driver), 3 points (= middle driver) or 9 points (= strong driver). The points of the individual components are added up afterwards. High score components are candidates for building modules. These module candidates can form their own module or be supplemented with lower rated components. The components should have similar assessment profiles, or at least not contradictory ratings. For example, you should not combine carry-over components with technology-push components in one module.

Function carrier / Module driver		Fan	Noise absorbent, fan	Electric motor	Damper	Noise absorbent, motor	Chassis	Bag	Filter	Triristor+knob	Switch+knob	Housing	Wire+contact	Grip	Rear wheel	Front wheel	Accessories	Bumper	Cover	Indicator	Seal, cover	O-ring	Wire collector	Bag lock	Brake+knob
Design and Development	Carry-over	●		●						●	⊘		⊘			●	○			●			●		⊘
	Technology push							●	●																
	Product Planning																								
Variance	Diff. specification	○	○	○					○	○	○		⊘												
	Styling									●	●	●		●	○				●						●
Manuf.	Common unit	⊘	⊘	⊘	●	●	●	●	⊘	⊘	⊘		○		⊘	●	●	●		●	●	●	●	●	⊘
	Process/Org.	●		●			●	●				●													
Quality	Separate testing			●							○														
Purchase	Black-box engineer.								●	●			●												
After sales	Service/maint.			⊘					○	⊘	○														
	Upgrading								●																
	Recycling			●			●					●											○		
●=9 ⊘=3 ○=1	**Weight of Driver vertically summarised**	**22**	**4**	**43**	**9**	**9**	**27**	**27**	**32**	**34**	**18**	**27**	**16**	**9**	**4**	**18**	**10**	**9**	**9**	**18**	**9**	**9**	**19**	**9**	**15**
	Module candidates	√		√			√	√	√	√		√											√		

Fig. 5.11: The Module Interaction Matrix (MIM) for a vacuum cleaner (Erixon 1998)

In the fourth step – evaluate concepts, the concepts developed in MIM are evaluated in order to select a concept for further elaboration. On the one hand, this includes an examination of the interfaces between the modules and, on the other hand, the actual evaluation with the help of key figures and rules from the areas of development, assembly and after-sales. The final fifth step – improve each module – involves the preparation of the modules. However, this step is not supported in the MFD method. Instead, reference is made to common development methods and DfX guidelines.

Module Process Chart

Blees (2011) combine product strategic reasons with a functional component-based approach for modularization using the module process chart (MPC). The development of modular product families can, according to Blees (2011), be described by a procedure to align modular structures with the product life phases, the so-called life-phase modularization. After designing variant-appropriate components as of the Tree of External Variety by Kipp (2012), the components are decoupled from a configuration point of view, and further modularization is thereby enabled (Fig. 5.12).

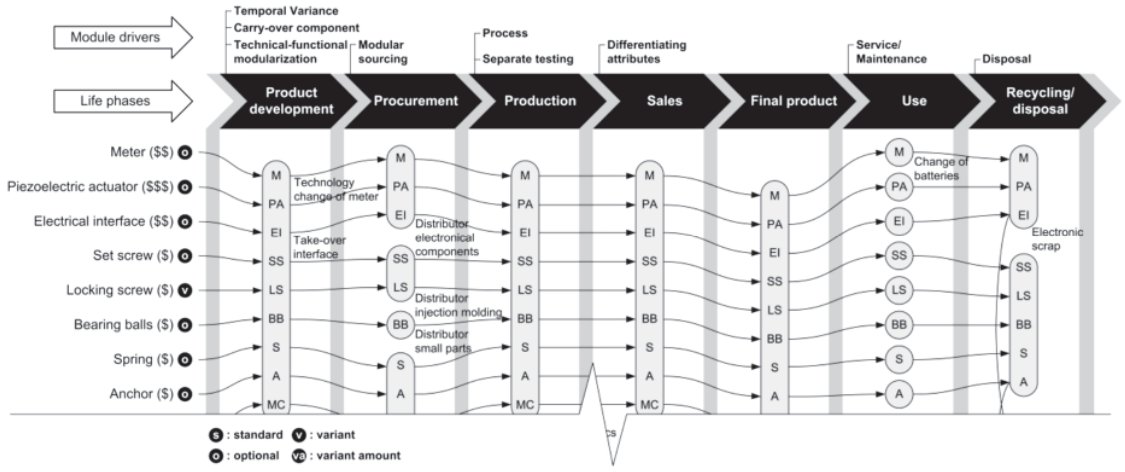


Fig. 5.12: The Module Process Chart (MPC) as a tool to allocate module drivers and module driver specifications to modules (Eilmus et al. 2011)

The goal of life-phase modularization is to consider the requirements of all phases of life in the product family. For this purpose, the product-strategic module drivers are included for each phase of life-system. Modulus drivers are, according to Erixon (1998), reasons why one or more components should form a module. An example of a life phase manufacturing module driver is separate testing. For the life phase modularization, in addition to the module drivers, their characteristics, for example poling test or function test, are recorded. In a network, the components that are affected by the module driver characteristic are connected to it and the modules of the life phase are formed accordingly.

Product Family Master Plan

Harlou (2006) utilizes customer needs variety diagrams to manage customer needs variety in the Product Family Master Plan (PFMP) framework (Fig. 5.13). The PFMP formalism was introduced by Harlou and Nielsen (1999) and later detailed by Mortensen (2000). Three types of elements constitute the PFMP modelling formalism: classes, attributes and constraints.

Besides these elements a PFMP consists of two types of structures. These structures are denoted part-of and kind-of structures. The aim of the PFMP is to create an overview of a product family describing both the structure of the product family and the variety within the product family. Three viewpoints that are of interest when modelling a product family are (Harlou 2006): (1) Customer view – A customer view should describe the product family from a customer's point of view. This implies that it should show the variety from a market point of view. The customer view should bring an answer to the question *"What are the features and application characteristics that have the customer's interest?"*. (2) Engineering view – An engineering view should describe the product from an engineering point of view. This implies that it should describe the organ structure of the product family and the variety of organs. It should hereby answer the questions *"How does the product family work and how does it vary from an organ point of view?"* (3) Part view – A part view should describe the physical entities of the product family and hereby bring answers to questions *"How is the product family realized physically and how does it vary from a physical point of view?".*

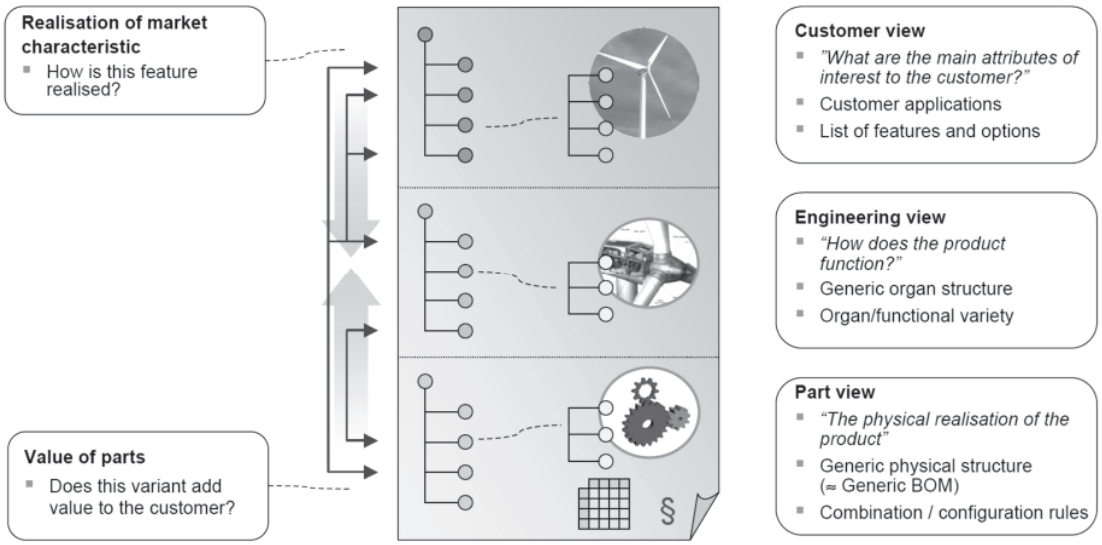


Fig. 5.13: A product family master plan includes a customer, an engineering and a part view. The views are linked together through causal relations (Harlou 2006)

What is of special importance is the links between the views. Each of the views is causally linked meaning that certain types of traceability can be described. The relation between customer view and engineering view describes how certain customer features are realized by means of certain functional units. The relation between engineering view and part view explains how functionality is realized by means of physical parts and sub-assemblies. Reading from the part view to the engineering view explains how a certain part contributes to delivering functionality of the products. From the engineering view to customer view the relation describes how

functional units deliver customer features and, hopefully, value to the customer view. These causal links are important for making decisions on product assortments and architectures. The PFMP is one of many ways to model the phenomenon of visualizing multiple products with regards to the underlying structural dependencies. Later, the PFMP framework has been expanded by Lindschou (2012) so that it includes a market, supply, organization, and work process domain.

How "Modular Product Design" Contributes to this Research

Many authors within the design research community refer to modular product design and is fundamental to defining modular platform architectures. Pahl and Beitz (1997) recognize the differentiation of functions and show how these can be used as the basis for establishing modular structures. The function-means tree by Otto and Wood (2000) further evaluates the structural dependencies based on functional requirements and design solutions and show how this can be used to establish conceptual designs. The functional structure diagram by Sudjianto and Otto (2001) contributes to this research as it shows how functional structures can be applied for modelling of product families as a basis for modularization of multiple platforms. Further, it founds the basis for the modelling formalism used in this thesis for the proposed model establishing medical device architectures.

The modularity heuristics by Zamirowski and Otto (1999) and Stone et al. (2000) introduce flows that found the basis for modularization criteria establishment, which enlighten the importance of interfaces between entities and show how this can be used to develop modular products. The MDF methodology by Erixon (Erixon 1993; Erixon 1998) builds heavily on modular product structures and offers a well-understandable and very widely applicable procedure. The module drivers enable a very comprehensive consideration of the product-strategic reasons for the design of modules. It is a coherent approach for identification of modules with starting point in customer requirements and module drivers. In this way, the method touches some of the essential parts of the identification of modules, which is central to this research. One of the core contributions of the module drivers is that it shows that incentives for introducing modules are not only related to the technical domain but are also reasoned in the life-phase systems.

The procedure proposed by Blees (2011) brings modular product development into the life-phase system and show how this can be applied for trade-off analysis, which contributes to this research by combining module drivers and life-phase system design, which plays a huge role in this research. The PFMP (Harlou 2006) contributes to this research by acknowledging the linkage of the three domains: Customer, engineering and part domain, and their mutual dependence. This creates a foundation for decision-making on assortment and architecture, which is central to this research study. The methods of "Modular Product Design" contributes to

this research by applying knowledge of product structuring, modularization of product, and its ability to define modular product platform architectures and the application for modelling product families based on modularization.

5.3.3 DESIGN FOR VARIETY

Erens (1996) takes up the topic of designing product families in his thesis. He argues that a domain-oriented approach for modular design is needed. This implies that one should understand the relations between the functional, the technological (i.e. organ structure) and the physical structures of the product family. This view point is identical to the Theory of Domains (Andreasen 1980). Erens (1996) proposes ways to formally define and document modular products. As a product family can be defined in three domains: the functional domain, the technology domain and the physical domain, each domain has one product model and a number of representations (Fig. 5.14).

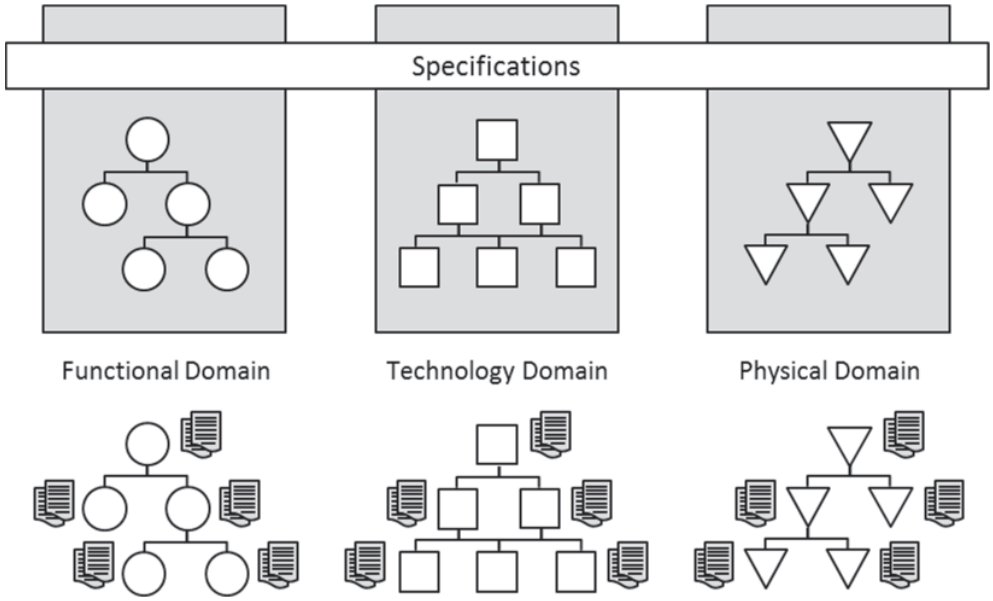


Fig. 5.14: A product family can be defined in three domains: the functional, technology and physical domains. Each domain has one product model and a number of representation (Erens 1996)

According to Erens (1996), it is essential to separate the stable and variable parts when designing a product architecture. The stable aspects create a framework within which a variety of products can be developed. The standardization of interfaces in one domain improves the possibility to combine components in such a way that a large variety in that domain is created. The architecture of a product family is decoupled from the architectures of its components. The variety of these components has no consequences for external interface of these components,

which reduces design complexity. Multiple methods under "Design for Variety" exist. In this section a number of tools and methods are described including generational variety index and coupling index, tree of external variety, variety allocation model, and module interface graph. These methods all emphasize design for variety based on the development of modular products and contribute to this research by their ability model, visualize, and balance external variety versus internal variety trade-offs.

Generational Variety Index and Coupling Index

The term "Design for Variety" was established by Martin (2001) and Martin and Ishii (2002). They describe a methodology for the development of architectures of products with a huge number of variants. The methodology is based on indices and is a comprehensible approach to assessing the technical coupling strength of components as well as planned future changes and to finally derive long-term stable platforms. To do this, the structure and design of the product is considered. In the first step, the Generational Variety Index (GVI) is determined, which expresses the amount of effort required in redesigning a component to meet future market requirement. In the second step, the coupling strengths of all components are determined using the Coupling Index (CI), which expresses the sensitivities of the components to changes in the connecting flow (Fig. 5.15).

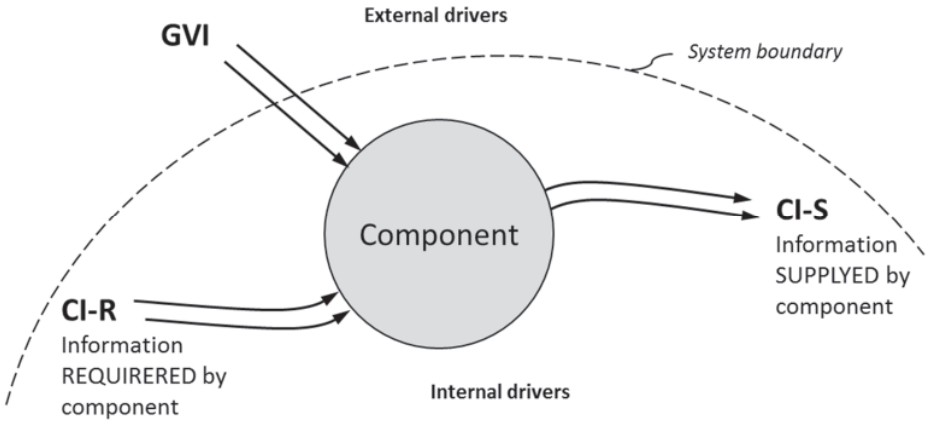


Fig. 5.15: The drivers of component change in the Design for Variety methodology (Martin 2000)

Using GVI and CI, the components are assigned to concrete guidance for standardization and modularization. These are the changes in the allocation structure between functions and components, freezing a specification, reducing internal couplings and oversizing of components. The determination of these indices is not only useful for the evaluation of product architectures; it also creates a deeper understanding for the coupling between functional elements and for the estimated changes between current and future generations of the product. One presented

possibility for the implementation of Design for Variety is the "increase of headroom of the specification", which generally can be referred to as "overdesign". The second mentioned approach is to add elements, in this case extension elements, to adapt the specific requirements of each variant. The term design is to be understood as the activities of the construction process, which determine the shape and dimensions of the components, their arrangement and their connections, as well as their material (Franke 2002). The term Design for Variety is to be determined as possibilities of design and product architecture, which minimize the costs of the development and production of variant products.

Tree of External Variety

A Tree of External Variety (TEV) aids analysis of the external variety (Eilmus et al. 2012; Krause et al. 2014). TEV is used to visualize the selection process of the customer by linking variant product properties relevant to customers and the offered product variants (Krause and Ripperda 2013). The variety tree visualizes the selection process of the customer by linking variant product properties relevant to customers and the offered product variants. The tool is used to visualize the variant product properties relevant to customers and the product variants offered. Internal variety can be analyzed at the level of functions, working principles and components (Fig. 5.16).

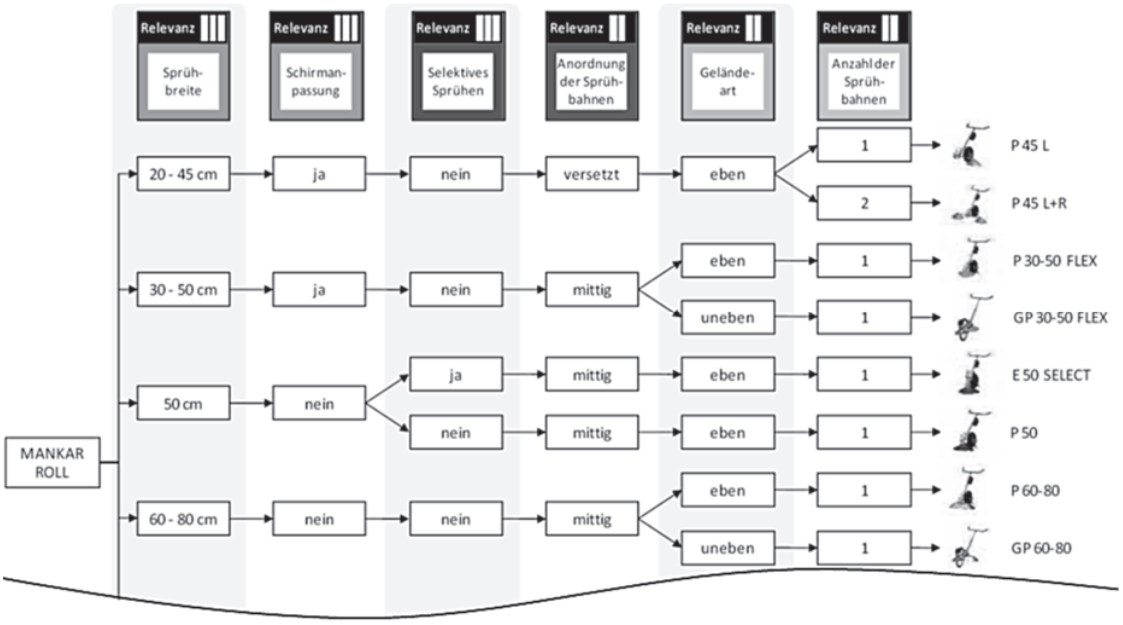


Fig. 5.16: Tree of external variety for a product family (Kipp 2012)

The upper lines form the distinguishing features, e.g. treatment width, material feed and speed measurement. In the columns, each branch of the TEV is assigned the respective occurrences of

the feature, whereby the tree spreads out from left to right. In the column on the right side of the TEV all existing variants of the product family are shown, so that it is easy to understand for each of the variants, which distinguishing features are assigned. The feature tree displays a differentiator in each column. The tree evolves according to the characteristics of the characteristics. Thus, each branch of the tree represents a product variant. However, only product variants that are to be offered on the market are included in the tree. Compared to a tabular illustration, a tree structure offers the advantage of an intuitively comprehensible representation in which the variety of variants is directly reflected in the width of the tree.

The variety trees are constructed to reflect the decision-making of the customers. The customer relevance of the distinguishing features therefore decreases from left to right. The level of detail of the feature tree is to be selected so that each branch clearly describes an existing variant of the product family. To allow for easy assignment, each individual variant is specified on the right using an image and a description of the addressed market segment.

Module Interface Graph

The Module Interface Graph (MIG) tool was first introduced by Blees (2011) with the aim of simplifying collaboration between design disciplines and company departments during modularization projects. The MIG uses a visualization in which the arrangement, rough shape, and variance of the components of the product family as well as their interfaces are displayed (Fig. 5.17). The MIG is a schematic 2D graph of a product family and its components. It arranges only the information that is essential for deciding modular structures and complements the product documentation typically used in product development (e.g. CAD models, bill of materials or function structures) by supporting communication and decision-making in a trade-off situation between the stakeholders of modularization.

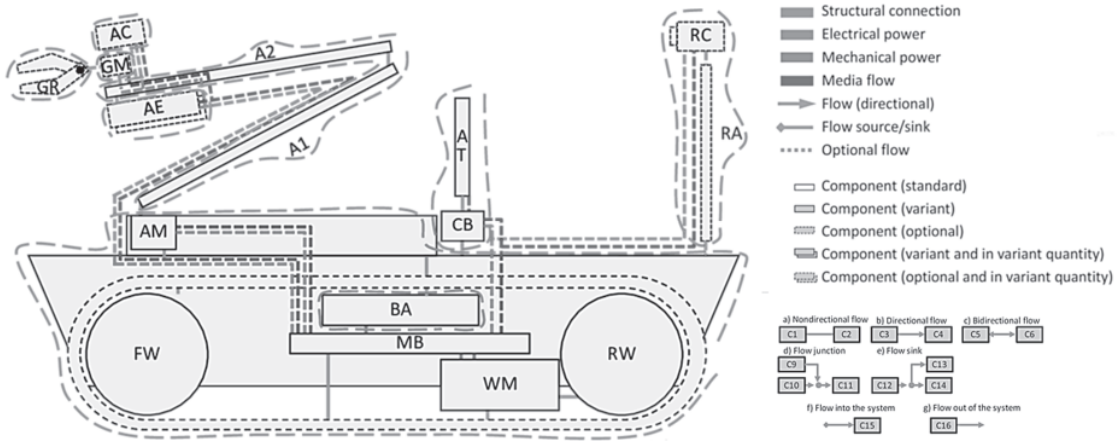


Fig. 5.17: Module Interface Graph for an unmaned ground vehicle (Otto et al. 2016)

The MIG is applied for the visualization and analysis of the variety of components and connecting flows (i.e., interfaces) in a product family. Particularly, the MIG also provides the information on the simplified spatial view of the real product. It supports the designing of the first three-dimensional platform concepts and interfaces.

Variety Allocation Model

The Variety Allocation Model is a variant-oriented product design method that fundamentally strives to: (1) differentiate in standard and variant components, (2) reduce the carrier of a variant product property, (3) enable one-to-one assignment of variant product properties to variant components, and (4) decouple the variant components (Krause et al 2014; Blees et al 2010). By meeting these criteria, the components of a product are designed in a way that enables the creation of a large external diversity based on a small internal diversity. As the components converge to the ideal state indicated in the four criteria, the VAM developed by Kipp (2012) serves as a supporting visualization. In VAM, the diversity of variants is mapped on the abstraction levels of development and engineering design methodology and brought into a causal relationship, which show the connections between the differentiating properties, functions, work principles and components (Fig. 5.18).

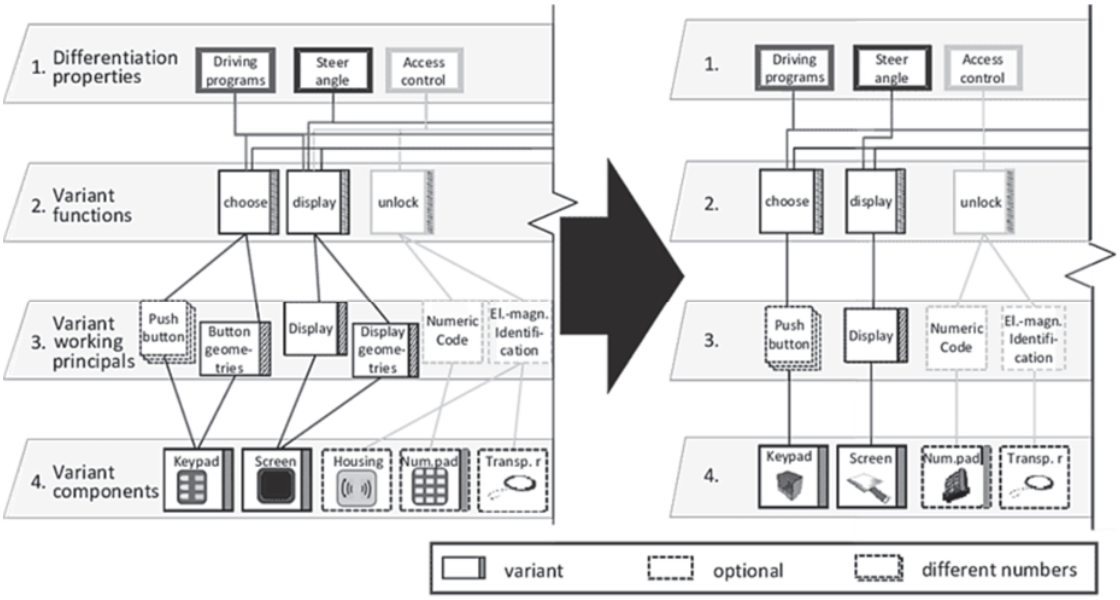


Fig. 5.18: Applying the Variety Allocation Model (VAM) as a tool to optimize the product family of herbicide spraying systems (Krause et al. 2014), originally Kipp (2012)

All relevant information required to carry out design for variety when preparing constructive proposals is visualized in the Variety Allocation Model (VAM). The connections between the levels demonstrate the allocations between differentiating properties, functions, working

principles, and components. In this way, VAM allows analysis of the degree of fulfillment of the four ideal characteristics. For variant conformity, any weak points in the design can be identified at all levels of abstraction. Thus, VAM is the basis for solution finding and selection of solutions in the methodical unit design for variety (Krause et al. 2014). For the sake of clarity, only variant elements are included in the model. The VAM therefore becomes increasingly simpler and more compact in the case of a variant-oriented design of the product family and thus shows a qualitative approach to the ideal state. All weak points in the design can be identified at all levels. Using the VAM, a solution for the design for variety concept can be found. In the search for solutions for variant-oriented product design, the VAM primarily serves to identify key action areas (Blees 2011). The goal is an unambiguous assignment of distinguishing features and components. In doing so, solutions are searched for on all levels of abstraction, whereby the model, starting from the components, is traversed through the principles of action and functions up to the distinguishing features of the product family.

How "Design for Variety" Contributes to this Research

One of the key learning points from the work of Erens (1996) is that three domains are needed for describing product families: The functional, technology, and physical domain, each with a product model and a number of representations. Based on the generational variety index (GVI) and coupling index (CI), Martin and Ishii (2002) show how this can be applied in order to identify the components of product variants that are most likely to require redesign in the future. These components can then be embedded with the flexibility required for them to be easily modifiable while the remaining components can be designed into a platform, which is a core contribution to this research study. The TEV by Kipp (2012) enable analysis of the external market-based and internal company varieties of the product family. It models the selection process of the customer by linking variant product properties relevant to customers and the offered product variants. Blees (2011) recognizes the need to visualize and analyze the variety of components and connecting flows and introduces the MIG for this purpose.

Kipp (2012) contributes to this research by acknowledging the allocations between differentiating properties, functions, working principles and components visualized by the connection of the four levels of the VAM. It allows for examining the variety-oriented product structure and any weak points in the design can be identified for variant conformity at all levels of abstraction, which can be used as the basis for solution finding, which is very interesting to this research study. The described "Design for Variety" methods generally contribute to this research by its acknowledgement of balancing external variety and internal standardization. The tools provide methodical approaches to aligning external drivers of variety with the design domain, especially requirements flow and life-phase system interaction modelling contributes to this research. Specifically, the ability to translate requirements across life-phase systems,

which is fundamental to design for variety methods, creates the foundation for the proposed tools in this thesis.

5.3.4 MATRIX-BASED DESIGN MODELLING

Matrix-based design modelling is a means to manage information flows and has been successfully applied for modelling design and processes for optimization. Elements and dependencies between the elements in any given domain can be represented by matrix-based modelling techniques. In short, Design Structure Matrices (DSM) introduced by Steward (1981) maps elements against each other, whereas the Domain Mapping Matrices (DMM) connects the DSMs (Danilovic and Browning 2004). Together these matrices form the MDM, which was introduced by Maurer (2007). There exist a vast number of algorithms that can be applied to the matrices and one can develop one's own to suit the needs of a specific case. The basic idea of a clustering algorithm is to reorder the rows and columns so that all marks, content representation, are as close to the diagonal as possible or form a tight cluster with other marks. In this section, the many different algorithms will not be described, but instead a number of relevant "Matrix-based Design Modelling" methodologies will be introduced, i.e. design structure matrix, change propagation methods, integration analysis methodology, structural complexity management, and its extensions. Common to these methods is its ability to systematically model design structures from both a functional and physical perspective while they carry the ability to detect various discrepancies and changes in design and process information flows.

Design Structure Matrix

Design Structure Matrix (DSM) and its methods are becoming more mainstream, especially in the areas of engineering design, engineering management, management/organization science, and systems engineering (Browning 2016). Within the DSM methodology (Steward (1981)) two main categories exist (Fig. 5.19): Static and Time-based. Static DSMs represent system elements existing simultaneously, such as components of a product architecture or groups in an organization. Static DSMs are usually analyzed with clustering algorithms. In time-based DSMs, the ordering of the rows and columns indicates a flow through time: upstream activities in a process precede downstream activities, and terms like "feedforward" and "feedback" become meaningful when referring to interfaces (Browning 2001). Time-based DSMs are typically analyzed using sequencing algorithms and is applied in order to organize product development tasks or teams and thereby minimize unnecessary design iterations and thus help manage and speed up the development process (Ulrich and Eppinger 2004). The objective of a component-based design structure matrix is to encapsulate subsystems or components into modules/chunks. This is done by studying the interfaces and interactions among the

subsystems/components and hereby proposing a module structure with limited interactions among the modules/chunks (Baldwin and Clark 2000). The objective of a time-based design structure matrix is to analyze the structure of system design processes, which can be applied to manage projects (Browning 2001).

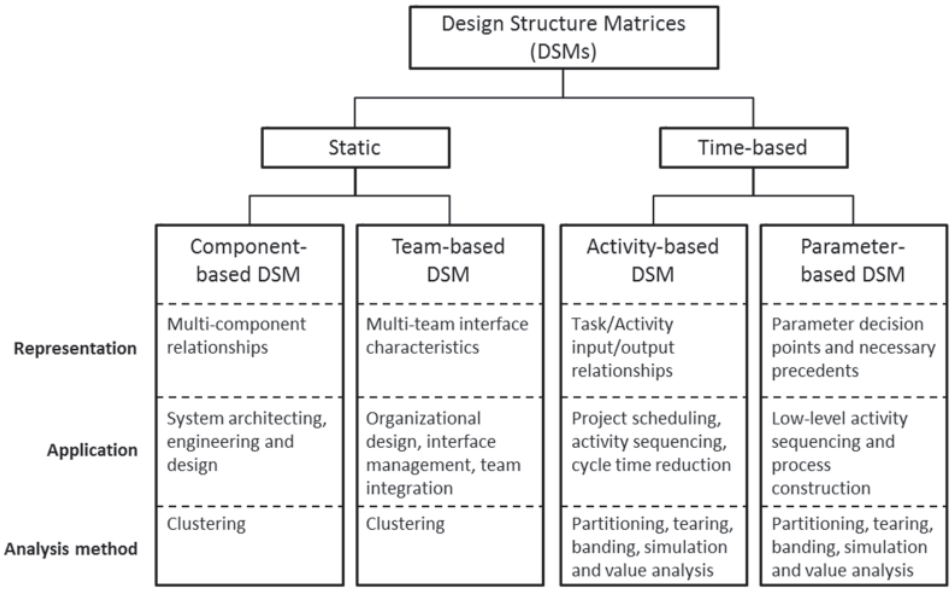


Fig. 5.19: The four basic types of design structure matrices, based on Browning (2001)

Browning (2001) and Eppinger and Browning (2012) consider modelling system architectures based on components and/or subsystems and their relations and finds that this can be modeled using DSMs. Further, the component-based DSM can be used to define modules within the product architecture. In the component- or function-based DSM, also called product architecture DSM, components or functions are placed on the row and column headers of the matrix. Components or functions are then mapped against each other and their interactions are marked in the matrix (Fig. 5.20). By using algorithms, it is possible to encapsulate components into modules or chunks that are closely related to each other from an interaction point of view (Steward 1981).

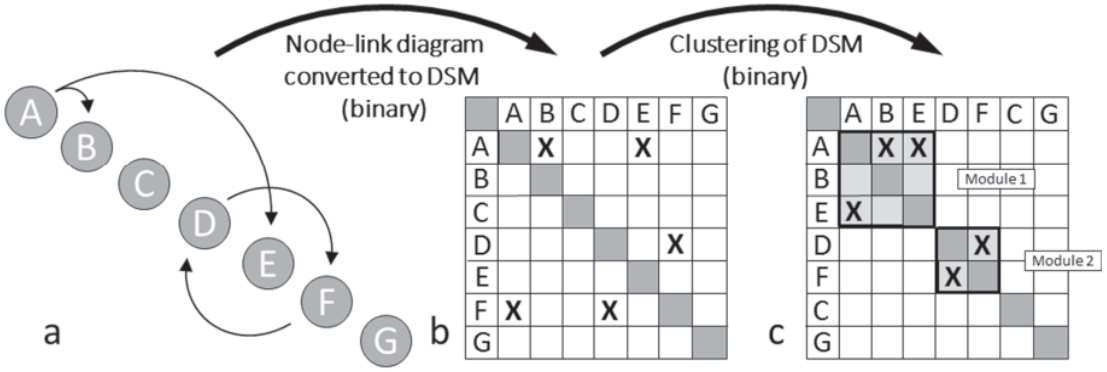


Fig. 5.20: Component-based binary DSM: (a) Node-link diagram (directed graph) of a system, (b) Un-clustered DSM representation of the dependencies, and (c) the result of analysis using a clustering algorithm, based on Pimmler and Eppinger (1994) and Browning (2015)

The DSM is designed especially for quick rearranging of the architecture based on the interface interactions. The method concentrates on the interfaces of the modules to simplify the design process and the apparent complexity of the product architecture. The method leaves more business-oriented factors and product functionality up to the designer's judgment after first simplifying the architecture. Sosa et al. (2004) further developed the DSM approach by introducing a so-called delta-DSM to find differences in the structure between two DSMs, specifically differences between product structure and process structure. Kreimeyer et al. (2007) applied delta-DSM to find and calculate the differences between a planned process structure DSM and planned organizational structure DSM. As Hickeithier (2012) states, the delta-DSM can make it easy to compare many indicators for information flows, and to identify deviations. Thus, the delta-DSM can be used to detect misalignment across domains, hence the importance of aligning multiple architectures.

Change Propagation Methods

Change propagation methods (CPM) can provide an indication as to how changes may propagate through a product. Change propagation practices explore how changes made to one version of the application are migrated to other living versions of the application. To minimize design and requirement variations during product development, change propagation analysis can be employed to identify product variants and predict the changing effects of the requirement. Change propagation can be defined as the process by which a *"change to one part or element of an existing system configuration or design results in one or more additional changes to the system, when those changes would not have otherwise been required"* (Giffin et al. 2009). Eckert et al. (2004) introduce change propagation behaviors to quantify the impact of changing the requirements and behaviors, and defined different components with regard to change propagation as falling into several categories, paraphrased here: (1) constants – components

unaffected by change, (2) absorbers – absorb more changes than they cause, (3) carriers – absorb and cause a similar number of changes, and (4) multipliers – generate more changes than they absorb. As follow-on, Clarkson et al. (2004) described a method for predicting change propagation paths using DSMs. They introduce a change prediction method to determine the risky area and understand complex dependencies between components based on design changes. Thus, several change propagation analysis methods such as change design structure matrices (delta-DSMs) and the change propagation method (CPM) have been developed, all using the DSM as the founding modeling technique.

Integration Analysis Methodology

Pimmler and Eppinger (1994) introduce the Integration Analysis Methodology and define four classes of interactions: Spatial (adjacency or orientation), energy (energy transfer), information (information or signal exchange), and material (materials exchange). The interactions can be represented with coupling coefficients -2, -1, 0, 1, or 2 depending on the strength of the relation and whether the relation is beneficial or undesired (Fig. 5.21). Once functions or components and their interactions are placed in the DSM, a clustering algorithm can be applied to group the functions or components so that the interactions within clusters are maximized and between the clusters minimized.

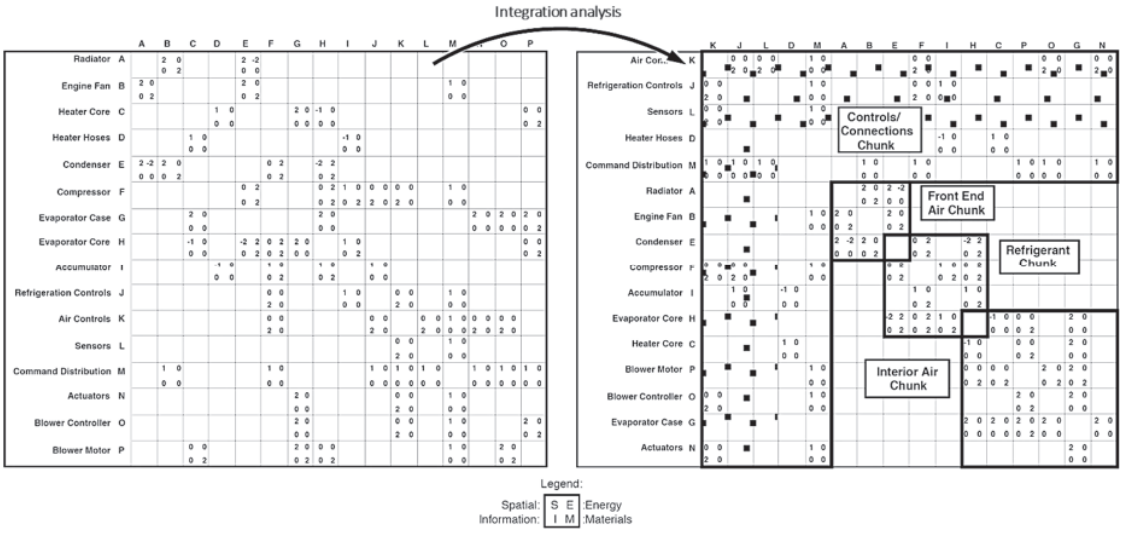


Fig. 5.21: Integration analysis of a climate control system: (a) Un-clustered matrix with dependencies and (b) clustered interaction matrix using heuristic swapping algorithm (Pimmler and Eppinger 1994)

Matrix and clustering approaches are often seen in publications about modularization. Helmer el al. (2010) suggest a component-based DSM clustering approach for definition of modular product architectures. Component-based DSM is suggested also in the approach by Simpson et al. (2012) as a supporting tool for defining differentiation plan and for studying the interactions

of components and sub-systems. In general, matrices are easy to use for mapping relations, even though in cases in which the number of elements is high, matrices might become cumbersome to read and modify. Partitioning is often done using algorithms that help to reorganize the matrix in order to make architectural decisions. Matrix-based methods are not comprehensive alone for holistic modularization as they do not consider strongly how to create the relevant information related to the suggested key engineering concepts. Modular product family development needs a case specific target setting from different perspectives that would explain the reasoning why a product family should be partitioned in a specific way.

Structural Complexity Management

Based on the design structure matrix methodology, Maurer (2007) introduces the multi-domain matrix (MDM) that have broadened the capabilities and applications of matrix-based models of complex systems and provided further insights. Such capabilities have become recognized as increasingly beneficial and important in this age of ever-more complex projects, products, processes, organizations, and other systems (Browning 2016). While the elements of a domain are related in a DSM, different domains are contrasted in DMMs. In the MDM, the DSMs are therefore on the diagonal of the matrix, while the remaining matrix elements are occupied by DMMs. For example, the first element of the MDM (Fig. 5.22) is formed by the DSM of the components, while the neighboring element relates components and functions in a DMM.

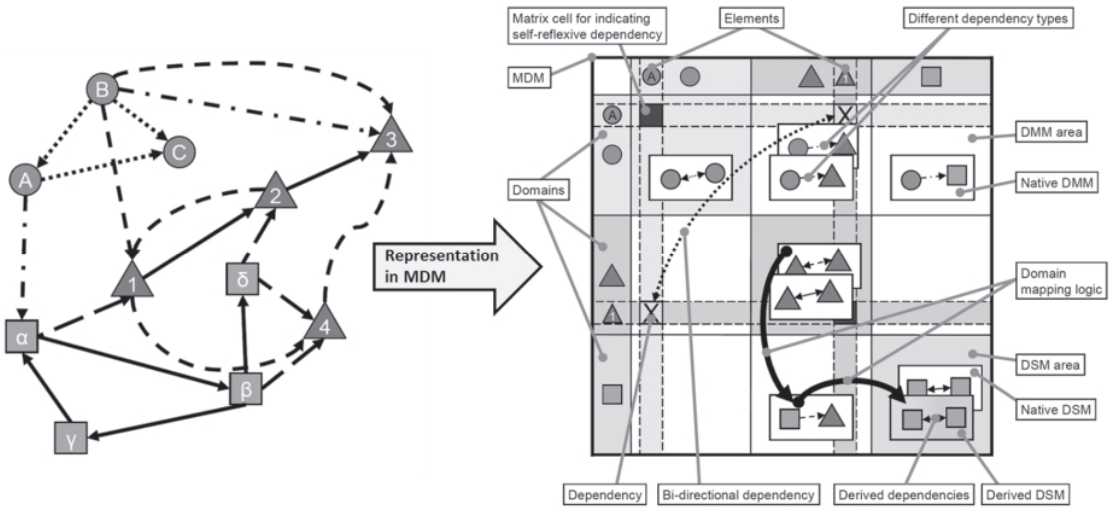


Fig. 5.22: Representation of dependencies in a multiple-domain matrix (Maurer 2007)

The domains are determined by components, features, features, and production constraints, as well as the dependencies between them. In the MDM, both direct (intra-related) and indirect (inter-related) relationships between elements are determined. For indirect relationships,

elements of one domain are coupled through another domain. For example, components are indirectly coupled through the domain of functions when serving a common function. In addition to the matrix of direct geometrical couplings of the components, additional matrices are therefore set up, which map the derived, indirect couplings of the components. In the subsequent structural analysis, as already known from the Integration Analysis Methodology introduced by Pimmler and Eppinger (1994), the module formation takes place through a cluster analysis. Since functional relationships between components are considered crucial for module formation, cluster analysis is applied to the matrix of functional relationships. The results of the analysis are thus functionally strongly coupled clusters. In order to consider not only functional couplings but also direct geometrical couplings and couplings via features, the corresponding matrices are permuted analogously to the functionally coupled matrix and superimposed therewith. Thus, MDM allows for analyzing a system's structure across multiple domains, condensing each single analysis into one DSM that represents multiple domains at a time.

Gorbea (2011) introduces the delta-MDM, a procedure analogous to the earlier described delta-DSM method, where two MDMs can be compared by means of matrix subtraction, given that both MDM are of the same dimensional structure. The MDM subtraction by fields is useful only when the component and functional indexes of compared sets match each other. The delta MDM method can be used in comparing two distinct architectures, or one product architecture that has been updated through the development process by tracking its element index changes through time. Index changes indicate that a component or function has been added or dropped (Fig. 5.23).

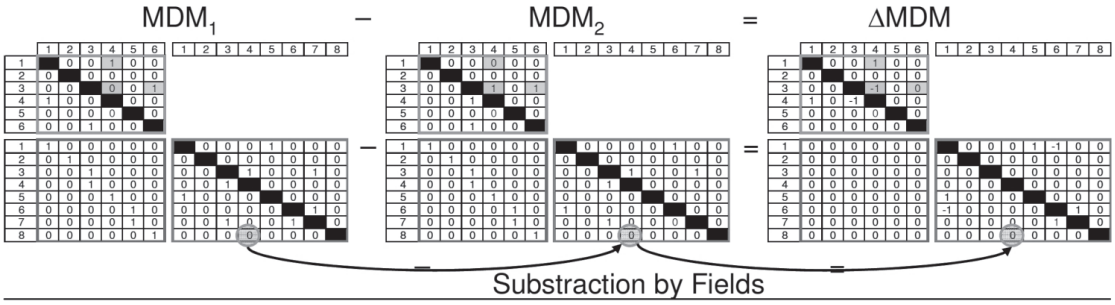


Fig. 5.23: Creation of a delta-MDM (Gorbea 2011)

Gorbea (2011) applies the delta-MDM method to compare two vehicle architectures and finds that two benefits of the delta-MDM method were recognized in practice. First, the changes in components used and functionality provided were easy to detect. Secondly, the method was very useful in catching logical errors in matrices filled by hand within a workshop environment.

Further, Gorbea (2011) introduces the sigma-MDM, which is built by the addition of two or more MDMs, and is based on the work with DSM matrix addition. Like the delta-MDM, the matrices being added must match in terms of the function and component elements within the matrix position indexes (Fig. 5.24).

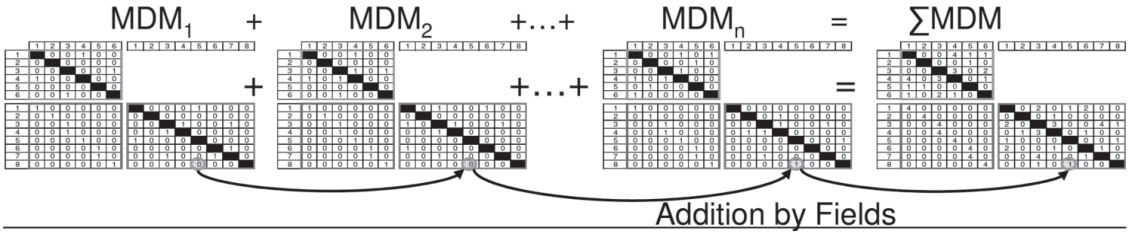


Fig. 5.24: Creation of a sigma-MDM (Gorbea 2011)

According to Gorbea (2011), the addition of these MDMs enables determination of information that could lead to the formulation of design rules or requirements. For example, components are found to apply to all architectures are easily identified in the delta-MDM by cells showing a sum value equal to the number of total MDMs in the sum. Likewise, function or components showing fields with a result of "1" show that the function or component is unique to only one particular architecture from the original set. This information can be helpful to make more targeted technology investments. Further analysis is accomplished by the identification of components are always present together and components that cannot be found together in particular vehicle architectures. The architecture information contained in the MDMs leads to a number of design synthesis "if – then" statements, which Gorbea (2011) uses for developing a configuration synthesis methodology.

How "Matrix-based Design Modelling" Contributes to this Research

Although DSM (Steward 1981; Browning 2001) is a relatively simple modeling tool, its ability to map iterations makes it powerful relative to, e.g. networks used in critical path methods. The matrix format enables the use of algorithms to optimize the sequence of flows across elements in the matrix, and it enables the deduction of dependencies and the comparison of relationships between elements through mathematical operations. The DSM contributes to this research by providing a strict methodical approach to map entities and their interactions, which is used as the founding modelling technique in the following. Engineering change, or change propagation, plays a critical role in complex systems design. Giffin et al. (2009) contributes with the acknowledgement of changes in systems, its behavior and resulting disturbances, and its detection using change propagation analysis. It contributes to this research by recognizing the importance of ripple effects when developing new products or changing existing designs.

Pimmler and Eppinger (1994) contribute with the Integration Analysis Methodology, the four classes of interactions, and the interaction rating system. The MDM introduced by Maurer (2007) contributes to this research by showing how multiple domains can be modeled using matrix-based techniques, which is one of the key topics of this research study. Further, the extension by Gorbea (2011) introducing the delta- and sigma-MDM, contributes to this research by showing how discrepancies can be detected across multiple domains using the delta-MDM method, which crucial to this research. Thus, the methods under "Matrix-based Design Modelling" contribute with systematics to model complex systems including entities and their interactions and provide methodical approaches to structural complexity management.

5.4 Evaluating the Current Solution Space

This chapter has provided an overview of some of the key contributions related to the research area of developing modular platform architectures and product families. The contributions mentioned within this chapter have showed that modular platform architecture design is a multifaceted subject of study, and that many aspects are relevant to such development. As earlier mentioned, the three topics of critical relevance of this research is: (1) Scope – The abstraction of manipulation, (2) Aspect – The inclusion of early stage life-phase systems, and (3) Purpose – Synthesis for new product development or analysis for rationalization. Within this chosen scope of the state-of-the-art literature review, the following conclusions can be presented (Tab. 5.4):

Strategic modularization – Focuses on the strategic management of modular platform architecture development. A concrete support of the variant-oriented design of a product family is not the aim of these methods. The focus of the method is the balancing and compromise between the differentiations of product variants offered to the marketplace. During product structuring, it is determined which components that are to be standardized or structurally reconfigured. The methods thus derive tasks for a constructive, variant-oriented design of the components, but do not support them per se. The methods large manipulate at family level, they focus largely on smaller groups of products, their similarities and seeks to optimize it in accordance with a given company strategy. Through the methods, the importance of aligning the different architectures is emphasized, but still the exploration of regulatory domain and test domain, and its intra-/inter-relations have yet to see the light. Several authors point out that application of architectures, platforms, and modularization for product families can be of strategic importance for a company's business. Thus, the development of modular platform architecture is not just a technical discipline; it can be reasoned in all functional areas within the company as well as life-phase systems. The methods are mainly designed for analysis and rationalization purposes but still some, e.g. the platform-planning process, strives to support new product development.

Modular product design – Focuses on reducing internal variety based on external influencers. With regard to the variant-oriented design of the product structure, the focus in the methods described, is on the differentiation between creating variety while increasing standardization through modularization, hence reduction of technical variety. Considering the diversity of variants thus remains unspecific in both cases, which is why these methods do not offer comprehensive support for variant-oriented product structuring and this is also why the methods are targeting single products for manipulation. Module drivers for example, are seen as generic heuristics and therefore a project team may introduce new or modified heuristics which are company specific such as financial caps, geographical constraints, governmental regulations, etc. Lange and Imsdahl (2014) suggested a "Regulations Complaint" module driver for the medical industry that develops and markets test equipment that is required to certify sub-systems with the Food and Drug Administration for products sold in the US market, but as with other suggestions these new differentiated module drivers have not been developed and potentials not been investigated.

The methods support a large variety of life-phase systems, but they do still not consider aspects of regulation and test documentation, which is critical to manufacturing companies operating under restrictive regulatory requirements. The methods seem to either support analysis or synthesis purposes – no method is found to mutually support rationalization and new development simultaneously.

Design for variety – Focuses on developing modular product architectures based on the design of stable components over time. The methods primarily have a single product focus, only design for variety by Martin and Ishii (2002) does include families of products for manipulation – no method seems to support program design. The methods explicitly aim to reduce internal variety while they support the development of modular platform architectures for the design of multiple diverse product variants satisfying the marketplace.

However, in addition to product structuring, the methods only include the design of components and do not offer sufficient support for variant-oriented design in all life-phase systems. Namely, do the methods lack support in modelling regulatory requirements as the dominating external influencer of product design in medical industry, and they do not treat the testing as internal complexity driver. These aspects are critical to medical device manufacturers and therefore, research is needed to investigate the possibility and potential of including these domains in the design for variety methodology. Further, the methods primarily are suitable for post-launch purposes – it would be beneficial to look into the possibility of supporting new product development based on design for variety thinking patterns.

		Comparative criteria											
			Scope			Aspect					Purpose		
		Compliance driven modularization	Top (product program)	Mid (product family)	Low (single product)	Customer needs and preferences	Law, legislation, and regulation	Engineering design	Verification and validation testing	Compliance documentation	Rationalization (analysis)	New development (synthesis)
State-of-the-art methods and tools for modular platform architecture development												
Strategic Thinking	**Power Tower / Leveraging Strategy** (Meyer and Lehnerd 1997)	(✓)	◑	◑	○	◑	○	●	○	○	◑	○
	Platform-Planning Process (Robertson and Ulrich 1998)	(✓)	○	●	○	◑	○	◑	○	○	○	●
	Factors for Platform Strategy (Krisjansson and Hildre 2004)	(✓)	○	●	○	◑	○	◑	○	○	◑	○
	Strategic Modularization (Sanchez 2001; Sanchez 2013)	(✓)	◑	◑	○	○	○	○	○	○	◑	○
Modular Product Design	**Baukästen System** (Pahl and Beitz 1997)	(✓)	○	●	●	○	○	○	○	○	◑	○
	Function-Means Model (Otto and Wood 2000)	(✓)	○	●	●	○	○	●	○	○	◑	○
	Function Structure Diagram (Sudjanto and Otto 2001)	(✓)	○	●	●	○	○	●	○	○	◑	○
	Modularity Heuristics (Stone et al. 2000; Zamirowski and Otto 1999)	(✓)	○	○	●	◑	◑	●	○	○	○	◑
	Modular Function Deployment (Ericsson and Erixon 1999)	(✓)	○	○	●	●	○	●	○	○	○	◑
	Module Process Chart (Blees 2012; Krause and Eilmus 2011)	(✓)	○	◑	●	●	○	◑	○	○	○	◑
	Product Family Master Plan (Harlou 2006; Mortensen et al. 2012)	(✓)	◑	●	○	●	○	●	○	○	●	○
Design for Variety	**Generational Variety** (Martin and Ishii 2002)	(✓)	○	●	●	●	◑	●	○	○	◑	●
	Tree of External Variety (Kipp 2012; Eilmus et al. 2012)	(✓)	○	◑	●	◑	○	●	○	○	●	○
	Module Interface Graph (Blees 2011; Gebhard et al. 2014)	(✓)	○	○	●	○	○	●	○	○	●	○
	Variety Allocation Model (Kipp 2012; Krause et al 2014)	(✓)	○	◑	●	○	○	●	○	○	◑	◑
Matrix Modelling	**Design Structure Matrix** (Steward 1981; Browning 2001)	(✓)	○	○	●	○	○	●	○	○	●	○
	Change Propagation Method (Eckert et al. 2004; Clarkson et al. 2004)	(✓)	○	◑	●	◑	○	●	○	○	◑	◑
	Integration Analysis Methodology (Pimmler and Eppinger 1994)	(✓)	○	○	●	○	○	●	○	○	●	○
	Structural Complexity Management (Lindemann and Maurer 2007; Gorbea 2011)	(✓)	○	◑	●	●	◑	●	○	○	●	◑

✓ Applies to (✓) Partially applies to ● Considered ◑ Partially considered ○ Not considered □ N/A

Tab. 5.4: The theoretical contributions related to the research subject of interest to this thesis

Matrix-based design modelling – Focuses on the applicability of matrix-based modelling techniques for development of modular platform architectures. Usually these methods do not specify a concrete goal or the design object. Concrete support for the development of variant-oriented product structures is generally not offered by these methods. The methods mainly have a single product focus, so the inclusion of families or even programs of products using these modelling formalisms still is yet to come. The methods imply that one should understand the relations between the different domains related to the development of a product family or even a product program. Multiple aspects have been studied in the last decades using matrix-based modelling techniques, especially with regards to product design, i.e. functional and physical characteristics, and design processes, i.e. development activities. Still no research has been carried out on regulation as an external influencer to the design and test documentation as an internal complexity driver, but such support could potentially be developed on the basis of these methods. The tools and methods described under "Matrix-based Design Modelling" generally is developed for systems analysis purposes, but the inclusion of synthesis aspects using such modelling techniques still lack in scientific literature.

While modular design has received considerable attention in engineering design research, the design of modular product platform architectures with regards to the medical domain and especially the regulatory constraints, i.e. the requirement of extensive verification and validation test documentation has received little to none. As the literature study shows, modularity can be exploited from both a customer-oriented and technical standpoint with great potentials and results – the study also show that little to no research has been done from a regulatory and documentary point of view, although there seem to be a great potential for harvesting benefits of having such common platform within heavy-regulated industries, cf. the industrial case examples presented in the beginning of the thesis. Finally, and perhaps most importantly, it seems that the concept of modular platform architectures provides excellent inroads into product program design using modularization as the means for the reuse of requirements and documentation, which could provide great potential competitive advantages to medical manufacturers.

"Regulation isn't an obstacle to thriving free markets – it's a vital part of them."

– James Surowiecki

Chapter 6

DEVELOPING MEDICAL DEVICE PROGRAMS BASED ON MODULAR PLATFORM ARCHITECTURES

The objective of this chapter is to introduce the concept of Compliance Driven Modularization (CDM) and provide a support tool that can be applied for modelling modular platform architectures for manufacturers subject to restrictive regulatory requirements. The tool is called the Compliance Architecture Concept Exploration (CACE) modelling tool and aims at modelling architecture concepts for regulation sensitive product programs from a product and compliance point of view. The CACE modelling tool is built on a multiple domain modelling (MDM) methodology, where relevant domains are modelled to meet the challenges of the medical industry. The tool enables traceability and prioritization, it provides discrepancy analysis based on the so-called Delta-Domain Mapping Matrix (ΔDMM) and it provides a structural module-based approach to new medical device development. As part of this chapter, a new driver that emphasizes modularization for compliance testing and documentation reuse is introduced, which establishes an underlying modular platform architecture accounting compliance. Lastly, an explanation of how the CACE modelling tool can be applied to evaluate conceptual designs based on the architecture views of the program, will be provided. CACE with its underlying mechanisms, constitutes both the theoretical and practical contributions of this thesis.

6.1 COMPLIANCE DRIVEN MODULARIZATION

To remain competitive, medical manufacturers must continuously seek to improve their business by meeting diversified customer needs and manifold regulatory requirements that

continuously is tightened. Handling the development of products, the change of customer needs is essential, though if a company is to manufacture products subject to restrictive regulations, these play a substantial role in the success rate of bringing the products to market. Legislative requirements are set by public authorities, who continuously demand increasing compliance testing and documentation for the approval of new product variants as well as continuous compliance work on products already brought to market. As the state-of-the-art literature study showed, although significant research has been carried out on modular platform architecture, little to no emphasis has been on modelling the compliance aspect using modularization as the foundation, in order to address the verification and validation test and documentation burden of manufacturers developing products subject to strict regulations.

In this thesis, modularization with emphasis on the compliance aspect of new product development is referred to as Compliance Driven Modularization (CDM). This is a concept that centers around two views on the product program, i.e. the product view and compliance view (Fig. 6.1). From a product view, the concept is about building products based on modules that when observed from an engineering design viewpoint, is about clustering of design elements or physical building blocks with standardized interfaces allowing different sizes or versions of a module to be interchanged or swapped, resulting in the potential of creating the needed variety to meet market needs. From a compliance viewpoint the concept is about understanding the effects of modularization brought to the testing and documentation structure, viewing the product program from a compliance aspect lead the designer to integrate compliance as an important parameter in the early stage of developing new products. As with the product view, compliance is built by testing and documentation elements that can be interchanged when couplings have been sought in the right manner.

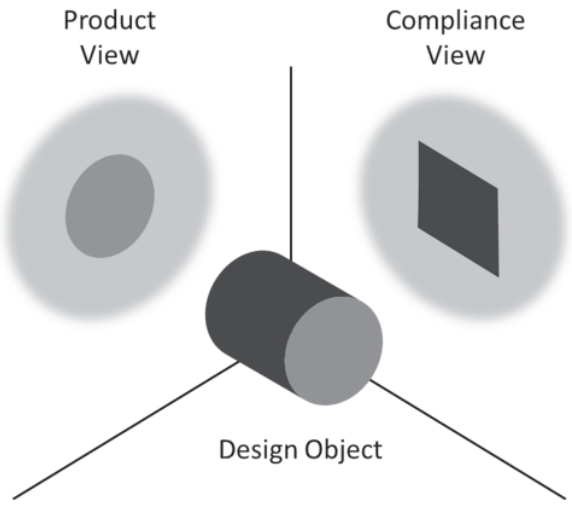


Fig. 6.1: Compliance driven modularization entails two central views on the design object: The product view and the compliance view

The concept of CDM explores the coupling principles (intra- and inter-relations) across the product and compliance domain in order to understand how variety can be encapsulated in such a way that test and documentation is not compromised. These coupling principles are inherent to developing heavily regulated products.

The reason for this is that when products undergo integration tests and lifetime performance tests for example, all the components that the product is made of is tested together, which means that their physical characteristics and the resulting performance is now bundled in these tests. This obstruct the design of future variants based on existing product programs, which is in scope of this thesis. Simply put, new variants (the design object) cannot be brought to market without re-designing both the product and the compliance test- and documentation setup.

By modularizing with respect to compliance applying the concept of CDM, manufacturers will be able to more easily reuse compliance test results and documentation across product variants and thereby potentially achieve shorter time-to-market. Thus, the objective of this chapter is to establish a foundation by which medical manufacturers can efficiently develop and successfully launch medical devices to the global marketplace. To reach this objective, the aim of this chapter is to provide a supporting tool by which the designer can:

1) Model product and compliance dependencies influencing the design of new medical devices. Establish a foundation for evaluating the medical device program in the early stage development based on its complex inter-related couplings or dependencies across the product and compliance aspects.
2) Analyze structural cross-domain dependencies with regards to relevant product life-phase systems evaluating the medical device program's sensitivity towards changing market situations considering both customer needs and legislative requirements.
3) Quantitatively evaluate new medical device designs by which the designer will be able to make qualified decisions during the early stages of new medical device development projects based on time and cost impact caused by compliance work.

Thus, the aim of this chapter is to establish a modelling tool for developing coherency between the market and product architectures to align test documentation and thereby enhance new product variant creation as well as product maintenance under legislative constraints.

This chapter introduces a tool that builds on the existing theoretical basis of modular platform-based architectures. First, an introduction to the proposed support is provided, i.e. here the Compliance Architecture Concept Exploration (CACE) modelling tool is explained step-by-step. Following the generics of using the CACE modelling tool, the application of the tool is described. Here, the Delta-Domain Mapping Matrix (ΔDMM) will be introduced as an underlying modelling formalism followed by an introduction to the Compliance Testing and/or Documentation Driver

for Modularization, which constitute a predominant mindset when modelling modular platform architectures subject to restrictive regulatory requirements. The chapter ends by summarizing the perspectives for Compliance Driven Modularization using the CACE modelling tool as an enabler for bringing new medical devices to the marketplace.

6.2 INTRODUCTION TO THE PROPOSED MODELLING TOOL

When developing complex systems, the V-model is often applied as the approach to grasp the development process of such systems. In the research contribution of this thesis, the V-model proposed by Forsberg et al. (2005) will act as input to the reading of the proposed CACE modelling tool. In the context of this research, the V-model is modified to fit the context of developing medical device programs looking into the compliance aspect developing new products and maintaining the products already brought to market (Fig. 6.2).

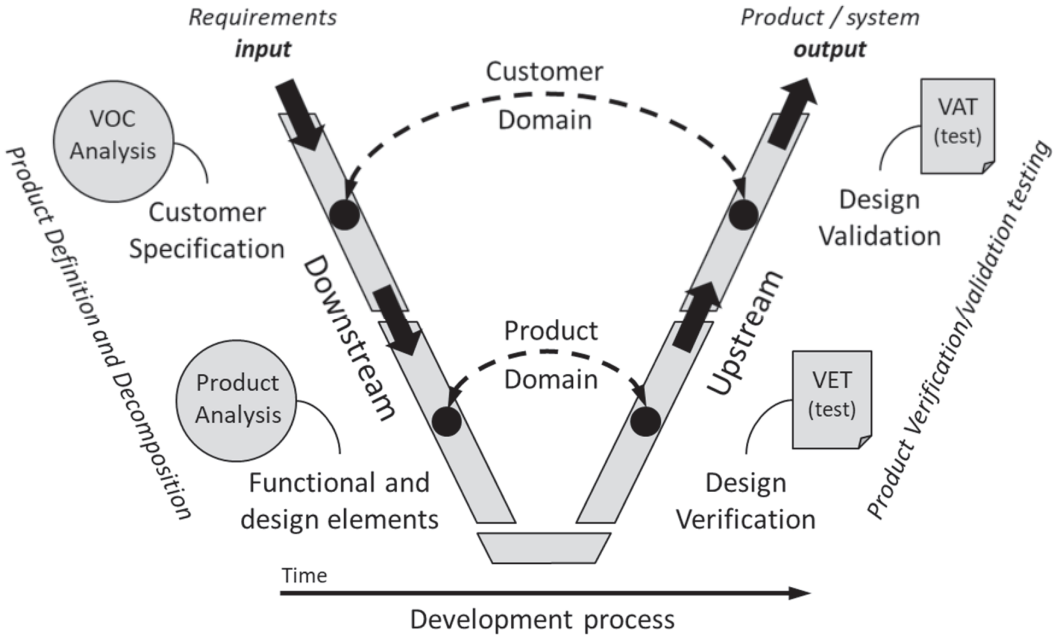


Fig. 6.2: The context-based articulated V-model based on Forsberg et al. (2005): An extended view on the V-model driving the SE process towards a more commonality-oriented approach

Whist the V-model by Forsberg et al. (2005) touch upon some of the core aspects of systems decomposition and integration, the modified V-model for the purpose of this research, interpret an alignment of the product and compliance view decomposing and integrating the systems design during the development process. Here, the model on the left-hand side shows the product view of the development process and on the right-hand side the related verification and

validation view of the development process. This conceptual V-model reflects the approach applied by the CACE modelling tool.

One of the predominant approaches to product platform and product family design (PPPFD) is architecture-based multi-product development. Be it top-down or bottom-up, the development of a module-based products supports the development of product families. Here, members are created by adding, substituting, and/or removing one or more modules from the platform architecture. Jiao et al. (2007) provide a model for developing product platform and product family designs. In the original overview, three views are presented, i.e. the customer, functional, and physical domain, upon which the product portfolio and the underlying product architecture can be reasoned. The research contribution of this thesis, the CACE modelling tool, is rooted in these relations, but is considerably extended denoting the downstream product view while applying the upstream compliance view to the model (Fig. 6.3).

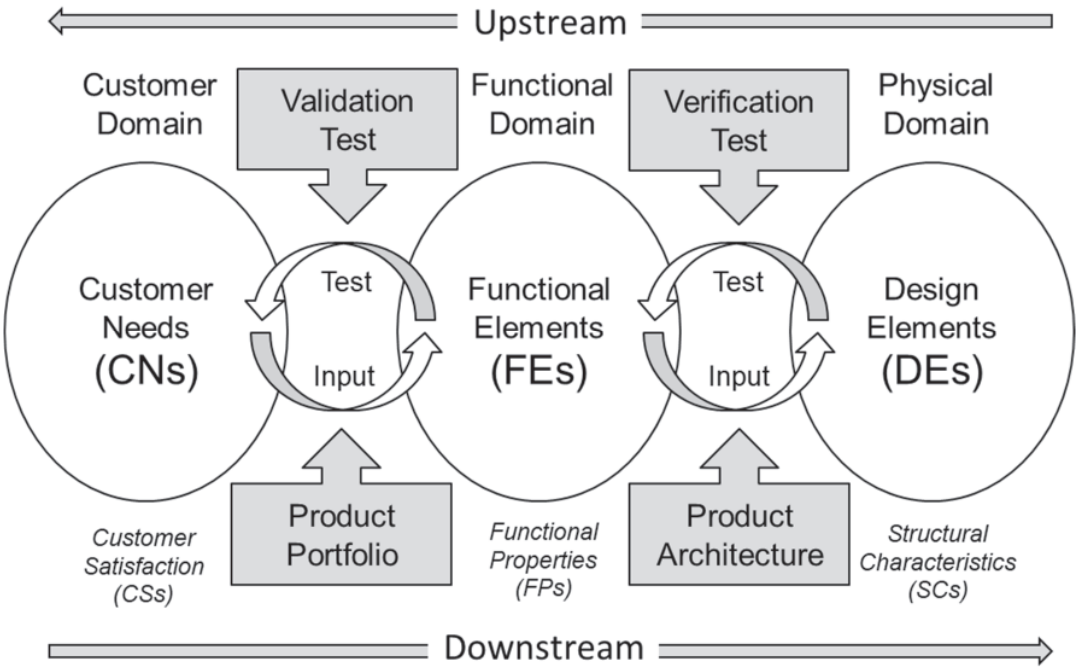


Fig 6.3: An extension of the product platform and product family design (PPPFD) model by Jiao et al. (2007)

This extended PPPFD model shows the articulated view on how to develop an architecture-based medical device program, which constitutes the core of the CACE modelling tool. Namely, when developing medical device programs, the designer should consider both a downstream product view driven by the market requirements and an upstream compliance view that represent the testing and documentation needed to bring the program of products to market.

The above illustrated model is useful for the analysis and synthesis of medical device program based on modular platform architectures. First, it includes the three views and the in-between constellations, which should enable a company to make better decisions regarding the product program and the variety of the program with regards to the products and the compliance test/documentation. In this research, combining the modified and extended views of the V-model and PPPFD model, respectively, is supporting the basis for introducing the CACE modelling tool. It provides valuable input to the reading of the CACE model and understanding the relations subjective to the proposed modelling tool.

The objective of the next section is to contribute to a formalism for modelling medical device programs considering product and test and documentation variety. The modelling formalism is based on the multiple domain modelling (MDM) methodology and is denoted the Compliance Architecture Concept Exploration (CACE) modelling tool emphasizing the coverage of intra- and inter-related couplings across product and compliance views, which is found to be essential when modelling medical device programs based on modular platform architectures.

6.3 The Compliance Architecture Concept Exploration (CACE) Modelling Tool

The CACE modelling tool described in this chapter entails a four-step process that is to leverage the needed control and management of new and existing medical device program designs:

1) Establish a structural product program model that entails both a product view and a compliance view of the medical device program variety visualizing intra- and inter-relations across the market, product and compliance views.

2) Analyze and disclose discrepancies of the product and compliance view creating a foundation for robust product program change and maintenance.

3) Modularize to develop a modular platform architecture for the medical device program to accelerate compliance processing while developing new products and maintaining existing product variants.

4) Calculate multi-domain change predictions establishing a thorough decision basis for new product introductions and program maintenance for manufacturers subject to restrictive regulations.

This section is structured by introducing the basic formalism of the CACE modelling tool. After the introduction of the general formalism, the customer, functional and physical domain modelling formalisms will be treated separately. The three views are followed by a description

of how the views are related to each other, i.e. the downstream product and the upstream compliance view, and finally how these relations are represented in the CACE modelling tool.

6.3.1 THE BASIC CACE MODELLING FORMALISM

To reach the three objectives outlined in the beginning of this chapter, the multiple domain modelling (MDM) methodology is applied and further developed. Quantitative measures of the specification flows across multiple aspects are identified and applied to quantify the overall sensitivity taking both external and internal influencing factors into account.

Sensitivity indicates the medical device program's robustness towards external changes, which can be used to analyze a company's ability to handle effects of the changing environment, i.e. customer and regulatory changes. Further, relations with applied quantitative measures across life-phases can be used to enhance decision making, on how to respond to market changes in the most profitable and efficient way taking the current situation of the company into account.

The proposed tool (Fig. 6.4), quantifying the synthesis of architectures is crucial to new medical device development, as it provides an overall holistic approach to the alignment and management of market and product dimensions whilst handling the related, and often very complex verification and validation test and documentation required when bringing new medical devices to market and maintaining market clearance for devices already marketed.

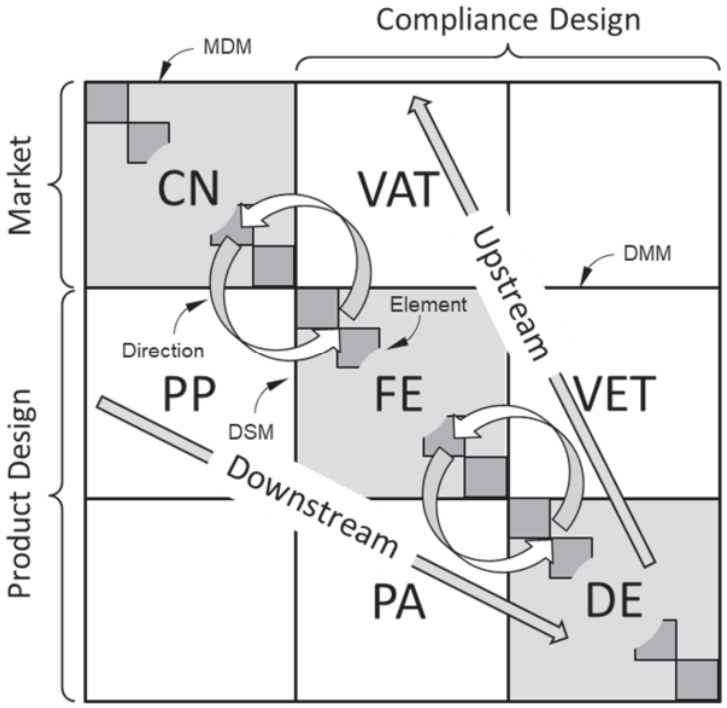


Fig. 6.4: The Compliance Architecture Concept Exploration (CACE) modelling tool

As the illustration shows, the CACE modelling tool is based on the multiple domain modelling (MDM) methodology. The tool is centered around three domains that are modeled by means of intra-domain matrices, also referred to as design structure matrices (DSM), which are represented by light-grey shaded blocks located along the diagonal with matching row and column tags (dark-grey shaded elements of the DSMs). These DSMs captures the customer domain that carries customer needs (CN) to the program, the functional domain that carries the functional elements (FE) of the program, and the physical domain that describes the realization of the program by means of design elements (DE), respectively.

Reading across the DSMs, the domain mapping matrices (DMM) are found. On the bottom left-hand side, the downstream product view is represented by means of the product portfolio (PP) view, which represent the inter-relations between customer domain and functional domain, and the product architecture (PA), which display the inter-relations between the functional and physical domain. On the upper right-hand side, two corresponding DMMs are found representing the upstream compliance view represented by means of the verification test and documentation (VET) view representing relations between the physical and functional domain and the validation test and documentation (VAT) view, which correspond to the product portfolio view and likewise represent the upstream relations between the functional and customer domain.

Accordingly, reading the CACE model, inputs and outputs between program elements are read counterclockwise. Scanning down a column reveals what other elements in that column provides to, whilst reading across a row reveals what other elements the element in that row depends on. Please note how the CACE tool builds on the modified V-model by Forsberg et al. (2005) and the extended PPPF model by Jiao et al. (2007), both introduced earlier in the chapter.

Thus, overall, three areas are considered when modelling the views of the medical device program, i.e. market, product and compliance design, which entails seven domain matrices in total enabling the modelling of the downstream and upstream view of the medical device program design.

The Downstream Product View

The market is modelled by means of two dimensions, on one hand the program design is influenced by customer needs (CN), and on the other, the regulatory requirements. Both dimensions can be modelled by a structural representation. Whilst the customer needs are related to the use phase of the product and the intended use of the desired product functionality, the layout of regulatory requirements (RR), covering geographical and application areas with device classification tiers showing the product performance, are related to the intended use leverage. These two dimensions, the customer needs and wants and the regulatory environment,

are central to modelling the medical device variety and sets off the downstream modelling of the program.

Two domains exist within the product design, the functional domain with its functional elements (FE) and the physical domain with its design elements (DE). Within the functional domain, properties are in focus and within the physical domain the characteristics of the physical elements are represented. Interactions in the functional domain and interfaces in the physical domain couple the different elements by discipline, i.e. mechanical, energy, signal/information and special arrangement.

The product portfolio (PP) describes the collection of products offered to the market by the program and is therefore modelled based on the meeting between the customer domain (market) and functional domain of the product view. The meeting is about the functional properties of the functional elements and how these relate to the customer need statements, perceptions and observations. The modelling of the portfolio describes the variety of the product program from a customer and functional point of view.

The product architecture (PA) describes the product functions and how these are allocated to physical elements and is constituted by a combination of design elements and interfaces. Within the physical domain, the characteristics of the physical elements are represented. The product architecture is modelled by means of property reasoning, a structural description of the relation between functional properties of the functional elements and their relation to the structural characteristics of the physical elements. These property models are identified providing the manufacturer with the ability to understand the nature of its product variety and its underlying architecture.

The Upstream Compliance View

Two compliance principles exist, the verification (VET) test and documentation, which answers the question: *"Have we built the product right?"* and the validation (VAT) test and documentation, which answers the question: *"Have we built the right product?"*. Depending on the customer need, the intended use and thereby the posed risk towards the human health and safety, classifies the products and thereby affect the test and documentation requirements (the upstream compliance view of the program). This influences the level of verification and validation tests required to prove compliance with regulation.

VET, which primarily are in focus in this research, are experiments of the property models outlined in the product architecture, thus these relations span across the functional and physical domain of the product design, and these relations are captured in the compliance view of the program.

Coherence Between the Views

The coherency, balancing the views of the program, supports the company to balance the different elements and their complex pattern of relations to control its ability to meet the customer needs, by a design that have the required performance level according to regulation, , and that the cross-domain knowledge is properly tested and documented and stored for the insurance of the human health and safety.

From an architecting viewpoint, the proposed tool aims at aligning market requirements with the product design and compliance design. By establishing coherence between market, product and compliance (test and documentation) views, it is possible to better manage the complexity of new medical device development. By applying the matrix-based modelling techniques, it is possible to establish a supporting tool for managing the complexities, which suggests a more holistic approach to medical device development. By applying quantitative complexity measures, the modelling tool allows for sensitivity and change effect analysis taking the critical elements into account. This enable medical manufacturers to predict change impact and thereby make decisions about where to focus its attention based on a more thorough foundation and potentially launch new medical device variants with less resources and at a reduced lead time.

6.3.2 Modelling the Customer Domain

The objective of introducing the customer domain is to describe the medical device program design from the customer's point of view while considering the regulatory influencers. The implementation of a product program strategy based on modular platform architectures for current and new product designs generally requires understanding the customer needs (performance segmentation) and the regulation (risk classification).

When implementing such strategic initiatives within the medical device domain, especially the test of requirements (verification and validation) plays a critical role in staying on market with current medical devices while it affects the success rate bringing new devices to market. Therefore, these elements are found to be key when establishing the customer domain for a medical device program.

The predominant aim of modelling the customer domain is to visualize the market stretches, i.e. deviations in customer needs and regulatory requirements by which a medical manufacturer must comply. The objective is to model the commercial variety of the medical device program while incorporating industry-specific influencers (critical external parameters) that affect the complexity of handling a medical device program. Therefore, when establishing the customer domain, the design team should take a variety of drivers into account when modelling the customer domain (Fig. 6.5).

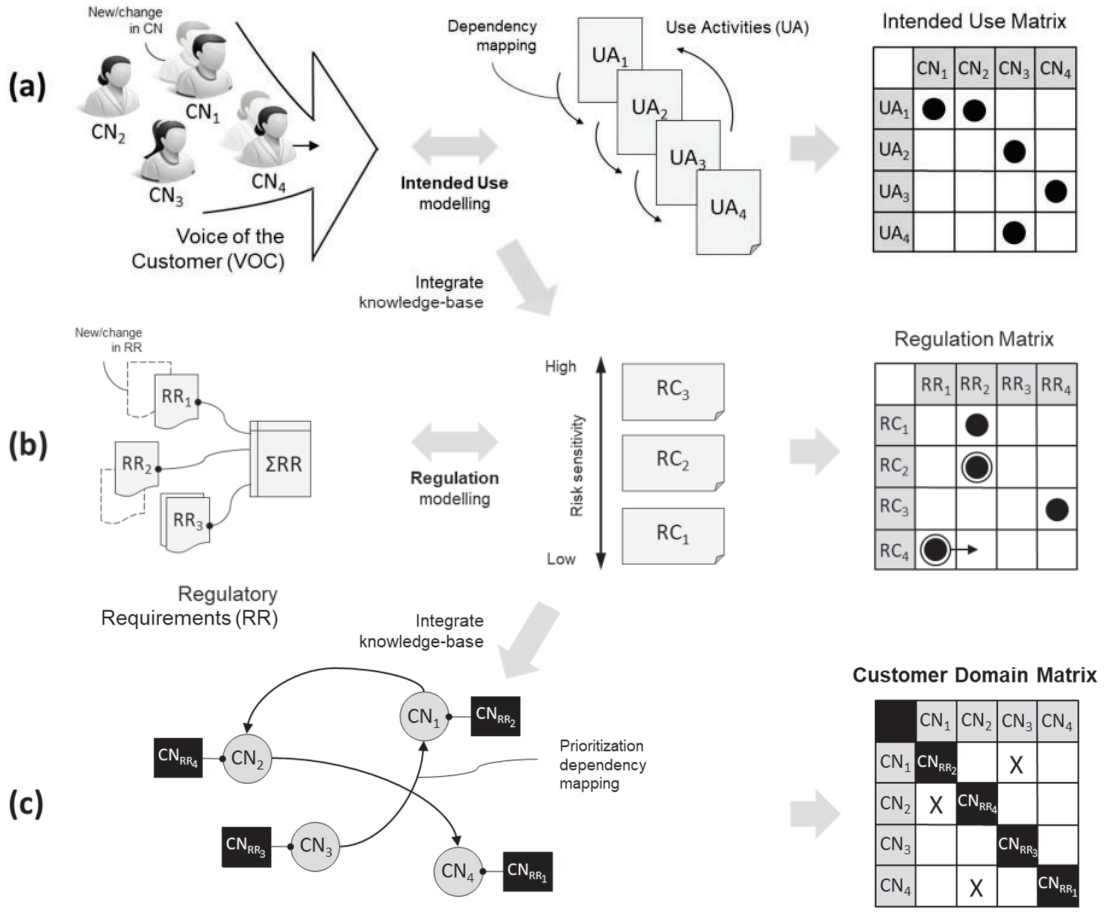


Fig. 6.5: Establishing the customer domain based on customer needs, regulatory requirements, and segmentation in accordance with intended use and its related risk.

Within the medical domain, it is crucial to know how regulatory requirements (RR) are related to the customer needs (CN). It is possible to identify which regulatory requirements are associated to which customer needs through the application of intended use (IU) and its related risk classes (RC). Intended use and regulatory requirements are linked through risk classes. Intended use is defined by mapping customer needs and use activities (UA). By finding the intended uses of the variety of the products under investigation and finding the relevant risk classes for those intended uses, it is possible to determine the regulatory requirements associated with each customer need.

Thus, in order to establish the customer domain, the following modelling exercises should be carried out to gain sufficient knowledge about the external parameters influencing the complexity of the program from a market point of view. Following the above illustration (Fig. 6.5), the subsequent modelling formalisms are applied for the customer domain:

Voice of the customer gathering and user activity modelling – The gathering of voice of the customer (VOC), which entail collective insights into customer needs, desires, perceptions, and preferences creates the starting point of establishing the first knowledge base of forming the customer domain (Fig. 6.5, a). The VOC process is a systematic and effective way listening to the stakeholders and assemble information that allows the design team to explore the solution space. Meanwhile, it is an important way to stay vigilant towards changes in the need's situation, which is a fundamental requirement stated by the public authorities, i.e. EC and FDA. Thus, such systematics can help prove compliance with given regulatory requirements directed towards new product development and maintenance of existing product programs.

When the customer needs have been gathered, the use situations should be analyzed through field studies, where the use activities (UA) are investigated. These activities are mapped against each other, as the order of one activity often is related to another, meaning that a customer is to perform one activity before another (sequential mapping), as this affects the risk of misuse (Fig. 6.6).

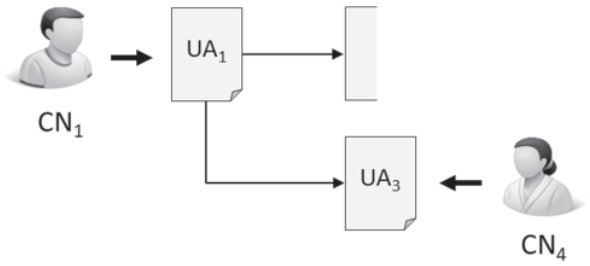


Fig. 6.6: Sequential mapping of use activities and analysis of how the different customer needs influence these activities. Gives rise to understand the change effect on the current situation.

Further, the activities are crucial to include in a combined data set as they give rise to the intended use of the medical device. Thus, the mapping of customer needs (CN) against the use activities (UA), is analyzed providing the intended use (IU) of the medical device as the customer needs and use activities founds the intended use of the medical device variants within the program (Fig. 6.7).

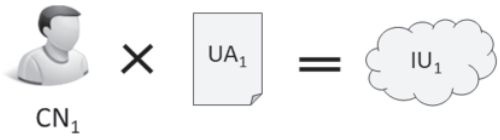


Fig. 6.7: Inter-relation between customer needs and use activities reveals the intended use of the medical device application.

Thus, when establishing the first knowledge base of the customer domain, the development team should:

- Gather customer needs (CN) through the voice of the customer (VOC) process
- Study the use activities (UA) related to the customer needs (CN) statements
- Sequential mapping of intra-relations between the use activities (UA)
- Establish intended use (IU) based on customer needs (CN) and use activities (UA)

Establishing the first knowledge base of the customer domain solely focus on getting insight into the customer preferences, the activities carried out, and the relations among these given the intended use of the medical devices. These modelling exercises are key to understand the market from a customer point of view. Next, this knowledge is integrated into a study of the regulatory influencers giving rise to understanding the regulatory environment.

Regulatory requirements and risk classification modelling – In this stage, the regulatory requirements (RR) by which the company must comply – conforming with rules, such as a specification, policy, standard or law to stay at market or bring new devices to the marketplace – is gathered and analyzed (Fig 6.5, b). These requirements are depending on the risk classification by which a medical device is related, and the medical devices are assigned to one of the risk classes (RC), which states the level of control necessary to assure the safety and effectiveness of the device. E.g. the RC of rubber gloves are lower than that of a pacemaker. If the pacemaker stops working the patient dies, which most certainly is not the case with rubber gloves. The mapping of RR and RC gives rise to understanding regulatory requirements are related to the classification by which the medical device is assigned (Fig. 6.8). This leads to a clarification of which RR the medical device is subject to through its assignment to the RC.

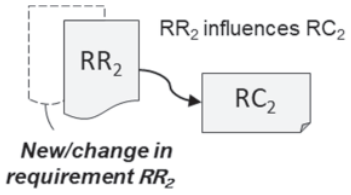


Fig. 6.8: Regulatory requirements to risk classification coupling. Changes in regulation affect the classification domain which then influences medical manufacturers' marketing products within that specific regulated class of products.

When establishing the second knowledge base of the customer domain, a market segmentation grid can be carried out based on RC as tiers and horizontal structure as business areas in the form of the intended use of the medical device variety provided by the program design. While this mapping helps focusing the product architecture towards the most appropriate and

favorable segments, it also helps identifying how well the medical device is performing by performance indicators (PI) in relation to the RC and its associated RR. Thus, the applications of the product are basically a segmentation of the market based on common intended use situations (Fig. 6.9).

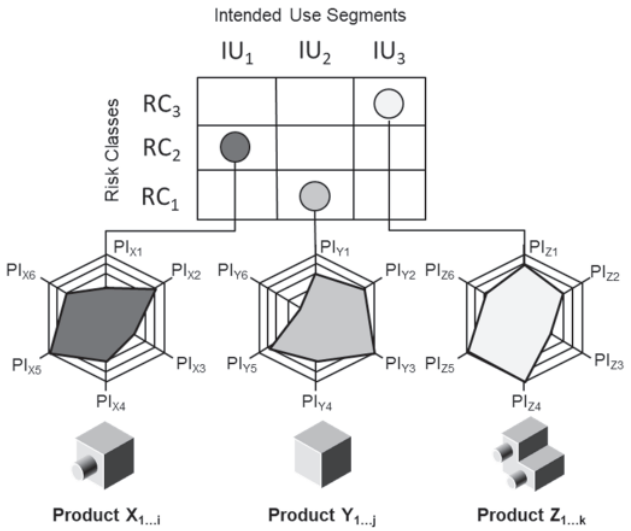


Fig. 6.9: Market segmentation grid: Evaluation of product property performance against market situation. Intended use segmentation against risk classification tiers.

The visualization of the requirements from each application (e.g. by radar diagrams) can serve to prioritize which applications to target the medical device program towards, where to improve the performance of the product variants against competitors and risk classes taking into account the fluctuations of the regulatory requirements while serving as a valuable input for medical device diversity and differentiation. The applications can be similar within intended use segments and across risk classification tiers. The radar diagrams show the total performance using performance indicators, e.g. procedural performance, of the product by mapping the properties capable of positioning the product against competitors e.g. by differentiation. As an example, PIs for a set of gloves could be abrasion resistance, puncture resistance, impact protection, etc. and will drive the product's competitiveness against others within that RC and IU segment.

Depending on the scope of the customer domain modelling, the market segmentation grid can be used as valuable input to the modelling of the composite nature of the external requirements influencing the medical device program. Nevertheless, it is important that the design team establishes a rigid understanding of the changes in markets, both from a customer and regulatory point of view. Now, when the regulatory aspects and the customer needs have been

mapped, it is time to integrate these influencers by means of the intended use by which the devices under inspections are related (Fig. 6.10).

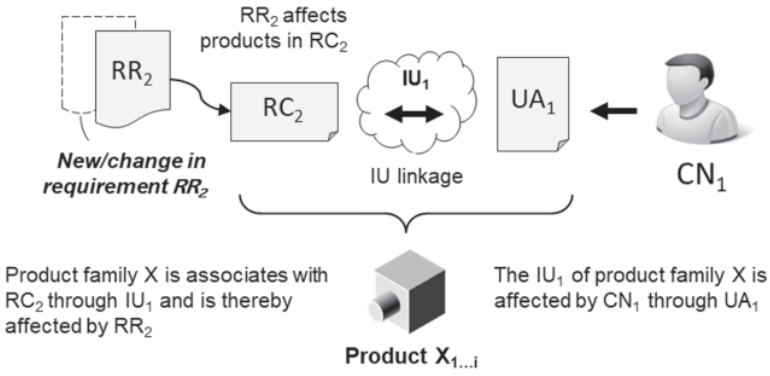


Fig. 6.10: The medical two-sided market and how it influences medical device development. On one side the changes in CN and on the other the changes in RR, and how this influences the IU by which the product design takes part.

From one side, the regulatory requirements affect the risk classes by which the medical devices are associated. On the other hand, the customer needs are affecting the use activities of those devices given the intended use. Meanwhile, the intended use, which result in a risk classification is subject to quality assessment, which can be applied using risk priority numbers (RPN) that identify risk sensitive use activities based on the probability (P), detection (D), and severity (S), towards the human health and safety. When establishing the second knowledge base, the regulatory domain is explored using inputs from establishing the first knowledge base handling the customer needs. This analysis gives rise to understanding the complexity of the market within which the medical manufacturer and the design team is operating.

Thereby, when establishing the second knowledge base of the customer domain, the design team should:

- Gather and analyze the regulatory requirements (RR) stated by public authorities
- Study the inter-relations between regulatory requirements (RR) and risk classes (RC)
- Establish market segmentation grid based on intended use (IU) and risk classes (RC)
- Understand and map the multitudes of requirements affecting the product program

As seen in the description, establishing the second knowledge base of the customer domain merely the focus has been on getting insight into the regulatory requirements, how the different devices are classified, and the relations between customer needs and risk classes. Use activities are to be explored during the sequential activity mapping and critical activity paths are to be

identified in accordance with the medical device risk classification scheme. Next, this knowledge creates the foundation for modelling the customer domain matrix.

Customer domain matrix modelling – Based on the obtained knowledge, it is possible to establish the customer domain matrix (Fig. 6.5, c). Customer preferences is complex by nature. Whilst this is the case, it is recommended that the design team investigate the sales potential of meeting these needs and the risk associated with designing new or updating existing variants to accommodate new market potentials. Based on this analysis, the design team should together with marketing and sales representatives prioritize the customer preferences. This prioritization provides input to the customer domain matrix (Fig. 6.11). Hence, the relations among customer needs illustrate the priority by which the design team is to meet those needs.

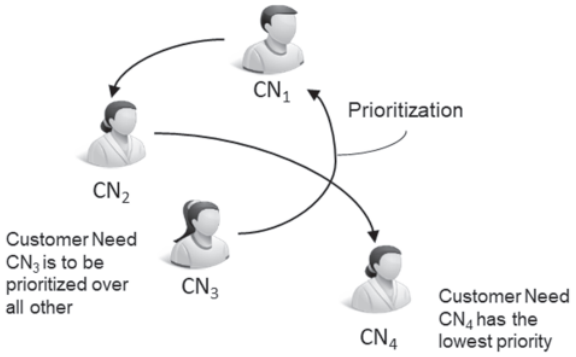


Fig. 6.11: Prioritization of design effort meeting the customer needs. Analysis based on market potential against the design effort required to meet these needs bringing the design to market.

This prioritization is based on the analysis of use activities, the intended use of the realization meeting the needs and the risk by which the design is classified. Hereby, the design team is provided with a thorough understanding of the situation and can prioritize the design effort put into bringing the solutions to market when considering the economic gain meeting these customer needs (the market potential).

Whilst this model the current state of the product program, it further enables the product design team to visualize and thereby get a transparent overview of how changes in customer needs influence the commercial variety of the medical device program through underlying analytical exercises. As the medical device market is two-faced, the customer domain matrix further entails the regulatory requirements (RR) and its influences on customer needs in the sense that it determines the risk criticality of the need statements with its related use activities. Whilst modelling the regulatory influencers to the commercial variety of the medical device program, regulatory requirements and risk classification (RC) changes over time due to tightening of legislations. Thus, both the customer needs and the related risk criticality are subject to change,

which should be accounted for in the synthesis of the medical device program. When establishing the customer domain matrix, based on the obtained knowledge, creating a thorough decision basis, the design team should:

- Map customer needs (CN) and their relations based on prioritization analysis
- Label customer needs (CN) with regulatory requirements (RR) based on its risks
- Establish customer domain matrix with intra-relations based on prioritization

As revealed in the description of establishing the customer domain matrix, it is a multifaceted task requiring a variety of inputs – on one side, it enables analysis and synthesis regarding customer needs (fluctuation of customer requirements), and on the other, it visualizes the deviations of regulatory requirements and thus embrace both side of marketing medical devices. It enables analysis for rationalization of the medical device program while it provides inputs to synthesis of the medical device program. The customer domain matrix will be used as input to the CACE modelling tool, but first the functional domain is to be established.

6.3.3 Modelling the Functional Domain

The aim of introducing the functional domain is to describe the purposeful behavior of the medical device system, to describe its ability to perform a set of actions (or activities) as analyzed in the customer domain and to reveal the functional variety of the medical device program. Generally, the functional domain corresponds to the viewpoint of the customers and should offer mutual functional variety to discriminate between the corresponding customer needs. Offerings are specified by introducing function variants meeting those needs specified by the customers.

The modeling of product architectures should encompass both the constitutive structural elements of the architecture and the behavioral functional abilities. The scope of the functional domain is to describe the latter, hence what the medical device program with its underlying architecture can or should be able to do and thereby characterize the “meeting” with the market (i.e. the customer domain).

The predominant objective of modelling the functional domain is to visualize the functional and thereby behavioral aspects of the architecture for the medical device program. This is because functional models are a valuable abstraction to synthesize the program, while it provides valuable insight into the functional variety of the program. Whilst the functional domain defines the required function or behavior of the medical device program to be developed or maintained, it captures the inherent flow of functional requirements and therefore, when establishing the functional domain, the following aspects are to be considered (Fig. 6.12).

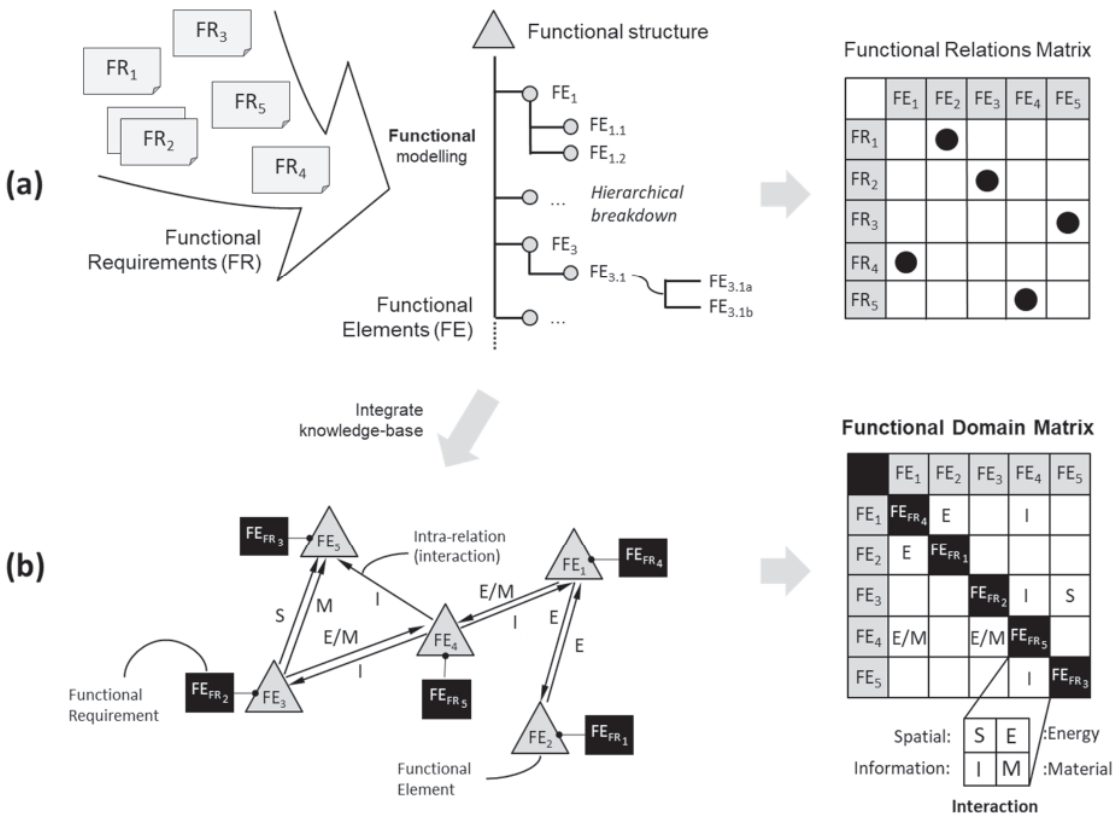


Fig.6.12: Establishing the functional domain based on functional requirements capture, breakdown of functional elements and their inter-relations.

Functional requirements and functional elements modeling – Functional requirements are to completely characterize the functional needs of the medical device program. The effect required by a design variant to achieve its process, action or activity, can be considered the functional requirement to that specific design variant. Thus, functional requirements are defined as the minimum set of independent requirements that the medical device program must satisfy from a commercial perspective (i.e. the customer domain) and constitutes the first step in establishing the functional domain (Fig. 6.12, a).

When the functional requirements are captured, specifying what the device can or should do (analytical or synthesis perspective, respectively), the functional elements are to be clarified. Whereas the functional requirements are associated with specifying the desired behavior of the device, the functional elements relate to the functional structure of the device. Thus, when establishing the first knowledge-base of the functional domain, the initial requirements provide valuable inputs to the functional elements of the product program. (Fig. 6.13).

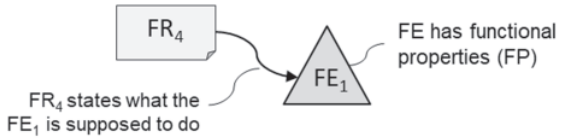


Fig. 6,13: Functional requirements states what functional elements are supposed to do. Change in requirements might change the functional element of the system.

If a main product function is too complex for a direct realization, it can be decomposed into sub-functions. This results in a hierarchical function structure, which represents the functional elements of the product on different abstraction levels (Fig. 6.14).

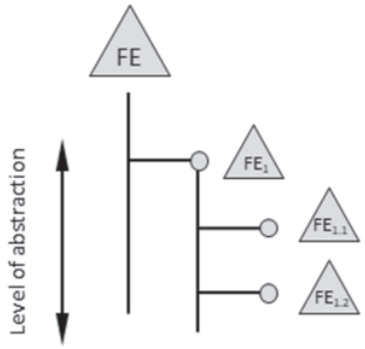


Fig. 6,14: Functional breakdown structure. Functional elements on same level of abstraction and level should be considered based on size of system being analyzed

During the establishment of the first knowledgebase, it is important to distinguish between solution neutral functions and the solution concepts that realize them. A functional element describes the transformation of input to output flows inside the product, while the functional requirement represents the effect that the product provides to its external environment.

In general, functions are described by combining verbs and nouns. Such combinations also determine whether the function is primitive and thereby can be mapped to a known solution principle or still abstract and needs to be decomposed into lower-level functions (cf. the function structure). Thus, when establishing the first knowledge base of the functional domain, the development team should:

- Capture functional requirements (FR) through analysis of systems effects and behavior
- Clarify functional elements (FE) and their level of abstraction through structuring
- Map the functional requirements (FR) to functional elements (FE) based on the "meeting" between the desired behavior and actual elements that realize them

Thus, this first stage focuses on capturing the functional requirements, clarifying the functional elements, and structuring these in accordance with the suitable level of abstraction, which provide the necessary understanding of functional requirements and its elements. Next, this gained knowledge is used for creating the functional domain matrix.

Functional domain matrix modelling – Based on the obtained knowledge from first phase of this modelling stage, it is possible to establish the functional domain matrix (Fig. 6.12, b). First, the functional requirements, the functional elements and their intra-relations is to be identified and classified. The functional requirements should provide a complete and unambiguous description of the program and is expressed in such a way that functional intra-relations (dependencies in the form of interactions) between elements that are relevant for product design are clearly indicated (Fig. 6.15).

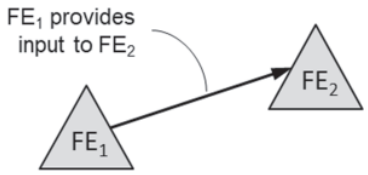


Fig. 6.15: Abstract representation of the interacting functional elements. Functional element FE_1 provides input to functional element FE_2

These dependencies (also referred to as intra-relations) concern definitions that cope with interactions between functional elements (Fig. 6.16). The interactions are represented as nonhierarchical relations, i.e. flows of material (M), energy (E), information (I), and spatial (S) interactions and are subject to requirements (Pimmler and Eppinger 1994). These requirements define how the system is required to interact with external systems or how the system elements should interact within the system. Thus, the design team should allocate the requirements appropriately to the interactions between functional elements.

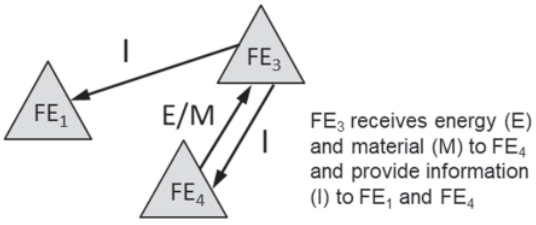


Fig. 6.16: Specification flow: Identified interactions between functional elements using energy (E), information (I), material (M) and spatial (S) flow definitions

When the interactions are established, the matrix, which is to be plugged in to the CACE modelling tool, then mutually represent how functional elements (FE) are intra-related based on their interactions and how these are constrained by functional requirements (FR). The model provides the design team with a structured way of mapping and visualizing functional variety of the medical device program. So, when establishing the functional domain matrix, based on the obtained knowledge, creating a thorough decision basis, the design team should:

- Map the functional elements (FE), their interactions (M, E, I, S) and related interaction requirements
- Label the functional elements (FE) with their individual functional requirements (FR) based on requirements analysis
- Establish functional domain matrix showing the functional elements (FE), their intra-relations and related functional requirements (FR)

As the description of establishing the functional domain reveals, this task is about responding to the needs of the customer domain and structuring this information in a way that makes it possible for the design team to comprehend the functional layout of the program. On one side, the development team should cope with the changes in customer needs, on the other, the team should consider the regulatory environment within which it operates. The functional requirements help the analysis for rationalization of the medical device program while it provides inputs to synthesis of the program from a functional point of view.

6.3.4 Modelling the Physical Domain

The purpose of introducing the physical domain is to describe physical implementation of the product program. The physical domain eventually describes the same program as the functional domain, but from a different viewpoint, namely it centers around how the products are materialized. Generally, the physical domain should offer mutual design variety to meet the functional manifestation of the program. Hence, the physical domain is the construction of the products and describe the products from an embodiment perspective. As mentioned earlier, the modelling of product architectures should encompass both the constitutive structural elements of the architecture and the behavioral functional abilities. In the functional domain, the behavioral functional abilities were modeled. In the physical domain, the constitutive structural elements are being modeled.

The aim of modelling the physical domain is to describe how the functional elements, the behavior of the products, are realized through design elements. The predominant objective of modelling the physical domain is to visualize the physical and thereby constructive aspects of the architecture for the medical device program. While, the physical domain defines the required

materialization of the medical device program to be developed or maintained, it captures the inherent flow of design parameters, the structural composition of the construction, including its relations (interfaces). Therefore, when establishing the physical domain, the following aspects are to be considered (Fig. 6.17).

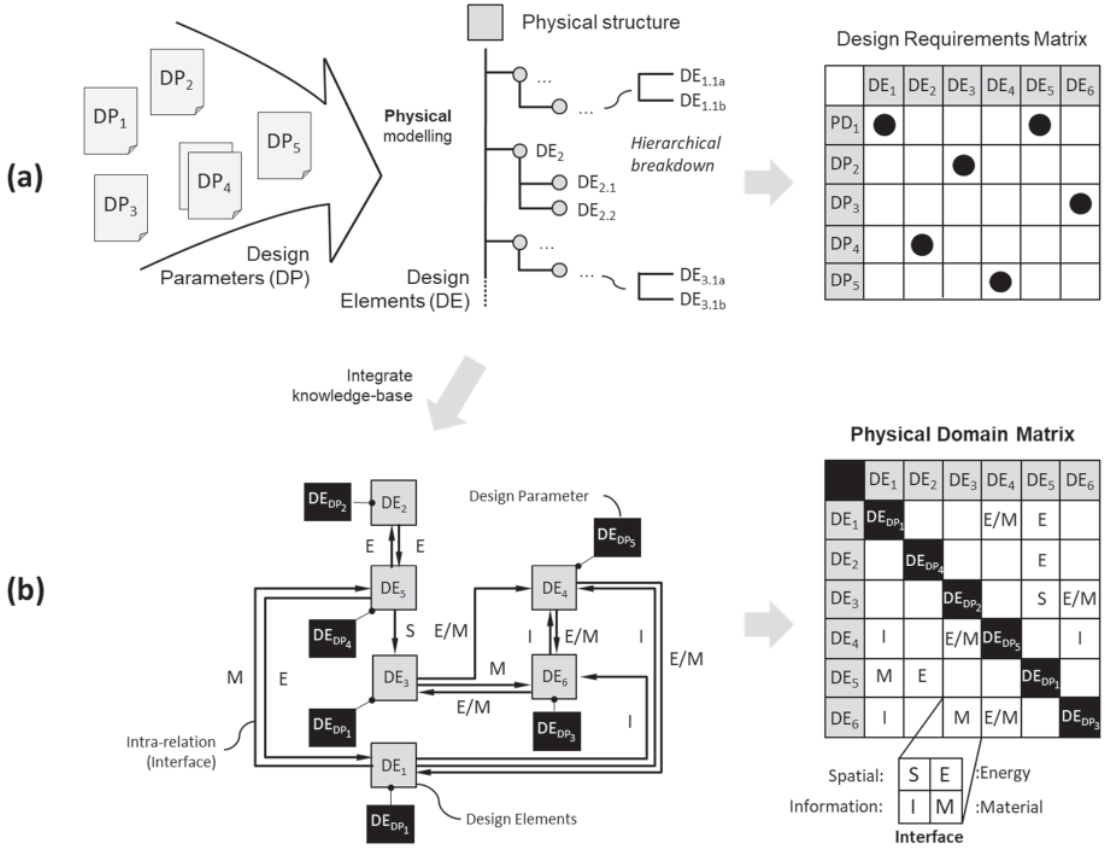


Fig. 6.17: Establishing the physical domain based on design parameter capture, breakdown of design elements and identification of their interfaces.

Design parameter and design elements modelling – Design parameters (DP), also referred to as non-functional requirements, specify requirements under which the system is required to operate. They define how the program is supposed to work, opposed to what it should do, which is stated by the functional requirements (treated above). Non-functional requirements typically include quality requirements and human factor requirements, which often centres around safety, performance, effectiveness, efficiency, reliability, maintainability, healthy, etc. These are closely related to the regulatory requirements stated by the public authorities. Thus, the regulatory requirements are translated into measurable design parameters by the design team, so that the medical devices, i.e. the program, under development can be measured against parameters that, if reached, prove compliance. This aspect of the development is also referred

to as the acceptance criteria for a certain design element (DE). Thus, design parameters are defined as a set of non-functional requirements that the medical device program must satisfy from a design perspective and constitutes the first step in establishing the physical domain (Fig. 6.17, a). When the design parameters, have been identified, specifying how the system should work, the design elements are to be clarified. Whereas the non-functional requirements are associated with specifying the desired quality of the system, the design elements relate to the physical structure of the system. Thus, when establishing the first knowledgebase of the physical domain, the initial design parameters provide valuable inputs to the design elements of the product program. (Fig. 6.18).

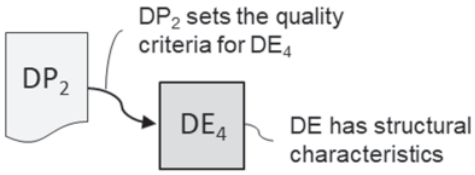


Fig. 6.18: Design parameters set the quality requirements of the design elements and determine the acceptance criteria of the design elements.

Design elements, which here is a central concept to the modelling of the physical domain, is characterized by its structural characteristics (SC), e.g. form. material, dimensions, surface quality and state. As an example, material determine properties like elasticity, strength, conductivity, etc. whereas surface quality determine wear, smoothness and reflection. These structural characteristics determine the functional properties of the functional elements, which is central to the modelling of the product architecture. As with functions, design elements can be decomposed into sub-elements or sub-assemblies. This results in a hierarchical physical structure, which represents the design elements of the product on different abstraction levels (Fig. 6.19).

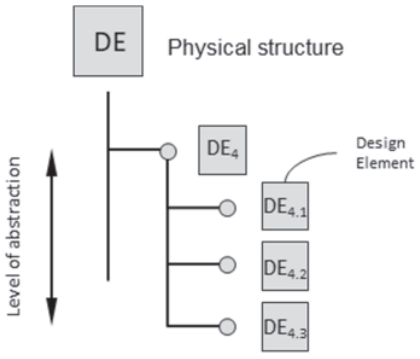


Fig. 6.19: Physical breakdown structure with levels of abstraction: Inputs to matrix should be on the same level of abstraction and level chosen should fit the size of the system being analyzed

The design team should decide on an equal level of abstraction to cope with the integration later in the process of establishing the physical domain. The level by which the system, or product, is integrated is determined by the program that is to be analysed or synthesized. When establishing the first knowledge base of the physical domain, the design team should:

- Identify design parameters (DP) through analysis of how the system should work
- Clarify design elements (DE) and decide on the abstraction level by decomposition
- Map the design parameters (DP) to design elements (DE) based on how the system should work and the elements that materialize them

Thus, this first stage focuses on identifying design parameters, clarifying the design elements that realize the functions, and structuring the design elements in accordance with the suitable level of abstraction. Next, this gained knowledge is used for creating the physical domain matrix.

Physical domain matrix modelling – Based on the analysis in the first phase of modelling the materialization of the product program, it is possible to establish the physical domain matrix (Fig. 6.17, b). Now, the design should be analysed for structuring given the design elements and their interfaces. As the design parameters sets the quality criteria for the elements, the next is to identify the structural composition of the physical domain. Namely the design elements and their interfaces are in focus. Thus, dependencies between elements that are relevant for the product design to works should be clearly indicated (Fig. 6.20).

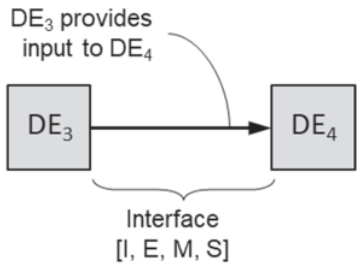


Fig. 6.20: Abstract representation of an interface between design elements. Design element DE_3 provides input to design element DE_4

Interfaces between design elements can be defined as something that describes what is, the features of the structuring, opposed to interactions in the functional domain, where these describe something that happens. The interfaces are represented as flows between elements, i.e. flows of material (M), energy (E), information (I), and spatial (S) interfaces (Fig. 6.21). These are often subject to requirements that define in what way the system is required to interact with external systems or in what way system elements should interact within the system. Thus, the requirements should be allocated appropriately to the interfaces between design elements.

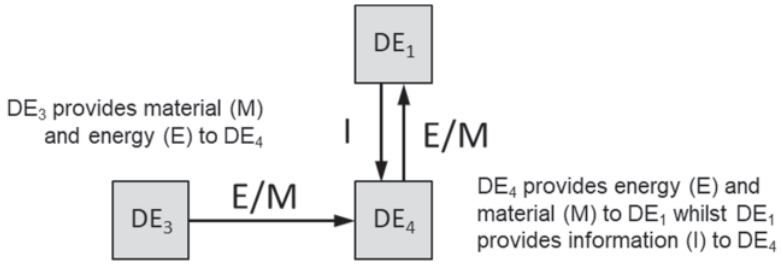


Fig. 6.21: Specification flow: Identified interfaces between design elements using energy (E), information (I), material (M) and spatial (S) flow definitions, based on Pimmler and Eppinger (1994)

When the interfaces are established, the matrix, which is to be plugged in to the CACE modelling tool, then mutually represent in what way design elements (DE) are intra-related based on their interfaces given the structure of the its elements. The model provides the design team with a structured way of mapping and visualizing design variety of the medical device program from a physical point of view. Thus, when establishing the physical domain matrix, based on the obtained knowledge, the development team should:

- Map the design elements (DE), their interfaces (M, E, I, S) and interface requirements
- Label the design elements (DE) with their individual design parameters (DP)
- Establish physical domain matrix showing the design elements (DE), their interfaces and related design parameters (DP)

The task establishing the physical domain is about "fitting" the functional domain and structuring this information in a way that makes it possible for the design team to materialize the functions of the medical device program. The design parameters, describing the quality criteria of the design elements, the structure of the design elements given by the interfaces and the interface requirements stating how the elements should interact with others creates the basis for the physical domain, and help the design team analyze the program with regards to rationalization while it provides the basis for future synthesis of the program. The physical domain matrix will be used as input to the CACE modelling tool.

6.3.5 Downstream Modelling: The Product Portfolio

The aim of introducing the product portfolio design matrix is to describe the medical device program from a product variety point of view. A product portfolio can be defined as the collection of assets (products, services or a combination of such) that the medical manufacturer offer to the marketplace. The product portfolio describes the product variety from a functionality aspect; hence, the meeting of functions of the product program and the customer needs of the market. Thus, the modelling of the product portfolio requires insight into both the

customer domain and functional domain, as the portfolio domain spans across these in the upper-level downstream product view of the CACE modelling tool. Therefore, market requirements laid out in the customer domain and the functional elements of functional domain is key to modelling the product portfolio domain. It is about taking the customer needs and separating these into functions and taking the use activities analyzed in the customer domain and apply these to shape the match between the functions and customer needs. Meanwhile, the design team should bear in mind the regulatory environment to which these fittings "matches", which constrain the functional variants, as this sets the requirements for the upstream validation testing and documentation. Therefore, when establishing the product portfolio design domain, the design team should take the following aspects into account (Fig. 6.22).

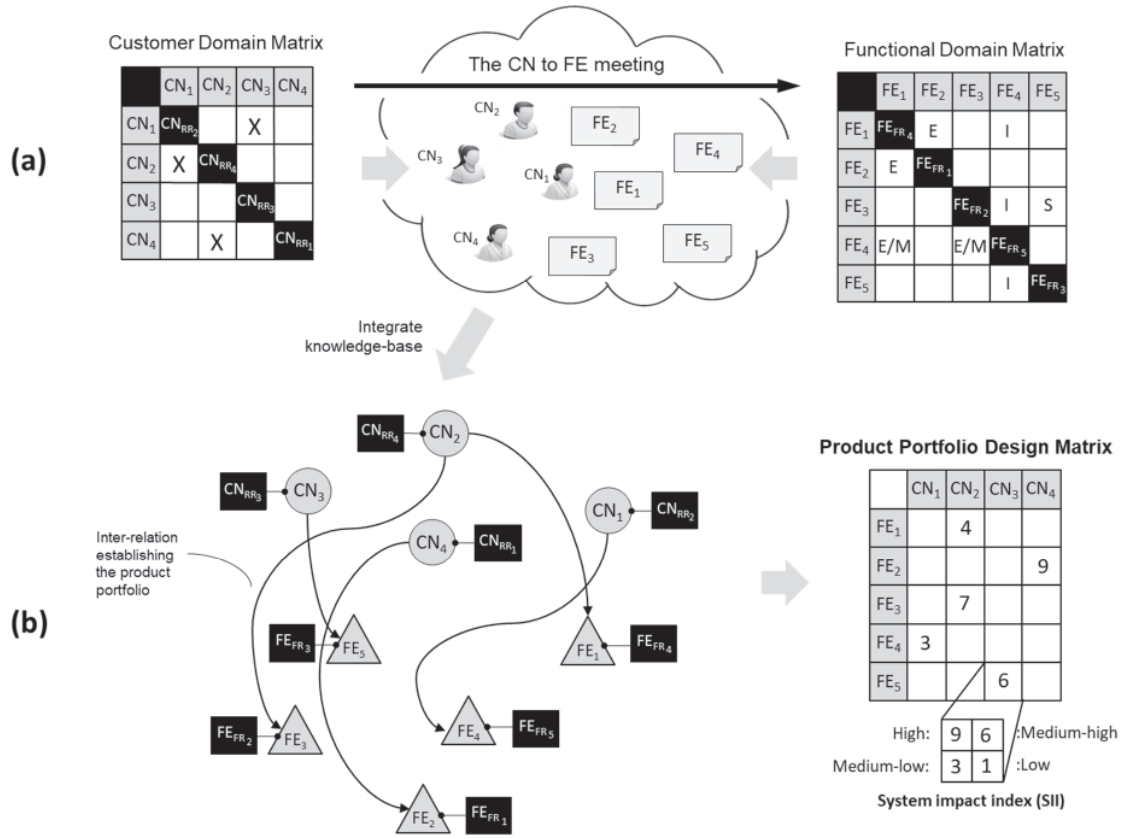


Fig. 6.22: Establishing the product portfolio design based on customer need to functional element meetings

When modelling the product portfolio using the CACE modelling tool, the following sequential actions should be taken to gain sufficient knowledge about the product variety based on the functional meeting with the market requirements:

Modelling the relations between functional and design elements – When the design team is to establish the product portfolio view (Fig. 6.22, a), the awareness of the customer and functional domain is key. Whilst, the information obtained during the VOC process establishes the one end of the meeting, the functional elements establish the other.

Modelling the product portfolio, the customer statements are to be met by the medical manufacturer. Such needs and the context within which they are to be fulfilled, namely the use situation, is key as it founds the intended use, which is then used building the market segmentation grid. When modelling the downstream product view, such correlations are important in order to gain full value of the CACE modelling tool.

Fundamentally, the functional elements are to satisfy the customer needs. These functional elements have functional properties, which then are to meet the customer need. Meanwhile, the functional element has functional requirements attached to it, which is based on the regulatory requirements framework. Thus, the design team should acknowledge these relations in order to make a thorough mapping between the two domains, i.e. the customer and functional domain. Thus, these relations are to be investigated in the first downstream product view, the product portfolio view (Fig. 6.23).

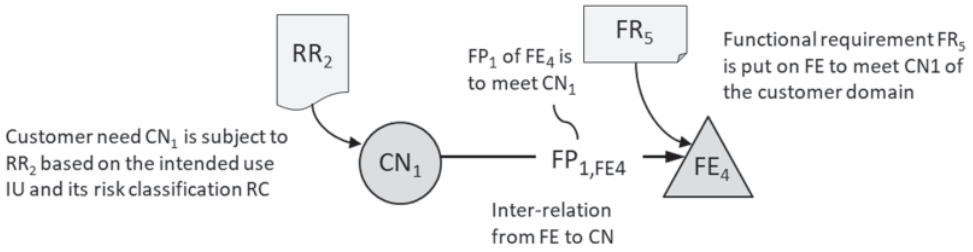


Fig. 6.23: The meeting between customer need and functional element, which founds the basis for the product variety, the product portfolio

As the illustration shows, the functional properties of interest for the customer is the one perceived using the product, hence the use activity laid out in the customer domain. Therefore, when customer needs and wants are gathered through the VOC process, "property statements" cover not only the behavior of the product but also how it should work in the use phase – what is being mapped in the validation test domain, modelling the upstream test view on the opposite side of the product portfolio domain in the CACE model.

A customer's perception of goodness, related to successfully performing an activity, can be described in terms of virtues like quality, flexibility, risk, time, efficiency, etc., as described by Olsen (1992). Based on this analysis, the design team should map the meetings between given

functions and how these meet the stated needs and wants of the customers. Thus, when establishing the first knowledge base of the product portfolio domain, the design team should:

- Investigate the customer needs (CN) to functional element (FE) inter-relations, the intended use and thereby the risk class/regulations that might affect the design
- Map the customer needs (CN) to functional elements (FE) based on the "match" between the perceived goodness by the user and the functions that deliver them

Thus, this first stage focuses on analyzing the customer needs from a product functions point of view and map out the meeting between these two domains. Next, this gained knowledge is used for creating the product portfolio matrix.

Modelling the product architecture matrix – In order to fill out the product portfolio matrix, the design team is supposed to analyze the meeting between functions of the products and market requirements (6.22, b). These relations should be quantitatively evaluated based on a predefined rating system (Tab. 6.1).

Rating	Description
9	Eliminates the customer satisfaction.
6	Causes major changes to the customer satisfaction and other parts *will* be affected.
3	Causes minor changes to the customer satisfaction and other parts *may* be affected
1	Causes minor changes to the customer satisfaction. No other parts to be affected.
0	No impact on customer satisfaction.

Tab. 6.1: System Impact Index (SII): Rating system for assessing the sensitivity and magnitude of impact changing a functional element (based on functional property) to the customer satisfaction

Using the above rating scheme, the design team can evaluate the product portfolio, the relations between market and functions, based on the sensitivity and magnitude of impact. This means, that a given function, if rated high and is to change, it greatly will affect the customer satisfaction of that element, or even eliminate the satisfaction, also referred to as the customer perceived goodness of the function, the functional property. By applying the rating system, the design team can evaluate the inter-relations between the customer and functional domain revealing the product portfolio design (Tab. 6.2).

		Customer needs (CN)	
Functional elements (FE)		CN_1	CN_3
FE_4	$FP_{1,FE4}$	Acceleration (3)	
FE_5	$FP_{1,FP5}$		Fluid range (6)
SII		**3**	**6**

Tab. 6.2: Evaluating the portfolio inter-relations by applying the system impact index (SII)

These evaluations and summations are to be plugged into the CACE modelling tool. As the illustration shows, FE_4 with its functional property $FP_{1,FE4}$ (acceleration) is meeting the customer need CN_1 and is given a rating of 3 as changes to the functional element will cause minor changes to the customer satisfaction, whereas FE_5 is related to CN_3 through $FP_{1,FE5}$ (fluid range), which is given a measure of 6, which means that changes to this functional element will cause major changes to the customer satisfaction. Mapping the complete structural dependency between the two domains using the rating system and schematic representation of the relations will reveal the product portfolio view of the program (Fig. 6.24).

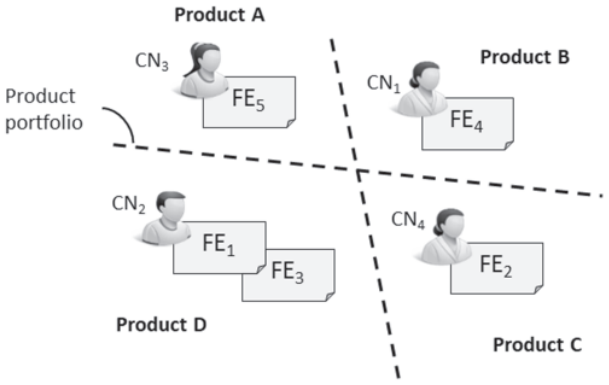


Fig. 6.24: The product portfolio view, which is constituted by the customer need to functional element meeting – the constituted variety offered to the marketplace

This exercise requires thorough analysis of inter-relations between the customer and functional domain. When the inter-relations, the allocations of customer needs to functional elements have been established, the matrix is to be plugged in to the modelling tool. The matrix modelling of these relations is a systematic approach to visualize the dependencies to the external environment, the customers of the medical manufacturer. Namely, the product portfolio domain

modelling matrix shows how customer satisfaction (based on their need statements and perceived goodness of the functionality) is dependent on the different functional element, which together represent the portfolio of products. Thus, when establishing the product portfolio matrix, based on the gained knowledge, the design team should:

- Rank the customer needs (CN) to functional elements (FE) dependencies based on customer statements and perceived goodness of the functionality (given the sensitivity)
- Establish product portfolio domain matrix showing the customer need (CN) to functional elements (FE) dependencies incl. ranking using the quantitative measures

As the description of establishing the product portfolio reveals, this task is about responding to the needs of the customers by mapping the functional elements of the product program to the customer domain. It is important, when mapping these inter-relations, that the design team draw attention to the regulatory environment by which the customer domain is associated, as this helps set the requirements, namely functional and non-functional requirements to the product program. This is depended on the intended use of the product, which again is based on the use activity supporting the need statement of the customer. Thus, these associations lead the design team to a structural mapping of the needs, requirements, and realization of these through well-designed functional elements. The product portfolio matrix will be used as input to the CACE modelling tool.

6.3.6 Downstream Modelling: The Product Architecture

The aim of introducing the product architecture is to identify the arrangement of functional elements, mapping these elements to the physical units and specifying the allocation of functions to the design elements. Every product has an architecture and the combination of design elements and their interfaces founds the architecture of the product. The product architecture can be defined as the way functional elements are assigned to design elements. Hence, the mapping or couplings between the functional elements and couplings between the design elements which were analyzed during the establishment of the functional and physical domain, and these cross-domain couplings of elements. The product architecture is a concept for describing relations among design elements and connecting these to the design elements within the product. Platform architecture describes the logical relations between common and unique elements for enabling profiled targeting of products based on customer preferences. The purpose of analyzing the underlying product architecture is to merge both the constitutive structural elements investigated in the physical domain and the behavioral aspects investigated in the functional domain. The aim of modelling the architecture is to shed light on how functional elements are arranged and how these elements are allocated to physical entities, the design

elements of the product program and by platforming of this, enable profiled targeting of the product verity. In the analysis and eventually the synthesis of the product platform architecture, the design team should further incorporate the concept of modularization aiming at creating a modular platform architecture for the medical device program. Thus, the design team should consider the following aspects (Fig. 6.25).

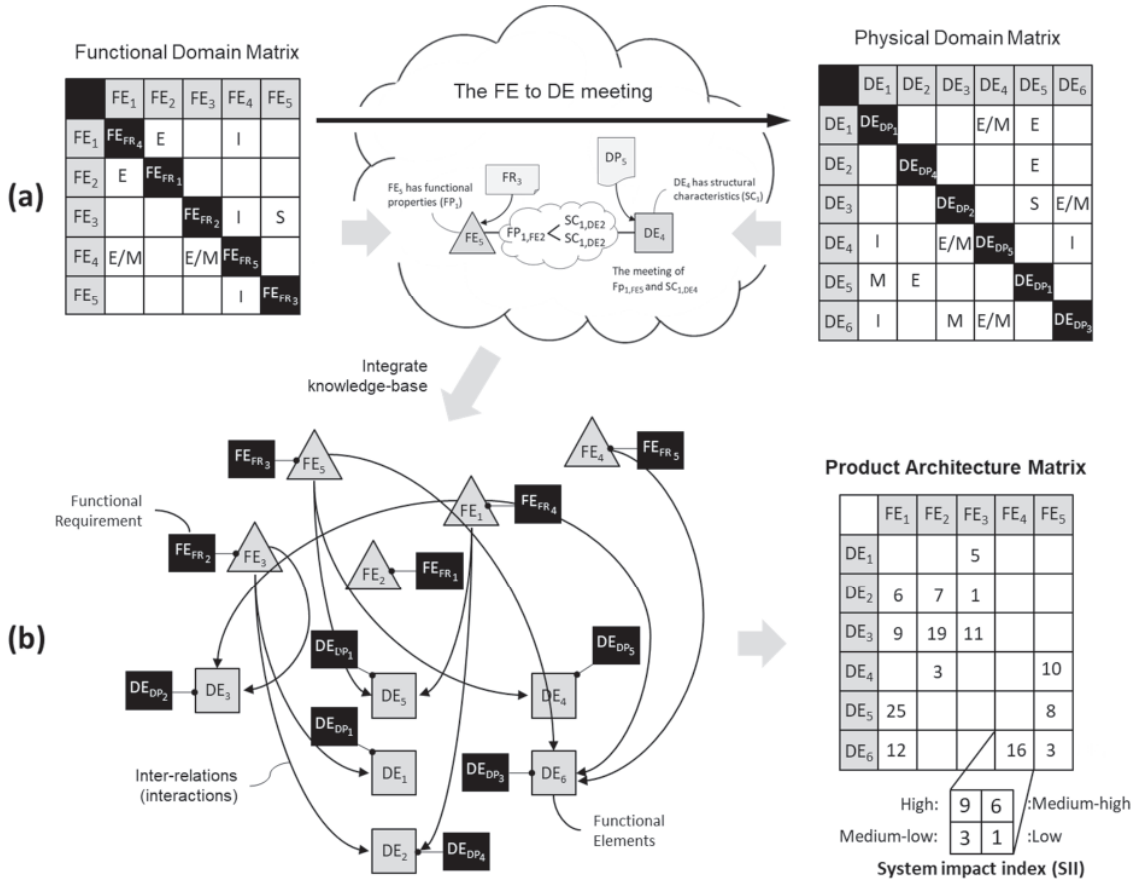


Fig. 6.25: Establishing the physical domain based on design parameter capture, breakdown of design elements and identification of their interfaces.

When modelling the product architecture, the following sequential actions should be taken to gain sufficient knowledge about the architectural composition of the product program design. The design team should have the concepts of modularity and platforming in mind when modelling the product architecture. Following illustration above, the subsequent modelling formalisms are applied for the product architecture domain:

Modelling the relations between functional and design elements – Cross-domain modelling is subject to complex thinking patterns. The modelling from functional to physical view constitute the second downstream domain modelling matrix and the first task for the design team is to

understand how behavior of the system or the program with its verity of products is embodied through elements and structures in the design. As earlier stated, functional elements are subject to functional requirements (Fig. 6.25, a). These are or should be satisfied through the functional elements of the product. Meanwhile, these relations are, in order to make the product work, related to the physical realization of the product, where these design elements and their relations is to meet the desired criteria of the non-functional requirements (parametric) set on the design elements. Thus, first these relations are to be investigated downstream the product architecture view (Fig. 6.26).

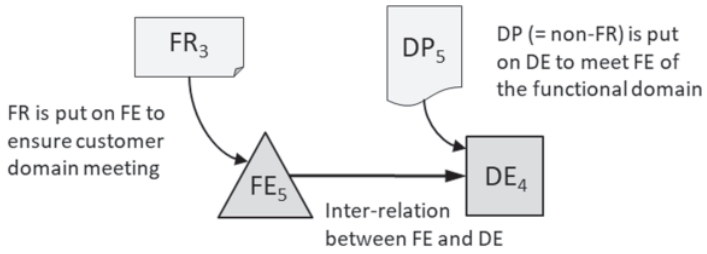


Fig. 6.26: Function to physical coupling of the product design. This establishes the first phase of investigating the product architecture layout

While investigating the cross-domain inter-relations of this downstream view, the design team should gradually build the conceptual layout of the architecture. The layout should aim at creating the functional boundaries of the products encapsulating the design elements materializing the functions of the products (Fig. 6.27)

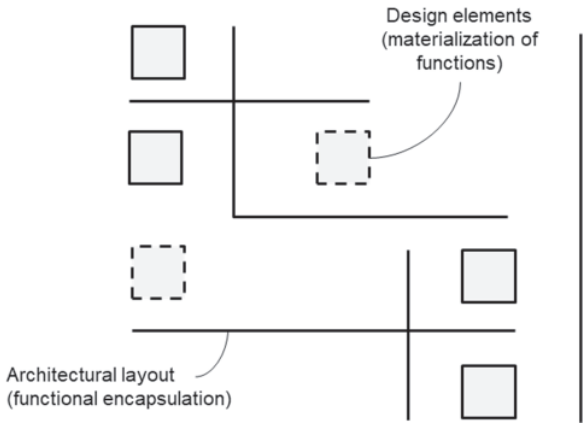


Fig. 6.27: Conceptual layout of product architecture, functional to physical domain.

In order to understand the relations between functional elements and design elements of the program, the design team should gain further insight into the underlying property models (Fig.

6.28). These models describe the engineering design phenomenon of the product architecture. Property model relates the structural characteristics (SC) of the design elements to the functional properties (FP) of the functional elements. In general, characteristics are a class of structural attributes of products and activities determined by the synthesis of the design. Properties are a behavioral class of devices' and activities' attributes, by which they show their appearance in the widest sense and create their relation to the surroundings (Andreasen et al. 2015).

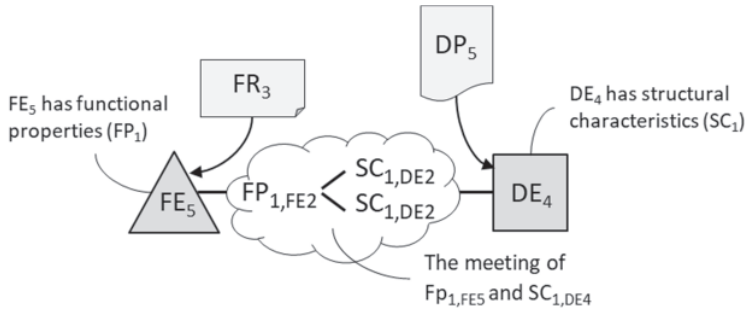


Fig. 6.28: Principle for investigating the architectural composition. How a functional element is related to a design element through functional property and structural characteristic

As the illustration shows, FE_5 relates to DE_4 through their functional properties and structural characteristics, respectively. In order to understand the goodness of the functions' realization, it is necessary to describe the relevant functional properties. In this generic walkthrough, it is found that FE_5 is related to both DE_4 and DE_6. Such constraints are important to understand in order to enter the modularization vehicle (Fig. 6.29).

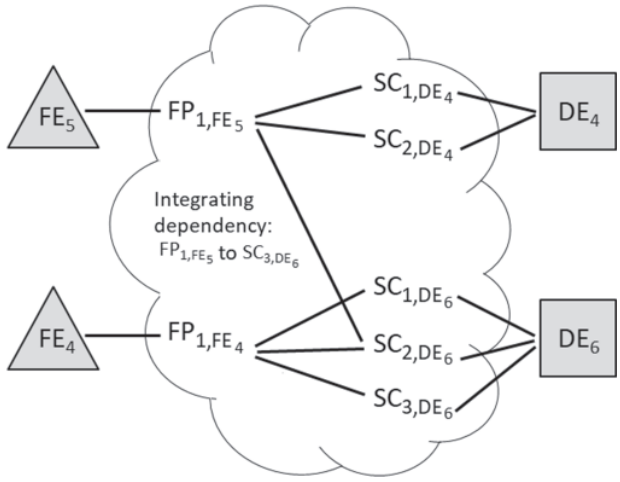


Fig. 6.29: Coupling principle between functional elements and design elements. One structural characteristic integrates the functional and physical composition of the architecture

As illustrated, FE_5 is related to both DE_4 and DE_6 through $SC_{1,DE4}$, $SC_{2,DE4}$ and $SC_{2,DE6}$. The latter constraints the modularization ability, as FE_5 and DE_6 are coupled together. These relations are important to further modularize providing a more agile architecture, if the design team can find solutions to decoupling this $FP_{1,FE5}$ to $SC_{2,DE6}$ dependency. Thus, the design team should decide on the functional elements that are to meet the customer needs, then find suitable solutions to these in the materialization of the product program, namely in the physical domain, but most importantly, the design team should investigate the inter-relations between the two domains given the underlying property models. This will enable establishment of the desired modular platform architecture. Thus, the design team should:

- Investigate functional element (FE) to design element (DE) inter-relations
- Analyze inter-relations based on the underlying property models revealing the functional properties (FP) and structural characteristics (SC) relations of the design
- Take initiative to drive the design towards a more modular design through decoupling principles of the property models

Thus, this first stage focuses on identifying functional element to design element inter-relations and analyze the underlying property models that describe these dependencies in detail (Fig. 6.25, a). Next, this gained knowledge is used for further enhancement creating the product architecture domain matrix.

Modelling the product architecture matrix – The design team should acknowledge that every cell in the product architecture domain modelling matrix is based on a thorough understanding of the underlying property models. The relations between functional properties and structural characteristics is in fact the relation between functional and physical elements (Fig. 6.25, b). In order to fill out the matrix, the design team should quantitatively evaluate the inter-relations according to a predefined rating system called the system impact index (Tab. 6.3).

Rating	Description
9	Eliminates the functional property.
6	Causes major changes to the functional property and other parts *will* be affected.
3	Causes minor changes to the functional property and other parts *may* be affected
1	Causes minor changes to the functional property. No other parts to be affected.
0	No impact on functional property.

Tab. 6.3: System Impact Index (SII): Rating system for assessing the sensitivity and magnitude of impact changing a design element (based on structural characteristics) to the system's functional properties.

In the product view (here the functional to physical elements and relations revealing the architecture), it is assumed that different design elements and their structural characteristics (SC) have different sensitivity of impact to a given functional property (FP) related to a functional element. Rating the inter-relations according to the SII rating scheme will expose those design elements that have a high impact on the functional elements when changed. These elements may be important to protect or understand in detail creating a compliant modular architecture, hence the property models (Tab. 6.4).

		Functional elements (FE)	
		FE_4	FE_5
		$FP_{1,FE4}$	$FP_{1,FP5}$
Design Elements (DE)			
DE_4	$SC_{1,DE4}$		Width (1)
	$SC_{2,DE4}$		Volume (9)
DE_6	$SC_{1,DE6}$	Surface (9)	
	$SC_{2,DE6}$	Flow rate (6)	Flow rate (3)
	$SC_{3,DE6}$	Depth (1)	
SII		**16**	**13**

Tab. 6.4: Evaluating the architectural level of modularity by applying the system impact index (SII)

These calculations are plugged into the CACE matrix revealing the integrality/modularity balance of the current product architecture. When the CACE modelling tool is used for synthesis, the relationships are continuously evaluated in an iterative process materializing the different functions by design element construction. Product functions are mapped to design elements revealing the product architecture. As the illustration shows, the functional elements and design elements constrains the design by cross-domain inter-related dependencies. The design team should evaluate constraining inter-relations and their effects for future product variety. Either the $FP_{1,FE5}$ to $SC_{2,DE6}$ is to be decoupled for easy interchangeability, or the DE_4 and DE_6 constitute a module for realization of F_4 and F_5 in the design. This decision should be based on further CACE analysis evaluating the upstream efforts (see 'Upstream Modelling: The Verification Tests'.

When all inter-relations like the FE_5, FE_4, DE_4 and DE_6 has been investigated, the complete picture of the architecture shows that more dependencies are found (Fig. 6.30). E.g. design element DE_2, DE_3 and DE_6 are found to be heavily integrated into the functional domain, which complicates the architectural modularity caused by cross-domain design-to-design integration.

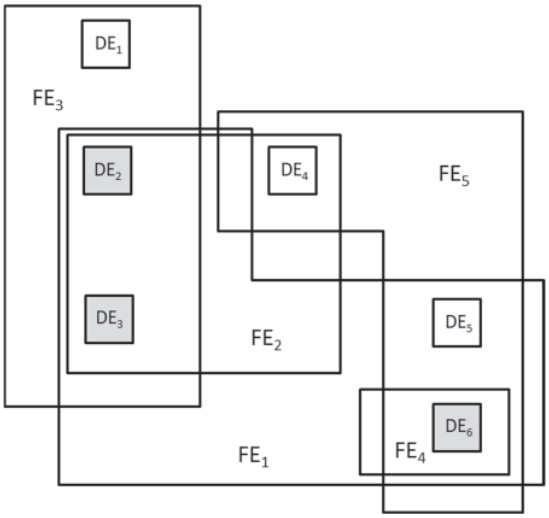


Fig. 6.30: The architectural composition of the product program revealing function-to-function, design-to-design, and function-to-design allocation.

When the inter-relations, the allocation of functions to design elements have been established, the matrix, which is to be plugged in to the CACE modelling tool, can be created. The matrix represents how the current architecture is, which give rise to changes (if possible), and enable synthesis of the product program. The model provides a systematic way to map and visualize inter-dependencies between the constitutive structural view and the behavioral aspects of the product program. Thus, when establishing the product architecture matrix (Fig. 6.25, b), based on the gained knowledge creating the decision basis, the design team should:

- Rank the functional property (FP) to structural characteristics (SC) dependencies
- Establish product architecture domain matrix showing the functional elements (FE) to design elements (DE) dependencies incl. SII ranking based on property modelling

The task establishing the product architecture domain is about structuring the information in a way that makes it possible for the design team to evaluate current and future architectural compositions of the medical device program. The property models, describing the underlying mechanisms relating the two domains, is a valuable take on the compositional development. The product architecture domain modelling matrix helps the design team analyze the product program for rationalization while it provides a rigid foundation on which the design team can

decide on modularity / platforming aspects of the architecture during the development process. The product architecture matrix will be used as input for the CACE modelling tool.

6.3.7 Upstream Modelling: The Verification Domain

When developing products, and especially medical devices, one of the major concerns is that the product does not meet the requirements. Products within the medical domain must not only satisfy customers' needs, they shall comply with any given regulation stated by the public authorities, which drives manufacturers to undertake extensive verification and validation testing. Thus, the aim of introducing the verification test and documentation domain, is to shed light on the verification testing aspect of the product design.

Verification tests can be defined as quantitative evaluations of a product to assure that the physical design of the products meet the function. Verification test literally evaluates the performance of the product. It evaluates whether a product or system complies with regulations, requirements, specifications, or imposed conditions, and are often carried out through testing and simulations.

Whereas validation tests are concerned with assuring customer satisfaction, the verification tests treats the physical to functional compliance of the system or program with its variety of products and thereby it often is an internal process of a company, which is in contrast to validation testing, which include external stakeholders (primarily customers but also other stakeholders of interest) in the conducted tests.

Hence, opposed to validations, the verification test domain treats the lower level upstream test and documentation efforts required by the design team. It reveals the verification tests and documentation that have or are to be carried out in order to ensure full compliance with the regulations, requirements, specifications of the functional domain.

Thus, the verification test domain unfolds underlying tests and documentation of the degree to which the constitutive structural elements of the product design, the physical materialization, is supporting the behavioral functional abilities ensuring compliance. Therefore, when the design team is to establish the verification test domain, the team should take the following aspects into account (Fig. 6.31).

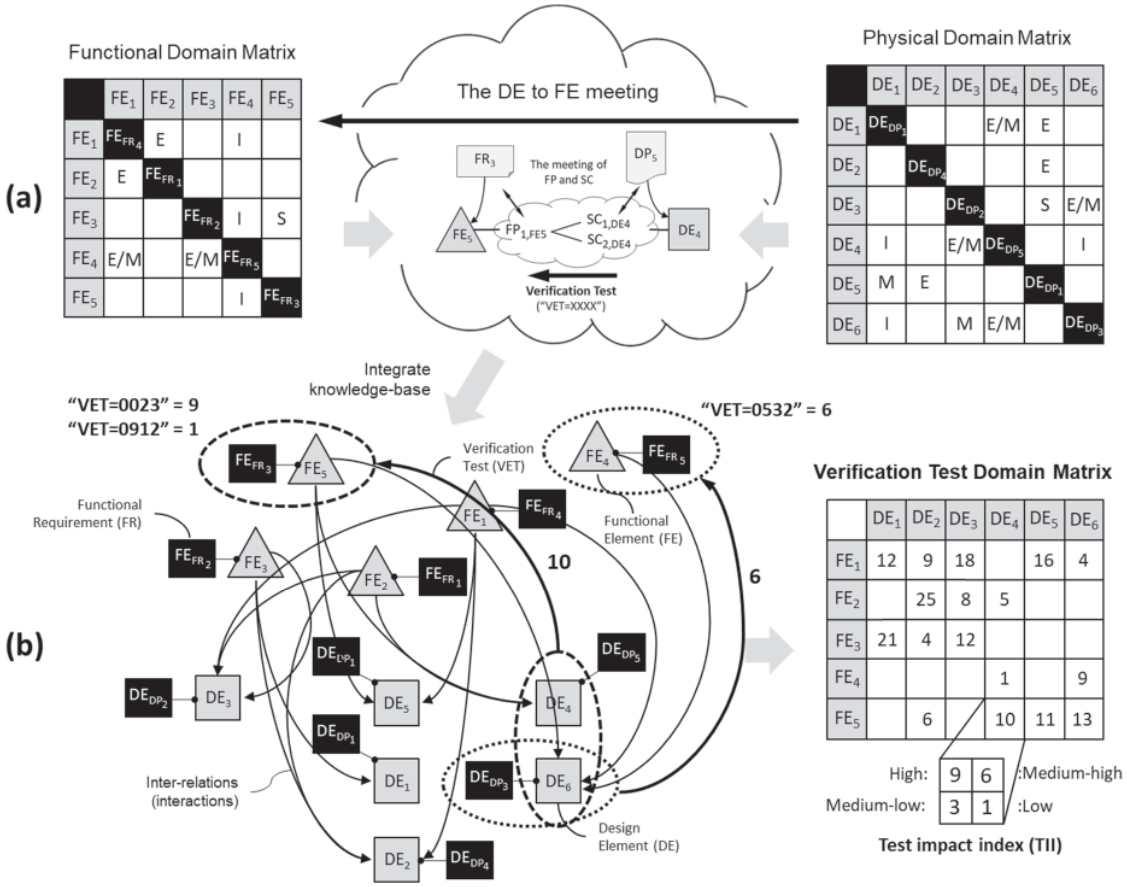


Fig. 6.31: Verification test structure based on property modelling, verification testing, and evaluation of tests constraining the design using quantitative measures

When modelling the verification test domain, the following sequential actions should be taken in order to achieve insight into the composition of the verification test and documentation structure. Following the illustration above, the analytical exercises should be conducted for the verification test domain.

Modelling the tests between the design elements and functions – During analysis and in the synthesis of medical device programs, verification tests and documentation involve performing targeted tests to simulation of a portion, or the entirety, of a system, following review or analysis of the results. Working with product programs, which is the objective of the CACE modelling tool, force the design team to increase the scope as product variety comes into play. Hence, the task is not to investigate single products, it is to take the temperature on how the entire product program is built from a verification testing and documentation point of view.

When looking into the verification test domain, design elements, functional elements, inter-relations between design elements and functions, and requirements constitutes the verification tests and documentation domain (Fig. 6.31, a). In the analysis, these structures are explored

through the investigation of test documentation, which contain codified test-related knowledge of the product design. This documentation constitutes a valuable input to the design team as it shows, or should show, which design elements have been part of the test evaluating a certain function of the product. A verification test is in fact the evaluation of whether one or more design elements meet the functions as stated in the requirements (Fig. 6.32).

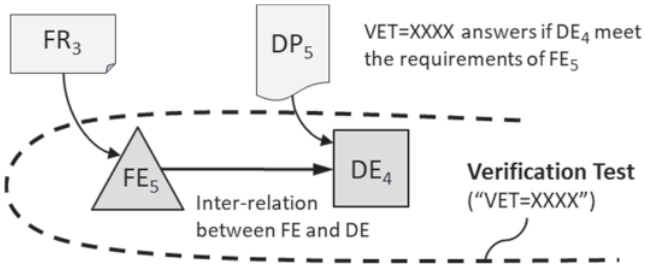


Fig. 6.32: Verification tests answers if the design elements meet the requirement of the functional elements

The above illustration shows a straightforward testing principle, namely that the functional element FE_4 is to be realized through the design element DE_6, while these are subject to functional requirements and design parameters. Regardless of the complexity of relations, namely the number of functional elements and design elements and their inter-relations, these relations should be tested from a verification point of view. This said, when modelling real-world product programs, the verification test view is subject to high complexity.

Regardless of the level of complexity at hand, the design team should analyze or synthesize all these relations verifying their establishment through testing. Simulations are only valid during explorative phases of the design but can help the design team in the product development phase establishing a rigid understand of the inter-relations between the two domains. For this, the design team should enter the property reasoning. Functional properties represent the goodness of the functional element and is to be tested against the functional requirement (Fig. 6.33).

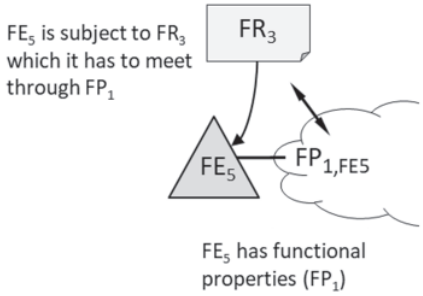


Fig. 6.33: How a functional element is subject to a functional requirement, how this element got functional property and how the property represent the goodness of that function, which is supposed to meet the stated requirement

This said, a product's functions cannot be tested separately from the entities that realize them, but the design teams should establish thorough knowledge about these interacting mechanisms of the functional domain, as these represent the goodness of the product's function.

As properties are key to link the customer needs to physical materialization, the technical solution of the product, should be understood for testing of the functional requirements, as these are subject for regulation. The other "end" of the inter-relation between the functional and physical domain is represented by the design element (Fig. 6.34).

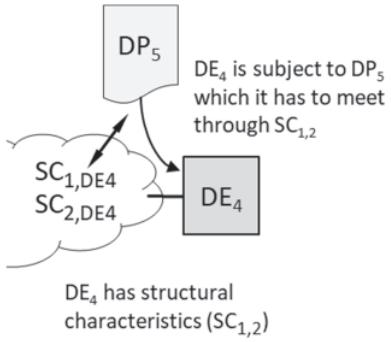


Fig. 6.34: How design elements have design parameters attached to them, how these elements got structural characteristics and how the characteristics represent the materialization of that element, which should meet the stated non-functional requirement

These elements and their relations describe the physical materialization of the product. The structural characteristics describe the nature of the design element and are subject to design parameters given the non-functional requirements. Thus, this answer if or to what extent, the design element with its structural characteristics meet the design parameters.

When unfolding the product architecture, it was found that FE_5 was relating to DE_4 through their functional properties and structural characteristics. What is being verified is whether the configuration of certain design elements and their structural characteristics, which are or should be documented in the design specifications stating the non-functional requirements, exhibits the intended functional properties, which are or should be documented in the functional requirements (Fig. 6.35)

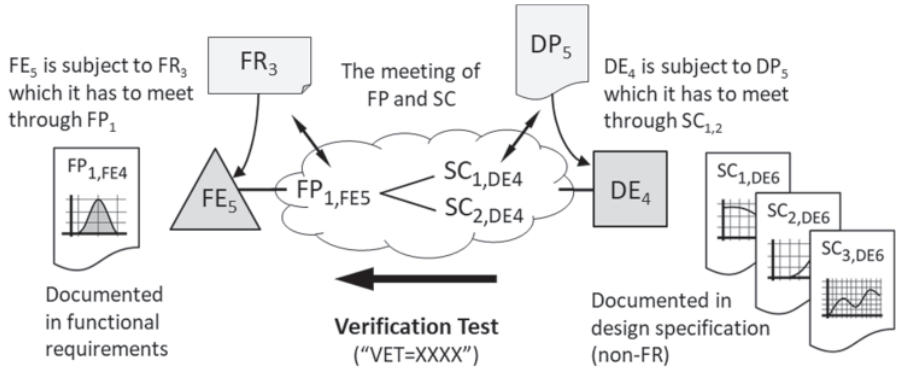


Fig. 6.35: A verification test that is to ensure that a design element meet the function of a product

What was further revealed during the analysis of the product architecture, was that design element DE_4 and DE_6 are related to different elements of the functional domain, namely FE_5 and FE_4 respectively. Meanwhile, it was found that the structural characteristic $SC_{2,DE6}$ of DE6 influence the functional property $FP_{1,FE5}$ of FE_5. Therefore, from a verification test point of view, both DE_4 and DE_5 should be included when testing FE_5 for its functional property $FP_{1,FE5}$. When looking at these two design elements, as only DE_6 relates to FE_4, this is the only element to be included in the test for $FP_{1,FE4}$ of functional element F_4 (Fig. 6.36).

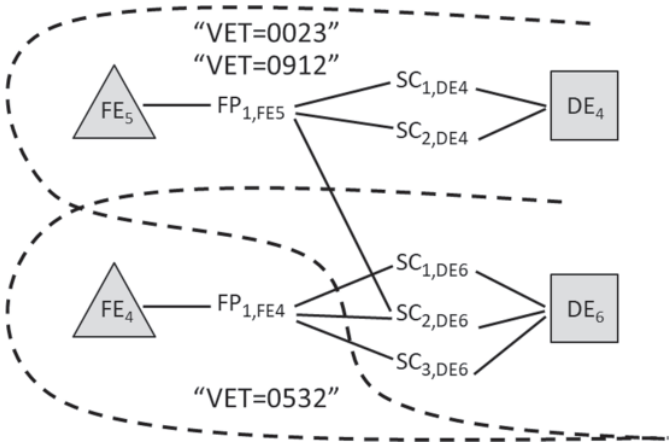


Fig. 6.36: Alignment of product and test view: The tests that are carried out "fits" the realization of the product

This is an important insight, as this reveal the structural composition of the test view. Thus, the design team should investigate how functional elements have been tested against the actual materialization of that product functionality. The design team should take the underlying property models into account when looking at the "fit" between the actual inter-relations from

a product perspective and the tested inter-relations provided in the test view. When establishing the first knowledge base of the verification test domain, the design team should:

- Understand the verification test (VET) view, what is being tested and what should have been tested from a functional property (FP) to structural characteristics (SC) view
- Investigate first glance "fit" between product inter-relations and tested dependencies

Thus, this first stage focuses on identifying how the design elements have been tested in relation to the functions of the product (Fig. 6.31, a). The design team should investigate the inter-relations that have been tested based on the underlying property models. Next, this gained knowledge is used for further enrichment creating the verification test domain matrix.

Modelling the verification test domain matrix – The verification view constitutes tests that span across the functional and physical domain. In order to fill out the verification test domain (Fig. 6.31, b), the design team should quantitatively evaluate the tests that have been, or are to be, carried out according to a predefined rating system (Tab. 6.5).

Rating	Description
9	Long duration [hours] and highly resource intensive [man-hours]
6	Long duration and medium- to low resource intensive
3	Short duration and highly resources intensive
1	Short duration and medium- to low resources intensive
0	No test has been / is to be carried out

Tab. 6.5: Test Impact Index (TII): Rating system for assessing the extent to which verification testing and documentation is affected by changes to design elements

Analyzing the verification test domain matrix, each function (functional properties) may have been documented in several tests with different configurations of design elements testing for the functional properties. These tests vary according to time-consumption [hours] and level of resources required [man-hours]. The same goes for synthesizing the product program, the verification test domain is to be filled out using the rating system evaluating the magnitude of the required tests that are to be carried out in order to ensure compliance of the product program.

The TII rating system thus helps the design team quantifying the extent to which the component-to-function relations are to be verified. These quantitative measures are applied to the

verification test domain to evaluate the correlating inter-relations established within the product architecture domain (Tab. 6.6).

Functional elements (FE)		Design elements (DE)					TII
		DE_4		DE_6			
		$SC_{1,DE4}$	$SC_{2,DE4}$	$SC_{1,DE6}$	$SC_{2,DE6}$	$SC_{3,DE6}$	
FE_4	$FP_{1,FE4}$	VET=0219	VET=0219	VET=0219 VET=0532	VET=0219 VET=0532	VET=0219 VET=0532	**3** **6**
FE_5	$FP_{1,FP5}$	VET=0023 VET=0912	VET=0023 VET=0912	VET=0023 VET=0912 VET=0341	VET=0023 VET=0912 VET=0341	VET=0023 VET=0912 VET=0341	**9** **1** **3**

Tab. 6.6: Quantitative evaluation of the verification test structure using the test impact index (TII)

The implied test structure shown above reveal cross-domain tests of the product program. Thus, it shows upstream verification tests, how these spans across the functional and physical domain and the burden associated with carrying out the tests. Thereby it enables the design team to measure the consequences of changing one or more design elements of the product program from a verification point of view. The complete quantitative estimates are plugged into the CACE modelling tool unfolding the integrality/modularity balance of the current verification test and documentation structure.

As the above table shows, two tests, namely VET=0219 and VET=0532 have been carried out testing the functionality of FE_4. The latter is rated a long duration test that is lightly resource intensive. What is more to this analysis, is that the first test VET=0219 includes both DE_4 and DE_6. One should recognize, based on the knowledge obtained modelling the product architecture domain, that DE_4 should not take part in this test.

This contradiction across the product and test view highly constrains the design as the architecture underlying the product program is locked from a test point of view. Meanwhile, three tests, namely VET=0023, VET=0912 and VET=0341have been carried out testing DE_4 and DE_5 against FE_5. Again, contradictions are found. In this case, both design elements with its structural characteristic should be included testing FE_5 for its functional property $FP_{1,FE5}$.

Thus, in the verification test view (the tests that have been carried out evaluating the performance in relation to the functional to physical elements), the rating system reveals the sensitivity towards changing the product design. Namely, it unfolds the resources and costs

associated with developing new product variants based on the existing test structure. It exposes the current test structure constrains the development of new product variants based on the product program (Fig. 6.37).

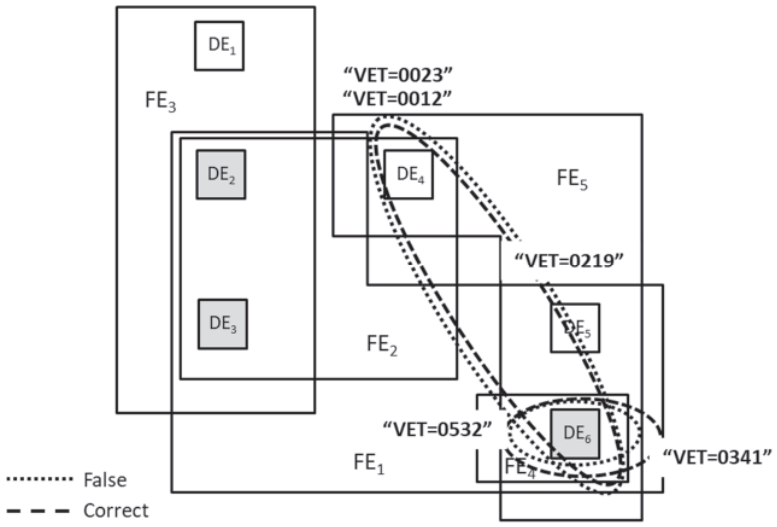


Fig. 6.37: The verification test view based on conducted tests, which reveals the verification test and documentation structure, the lower upstream compliance view on the medical device program

The task of establishing the verification test domain is about systematically compiling information about the test structure so that the design team has a foundation on which it can decide on how to proceed rationalizing and synthesizing the medical device program (Fig. 6.31, b). Thus, based on the gained knowledge creating the decision basis, the design team should:

- Rank the verification tests (VET) that spans across the functional and physical domain creating a holistic picture of the test structure
- Establish verification test domain matrix showing the tests including the ranking of time and resource allocation to the test (summed up in the matrix)

The verification test activity can, if undertaken as described in this section, enable a feedback loop in the design process, allowing for preventive actions prior to product launch. These tests are also referred to as explorative performance tests and constitute an important continuous evaluation during the product design process. Meanwhile, the analysis of the verification test domain provides valuable insight into the constrains of the design when developing future product variants based on an existing product program.

The aim of establishing the test view is to enlighten such constraints and enable the design team to take the necessary actions to possible conflicts across the domains. While the aim of the tests

is to reduce the risk of product failure, the design team can encounter trade-off situations where two or more requirements cannot be simultaneously satisfied by the design. It enables the design team to take the actions needed to meet the requirements. Meanwhile, the verification domain matrix helps the design team analyze the product program for rationalization while it provides a rigid foundation on which the design team can decide on modularity / platforming aspects in the development process. The verification test domain matrix will be used as input for the CACE modelling tool.

6.3.8 UPSTREAM MODELLING: THE VALIDATION DOMAIN

Products should always be subject to validation. When developing medical devices, validation testing is, like verification, subject to major concerns – that the product functionality does meet the market requirements. Validation testing ensures that the products meet the customer needs and is a process with procedures subject to regulation. Thus, medical device manufacturers should take thorough steps to ensure complete fit with the customer needs identified through voice of the customer processes.

The aim of introducing the validation test domain, is to shed light on the validation testing aspect of the product design, namely if the design reach customer satisfaction. Validation tests can be defined as quantitative evaluations of a product to assure that the functional design of the products meet the market requirements.

Validation is the evaluation of whether a product or system complies with regulations, requirements, specifications, or imposed conditions, and are often carried out interacting with human beings. It tests the product in the use context, hence the use activity identified in the customer domain, and often more tests are needed evaluating the environmental conditions under which the product is used. Hence, opposed to verification, the validation test domain treats the upper level upstream test and documentation efforts required by the design team.

It reveals the validation tests and documentation that have or are to be carried out in order to ensure full compliance with the regulations, requirements, specifications of the customer domain. Therefore, when the design team is to establish the validation test domain, the team should take the following aspects into account (Fig. 6.38).

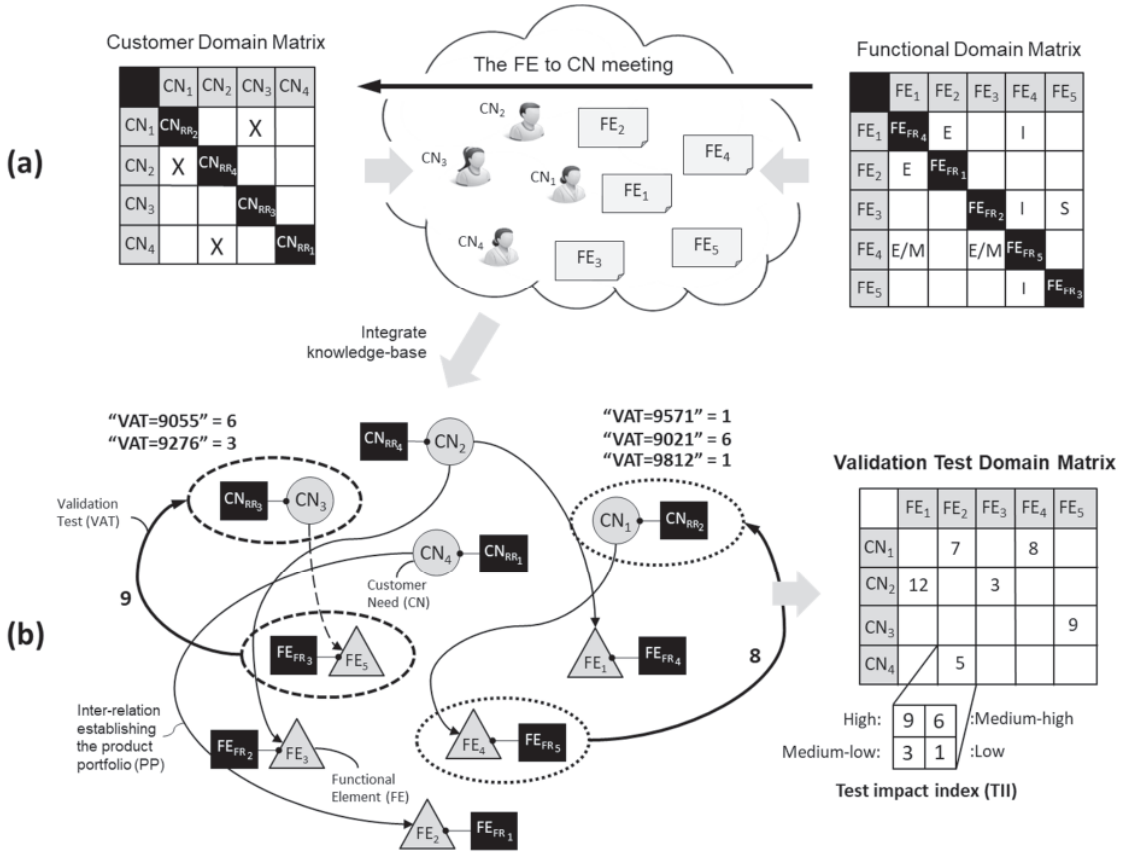


Fig. 6.38: Validation test structure based on property modelling, verification testing, and evaluation of tests constraining the design using quantitative measures

When modelling the validation test domain, the following initiatives should be taken to gain insight into the composition of the validation test and documentation structure. Following the illustration above, the subsequent modelling formalism should be applied for the validation test domain.

Modelling the tests between functional elements and customer needs – Analyzing and synthesizing the medical device programs, validation tests and documentation involve performing test with the external stakeholders to the manufacturing company. It concerns testing the functionality up against the customer needs (Fig. 6.38, a). As with verification, it is important, that the design team considers the intended use based on the use activities by which the medical device is to interact as this sets the risk class of the device and thereby the regulatory requirements that are to be followed during the testing of the functionality.

Here, the design team should also have the product variety of the program in mind as validation should account the entirety of the program as this is the aim when laying out the validation test structure using the modelling tool. In the analysis, these validation test structures are explored

through the investigation of test documentation, which contain codified test-related knowledge of the program validity. It is a valuable input to the design team as it shows, or should show, which functionalities of the program that have been part of the test evaluating a certain customer need against the product design (Fig. 6.39).

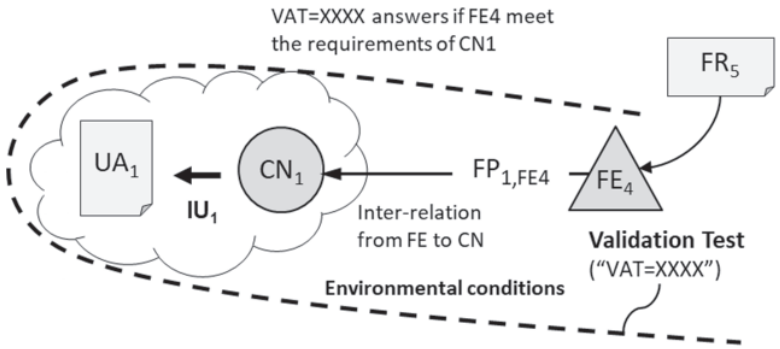


Fig. 6.39: Validation tests answers if the functional element meet customer need. This in a certain use situation with e.g. changing environmental conditions (more validation test for same need)

Based on the above illustration, the design team should investigate how the functional element of the product program meets the customer need while considering the use activity and environmental conditions. Further, the design team should deliberate the risk class to which the intended use of the medical device take part. This sets the requirements for validating the functionality of the product. Thus, when validating the product, namely the functionality, the design team should consider use situation (intended use), the risk class and related regulatory requirements while conducting the tests under different environment conditions if needed (Fig. 6.38, a). When establishing the first knowledge base of the verification test domain, the design team should:

- Understand the validation test (VAT) view, what is being tested and what should have been tested from a market requirements perspective, namely the customer needs
- Investigate first glance "fit" between customer needs and product functions, the inter-relations, and the tested couplings between these domains

Thus, this first stage focuses on identifying how the products' functionalities have been tested against the customer needs. The design team should investigate the inter-relations that have been tested. Next, this gained knowledge is used for further enrichment creating the validation test domain matrix.

Modelling the validation test domain matrix – The validation view constitutes tests that span across the customer and functional domain (Fig. 6.38, b). Like in the verification test domain, in

order to fill out the validation test domain, the design team should quantitatively evaluate the tests that have been, or are to be, carried out according to a predefined rating system (Tab. 6.7).

Rating	Description
9	Long duration [hours] and highly resource intensive [man-hours]
6	Long duration and medium- to low resource intensive
3	Short duration and highly resources intensive
1	Short duration and medium- to low resources intensive
0	No test has been / is to be carried out

Tab. 6.7: Test Impact Index (TII): Rating system for assessing the extent to which validation testing is affected by changes to product functions (the same rating system as goes for verification testing)

Analyzing the validation test domain matrix, each customer need (voice of the customer) may have been documented in several tests with different configurations of the product containing various functional elements and inter-related design elements. Like verifications, the validation tests vary according to time-consumption [hours] and level of resources required [manhours]. Likewise, when synthesizing the product program, the validation test domain is filled out using the above rating scheme forecasting the time and resources needed in order to prove valid compliance. These evaluations are applied in the validation test domain to ensure fit to the earlier established product portfolio design. As one cannot test functions on its own, these tests must be carried out using the products; hence the modelled product portfolio (Tab. 6.8).

	Functional elements (FE)		
	FE_4	FE_5	
Customer needs (CN)	$FP_{1,FE4}$	$FP_{1,FP5}$	**TII**
CN_1	VAT=9571 VAT=9021 VAT=9812		**1** **6** **1**
CN_3		VAT=9055 VAT=9276	**6** **3**

Tab. 6.8: Quantitative evaluation of the validation test structure using the test impact index (TII)

As the illustration shows, the validation test structure the upper-level upstream cross-domain tests of the product program. Thus, it shows upstream validation tests, how these spans across the customer and functional domain of the product program and reveals the burden (time and resources) associated with carrying out the validation activity reaching compliance with the given regulation to which the product variants take part. Further, it enables the design team to measure the consequences of changing one or more design elements of the product program. The complete quantitative estimates are plugged into the CACE modelling tool unfolding the current validation test structure.

As the function to customer need table shows, the VAT= 9571, VAT=9021 and VAT=9812 has been carried out testing the functional property of F_4 against the customer need CN_1. Meanwhile, VAT=9055 and VAT=9276 have been conducted testing the meeting between FE_5 and CN_3. Although only two tests have been carried out in the latter case, these represent a higher value. Further, it is revealed that no discrepancies exist between the portfolio and validation view of the CACE modelling tool.

Thus, in the validation test view (the tests that have been carried out evaluating the performance in relation to the customer need to functional elements), the rating system reveals the sensitivity towards changing the product design. Namely, it unfolds the resources and costs associated with developing new product variants based on the existing validation test structure. It exposes whether, and in which way if such, the current validation test structure constrains the development of new product variants based on the product program (Fig. 6.40).

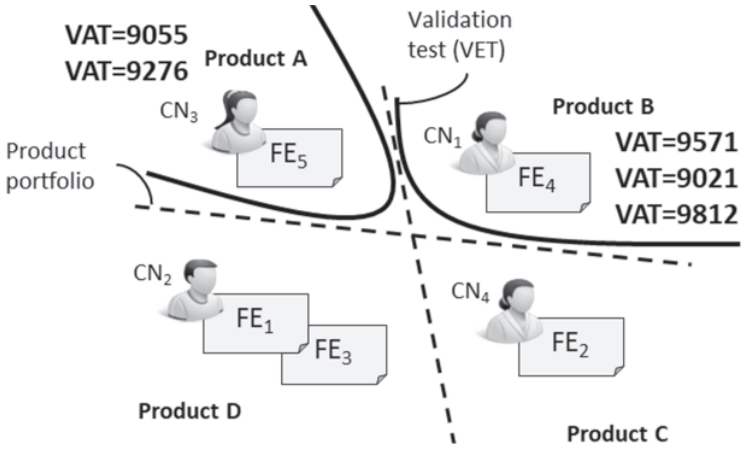


Fig. 6.40: The validation test view based on conducted validation tests, which reveals the validation test and documentation structure, the upper compliance view on the medical device program

The task of establishing the validation test and documentation domain is about systematically compiling information about the test structure so that the design team has a foundation on which

it can decide on how to proceed rationalizing and synthesizing the medical device program from a validation test point of view (Fig. 6.38, b). Thus, based on the gained knowledge creating the decision basis, the design team should:

- Rank the validation tests (VAT) that spans across the customer and functional domain creating a holistic picture of the validation test structure
- Establish the validation test domain matrix showing the tests including the ranking of time and resource allocation to the test (summed up in the matrix)

Like with verification test activity, validation can enable continuous customer feedback during the design process, allowing for corrections prior to product launch. These tests are also referred to as explorative tests and is important in the product design process. Meanwhile, the analysis of the validation test structure provides valuable insight into the current situation viewing the product program from a validation test perspective. The validation test and documentation domain matrix support the design team analyze the product program for rationalization while it provides a rigid foundation on which the design team can decide on targeted market segment in the development process. Further, it enables valuation of requirements to which the manufacturer must comply extending the product program. The validation test domain matrix will be used as input for the CACE modelling tool.

6.3.9 THE FINALIZED CACE MODELLING TOOL

After (1) establishing the three central domains to the medical device program, i.e. customer, functional and physical domain by means of design structure matrices (DSM), (2) the downstream product view by means of domain modelling matrices (DMM) models entailing the product portfolio and product architecture domain matrices, and (3) the upstream compliance view revealing the verification and validation test and documentation domain matrices by means of DMMs, respectively, by means of domain mapping matrices (DMM), the final overview can be shown by means of joint multiple-domain matrix (MDM) compiling the CACE model (Fig. 6.41).

Reading the MDM-based CACE model, from the upper left corner, the customer domain matrix is found representing the external influencers or drivers of change to the medical device program. Here the customer needs with its situated regulatory requirements (represented in the diagonal), which were found during the market analysis, is shown. Intra-relations among customer need statements are represented by means of a binary system. Note that inputs and outputs between program elements are read counter-clockwise, i.e. CN3 provides input to CN1, which provides input to CN2. Thus, CN3 have the highest priority, followed by the CN1, and last, the CN4. Moving down the diagonal of the MDM, the functional domain matrix entailing the

functional elements with its functional requirements is shown. Here relations among functional elements have been identified using the previously described interaction classifications during the analysis of the product program design, i.e. FE_2 interact with FE_4 providing energy (E) and material (M) and the functional element FE_4 then provides information (I) to FE_1 and FE_3. At last, the final DSM shows the materialization of those functional elements is described by means of the physical domain matrix found during the analysis of the materialization of the product program design. Here, the design elements that are to fulfill the functional variety of the medical device program are illustrated. The design elements are attached design parameters, here associated with non-functional requirements, and couplings among elements are defined using the interface classification definition scheme introduced earlier, i.e. energy, material, information and spatial relations. These three domains modeled by means of DSMs, i.e. the customer, functional and physical domain structure matrices, represent the three central cornerstones of the MDM-based CACE model upon which, the front-end medical device development manifestation can be modelled.

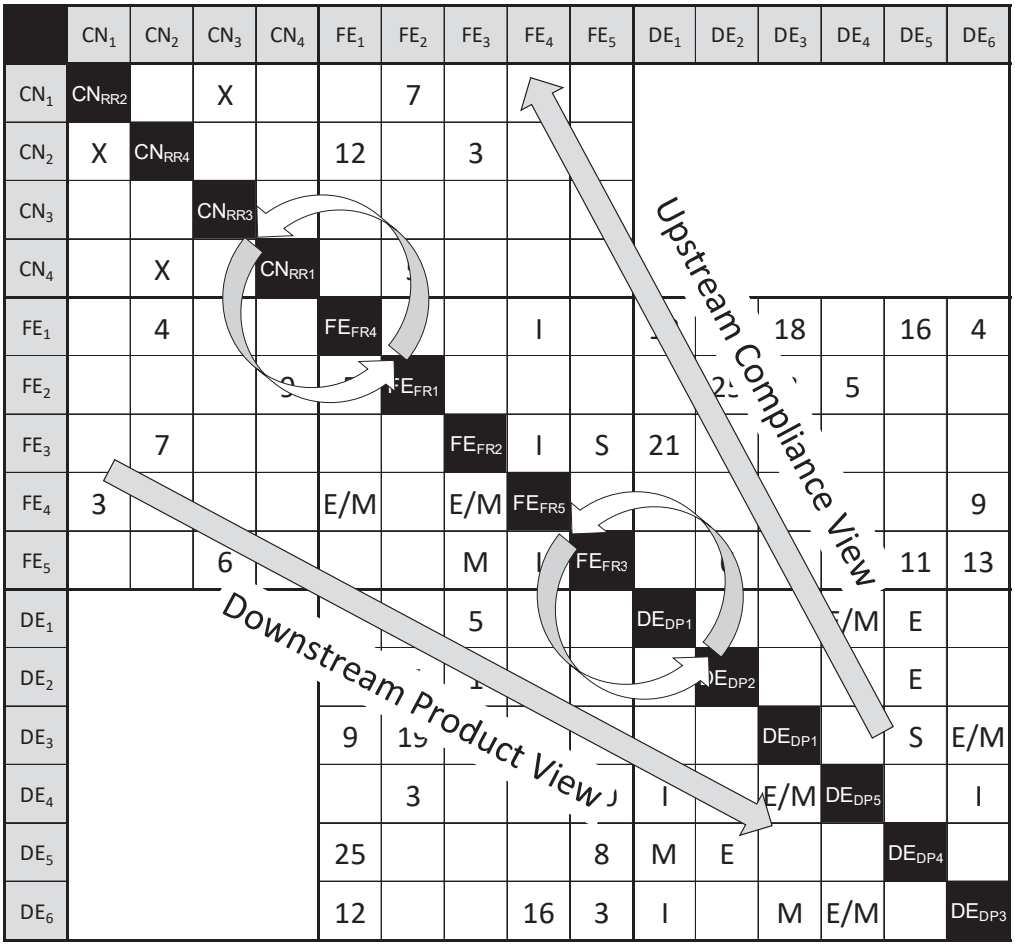


Fig. 6.41: The finalized MDM-based CACE model containing the seven domains of the medical device program, incl. system sensitivity and test impact measures across product and compliance view

Reading down the DMMs, the off-set inter-related product domains or views are found. These are denoted the product portfolio domain matrix and product architecture domain matrix and collectively represent the downstream product view of the CACE model. Please remember that quantitative measures applied using the system impact index (SII) in the final model represent a summation of the underlying product models analyzed. Thus, the above CACE model provides an overview of the collective cross-domain downstream dependencies (structural flows) of the medical device program, i.e. the interlinked design of the medical device program found during the analysis and modelling of the product portfolio and product architecture composition. First, the upper downstream domain, namely the product portfolio design is shown. Here, relations are identified based on analyzing how customer needs are met by functional elements of the program as the functional variety is to discriminate between the corresponding customer needs. The product portfolio domain matrix describes those couplings that form the collection of product offerings covered by the program and thereby reveals the product variety from a functionality aspect; hence, the meeting of functions and customer needs. Last, the lower downstream product view reveals the product architecture domain matrix. This domain describes the inter-relations between the functional and physical domain by means of the underlying product property models. Here, the nature of the program architecture, namely whether it is more or less modular, rely on the underlying configurations of the functional properties of the functional elements and the structural characteristics of the design elements. The architectural composition founds the basis of medical device program design.

Reading up the DMM, the corresponding off-set inter-related compliance domains can be found. These are denoted the verification test domain matrix and validation test domain matrix and collectively represent the upstream compliance view of the CACE model. Please recall that quantitative measures here are based on the test impact index (TII) and the indices shown in the final model represent a summation of the underlying test structures analyzed. First, the verification test domain is shown by means of a DMM and correspond to the previously described product architecture domain. Here, tests are quantitative evaluations of a product to assure that the materialization of the design meet the function variety of the program, i.e. if the structural characteristics of the design elements meet the functional properties of the functional elements.

Lastly, continuing reading up the compliance view, the validation test domain matrix is shown. Here, as with the verification test domain, inputs to the matrix show the tests that have been carried out examining to which degree functional elements meet the customer needs. Here, test impact indices are used illustrating the total amount of test that have been conducted for each functional to need relation in the product portfolio view. Thus, the upstream compliance view is a corresponding view to the product view and enable the design team to analyze and synthesize the medical device program accordingly to changes driven by the external environment.

Finally, as the illustration above indicates, the CACE model generally represent the front-end view of the medical device development process. It captures the elements of the model proposed by Jiao (2005) while it extends the view to entail critical parameters to the structural management of this part of the design process, namely the verification and validation test domains. Further, it provides systematics for capturing the elements of the V-model (Forsberg et al. 2005). It provides the downstream product decomposition and integration points while it enables alignment of the corresponding verification and validation test and documentation that should follow the product design process as the V-model proposes.

6.4 APPLICATIONS OF THE CACE MODEL LING TOOL

The objective of applying the CACE modelling tool to the front-end of medical device development process is to provide the design team with a more systematic approach to cope with the complexity of introducing new medical device variants while maintaining devices already brought to market. The application of the CACE modelling tool poses two main abilities:

First, the supporting tool provides the ability to systematically analyze for rationalization of an existing medical device program creating a solid foundation for future product variant creation. This part of the application enables:

- Traceability and prioritization using risk measures in multiple-domain matrix
- Cross-domain integration evaluating product-to-compliance discrepancies
- Architecture modularization for compliance testing and/or documentation reuse

Second, the tool provides the ability to synthesize a medical device program for new product launch by means of systematically and iteratively evaluating the conceptual designs based on the two predominant views on the design object. Thus, this part of the application enables:

- Evaluation of new variants based on compliance architecture concept exploration

The CACE modelling tool creates cross-domain transparency. It enables evaluation of external changes (customer and regulation) while it founds the basis for deciding on realization of new product variants. Thus, it enables modeling of inter- and intra-relations, their alignment and potential for complexity management and reduction. Meanwhile, it provides the ability to detect discrepancies for rationalization purposes, while establishing a sound foundation for new product development. Finally, it supports the modeling of conceptual architecture designs for the exploration of optimal new product introduction considering the regulatory environment and its effects on the product and compliance view of the product program design.

This section describing the applications of the CACE model has been scoped so that primary focus will be put on the product architecture domain and verification test domain, while reflections will be provided showing the applications of the product portfolio domain and validation test domain.

6.4.1 Prioritization and Traceability: Applications of the Multiple-Domain Matrix

The multiple-domain matrix on which the CACE modelling tool builds, provides traceability from external market requirements (regulations and customer needs) downstream the product view and upstream the verification and validation test view (Fig. 6.42).

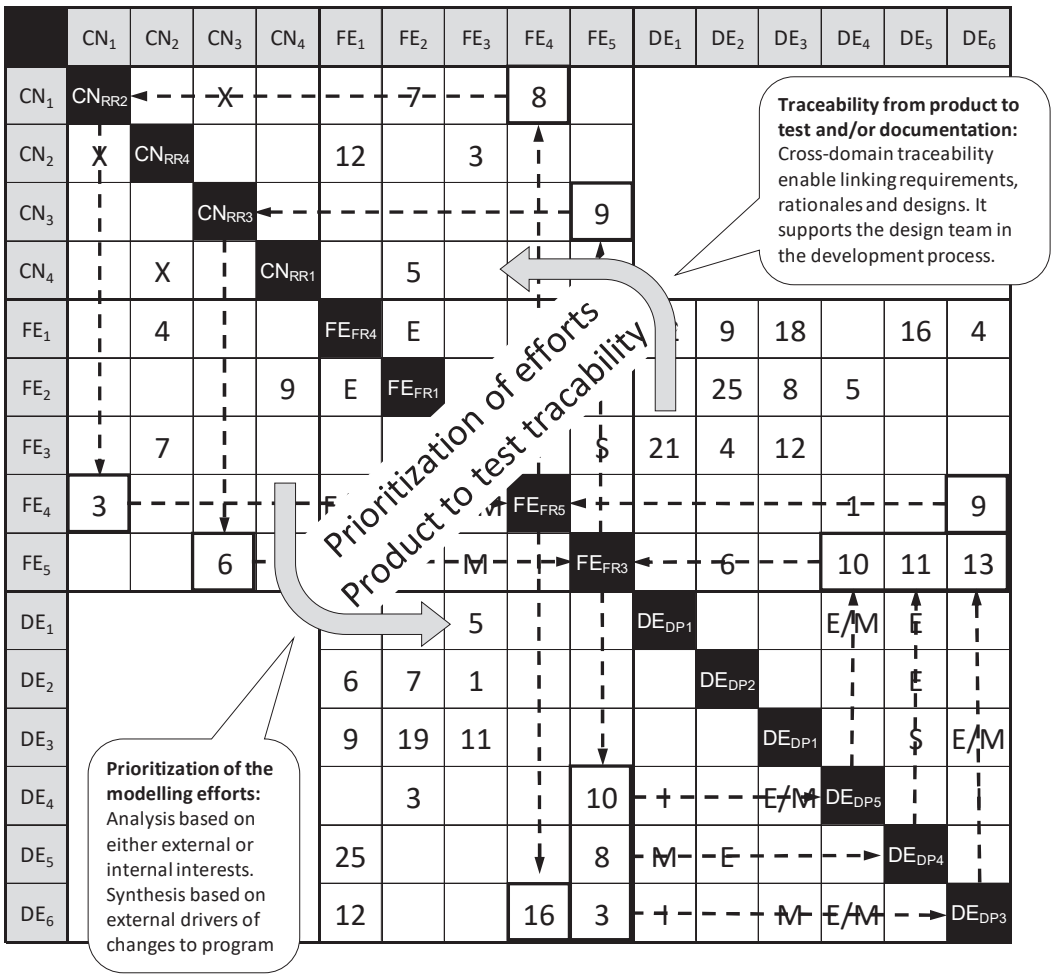


Fig. 6.42: Prioritization of company resources while enabling traceability based on a thorough decision basis established by the MDM-based CACE modelling tool

The tool provides the possibility to choose the elements of interest for the design team and analyse the resulting underlying property and test models. This is important, as especially when large systems are to be analysed and/or designed, a high number of elements and intra-relations within each domain. Inter-relations across the different domains will require multiple iterations and thereby resources thus when modelling the medical device program, prioritization is key when optimizing the resources spend modelling the complexity with its underlying models.

In general, two main prioritization mechanism can be used depending on the objective modelling the cross-domain product realization and test view of the program:

Analysis of the medical device program with the objective to rationalize the product-to-test view of the existing structural complexity of the product variants. Here, high-risk profiled use activities are used to prioritize which underlying models to identify and analyse. Risk classification and risk priority numbers can be applied to the modelling formalism ensuring focussed resource expenditures starting the investigation of the performance of the current medical device program. Meanwhile, instead of basing the focus on the external environment to the program, the design team could choose to start "insight" the program. When the total CACE modelling tool has been mapped using the MDM, the tool can reveal the cross-domain discrepancies. Please note that the model is only as strong as the data it is fed with. the tool is meant as a discussion tool, which may open new aspects that were previously not captured or discussed. Thus, the tool does not necessarily hold the answer itself, but is a catalyst for the solution. If, the design team finds that tests are missing according to the product realization view, this is where the design team should start the journey of establishing and analysing the underlying models as described in the above section about cross-domain integrations.

Synthesis of the medical device program developing new product variants based on the cross-domain view analysis of the current situation. Here, two possibilities exist: 1) New markets are to be conquered with new customer needs or the customer needs of existing markets changes, or 2) new markets with differentiated legislative enforcements are to be entered, changes occur in the regulatory environment, tightening of existing regulatory frameworks. Together, these two situations are referred to as market requirements:

1) New/changes to customer needs: Customers of unexplored markets put differentiated demands on the manufacturer, causing the company to deliver new product variants. These might partially be based on the existing product program. It is possible to trace those new requirements downstream evaluating the current match to such requirements, while if existing customer needs changes, e.g. improved performance of an already at market product, the company can identify which part of the product program will be affected, both from a product perspective and a test/documentation perspective. Thus, it is possible to evaluate how the company is affected by such changes,

but probably more interesting, it is possible for the medical manufacturer to assess the economic feasibility of meeting that new requirement based on the value of that market and the time and resources that the company must spend testing and documenting the new developments. Further, it is possible using the CACE modelling tool, to quantitatively evaluate (by analysing cross-domain change propagations and effects) different conceptual architecture-based designs that meet this new customer need finding the most suitable solution from a product and test point of view, please see the section about architecture concept exploration.

2) New/changes to regulatory frameworks: When entering new markets, the design team should be vigilant towards differentiated regulatory frameworks that set other, yet unknown, requirements to the company and its product program, i.e. product variants that are to be launched to these new markets. Meanwhile, medical manufacturers must constantly be observant towards changes to the regulatory environment because of the tendency that regulatory requirements tighten over time, which potentially affect the business. By applying the CACE modelling tool, it is possible to measure the ripple effect of such changes. When a new regulatory requirement arises or an existing requirement, to which the company must comply, changes due to legal jurisdictions, the CACE modelling tool provide a complete overview of where and to which degree this will affect the program from a product and test/documentation point of view. This is because the design team can visually see and quantitatively measure which functional elements and design elements that are to be affected using the CACE modelling tool. Changes in regulatory requirements (external to the system) will potentially cause changes to the functional and non-functional requirements (internal to the system), which may force the design team to take initiative to change these elements of the system in order to reach compliance with the newly required performance of the products. Based on the thorough knowledge gained filling out the MDM, i.e. how customer needs relate to use activity forming the intended use and thereby belongs to a given risk classification, which is subject to certain regulatory requirements, the design team can identify the elements that will be affect both from a product and test point of view.

As an example of the above drivers for changes, when looking at the illustration (Fig. 6.42) and the earlier descriptions of establishing the domains of the CACE modelling tool, the customer domain is to change. Regardless if the customer needs themselves, i.e. CN_1 and CN_3, or the underlying market requirements given the risk classification with its attached regulatory requirements are to change, the CN_1 and CN_3 will form the starting point of tracing the consequent effects downstream and upstream the MDM. Caused by the inter-relations downstream (product view), the functional elements FE_4 and FE_5 is found to be affected by these market changes. Not necessarily the elements themselves, but the functional requirements are,

if not already complying with the new external requirements, subject to change. Thus, the requirements stated by the manufacturer should be analysed for the new situation. When looking at the product architecture, consequently the design elements DE_4, DE_5 and DE_6 should be analysed, and the same goes for the non-functional requirements of these elements that materialize the functions offering the variants. Thus, here the design team should be vigilant towards the design parameters (non-functional requirements) of those design elements and consequently the performance of building elements.

Reading upstream the compliance view of the CACE modelling tool, it is identified that these design elements have been and/or are to be included in multiple verification tests against FE_4 and FE_5 given the functional properties those elements. In the previous section, it was found that multiple test lies in these cell and additional complexity has arisen because more design elements than needed from a product view has been added in the various tests. Therefore, these tests are subject for further investigation if CN_1 and CN_2 changes. The same goes for the upper-level upstream view, the validation test domain. Although, here the product portfolio view and validation test view represent a one-to-one mapping; hence, what is understood from a product view is what have been tested from a validation point of view. Thus, this is the way the design team should read the MDM model. High-risk profiled elements can constitute the starting point of the journey, when the design team is to analyse and evaluate the current compliance related performance of the medical device program.

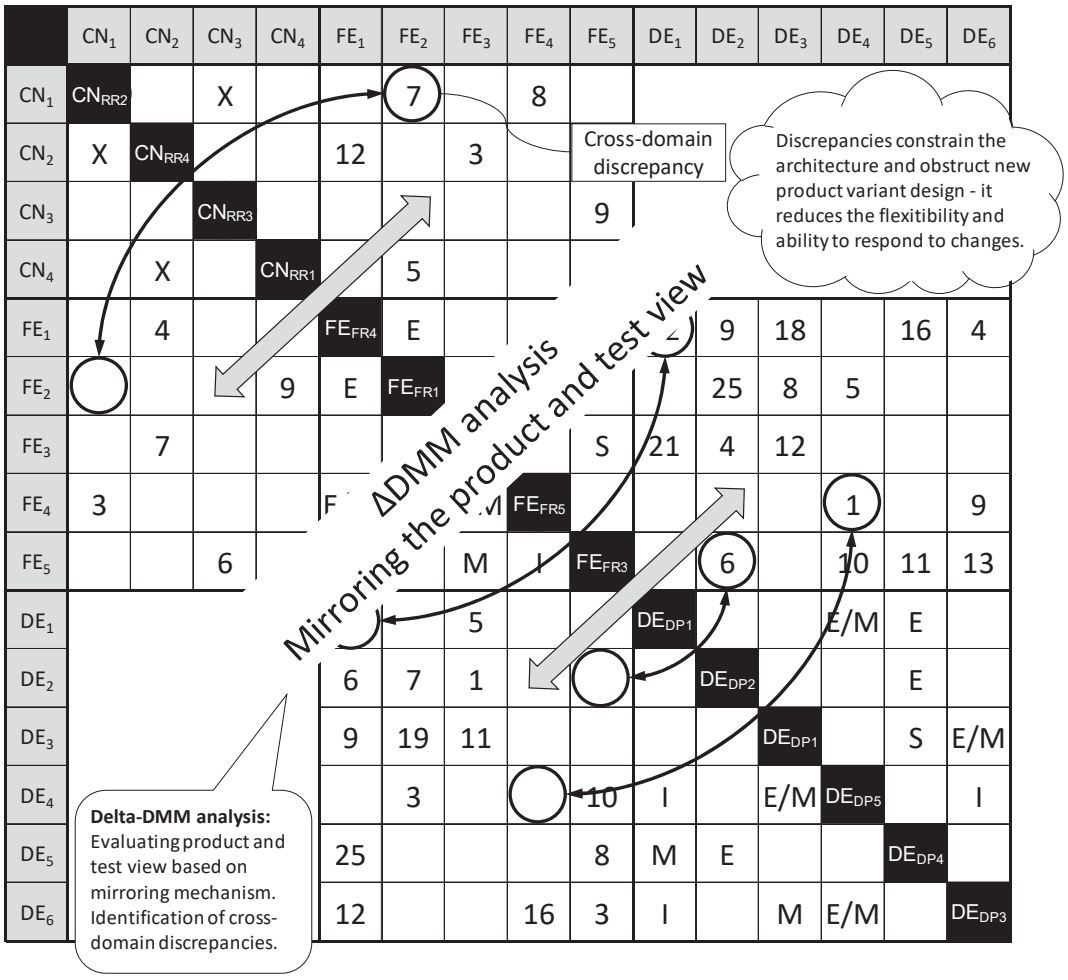
As the above description reveals, it is possible to focus resource expenditures depending on the aim, scope and information available at the time. Further, the CACE modelling tool is suitable for tracing changes regardless if these are driven by external or internal initiatives. Traceability plays a dominant role within the medical domain and therefore is perceived as a value creating feature of the supporting tool. One aspect is to identify external changes causing internal changes to happen, another is the ability to create rationales for changing requirements and redesigning the elements, be it functional or physical, of the system. The CACE modelling tool supports the design team in tracing product to test changes, rationalizing about the reason for this, it improves the overall traceability, and finally helps the team in responding to those changes with focused efforts.

6.4.2 Cross-Domain Integration: Applications of The Delta-Domain Mapping Matrix

One of the key features of the MDM-based CACE modelling tool is the possibility to identify cross-domain discrepancies. In medical device design, manufacturers must ensure that products are tested thoroughly in order to get market clearance for new product designs while the company should ensure continuous compliance of the already product variants (medical device program).

This should be done through product rationales, V&V testing and codification of the results into documents so that the company can show compliance to any regulatory authority of interest. Meanwhile, it has been found that medical manufacturers continuously are challenged with keeping up to speed with the necessary compliance testing and documentation.

The CACE modelling tool enhances the systems engineering V-model by applying the multi-domain modelling (MDM) technique enabling a systematic approach to modelling and controlling the product and test views of the medical device program (Fig. 6.43).

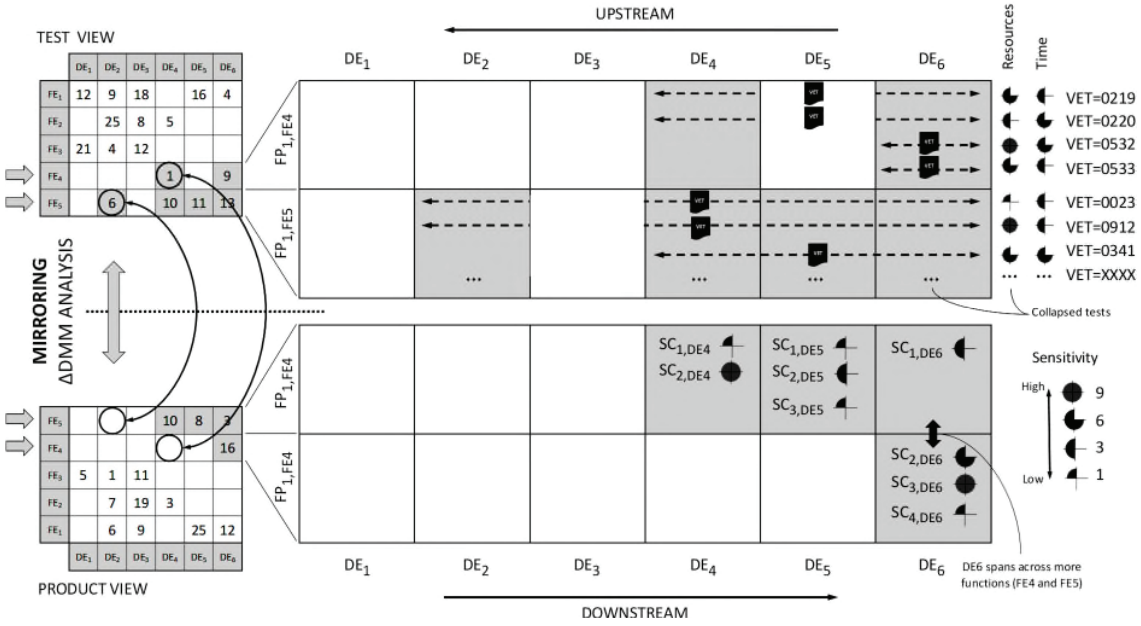


Tab. 6.43: Delta-domain mapping matrix evaluation using a mirroring technique: Identification of top-level discrepancies across the product and test views

This is done through a cross-domain mirroring technique that aims at analyzing the coherence between the product and test view. This mechanism is referred to as the delta-domain modelling matrix (ΔDMM), which provide the ability to evaluate the medical device constraints caused by verification and validation testing and the resulting compliance documentation. It involves

mirroring the product realization view and the V&V test and documentation view to align the structural compositions (architectures) of the two domains. The ΔDMM enable the design team to identify apparent deltas between the downstream and upstream views of MDM-based CACE modelling tool.

As illustrated above, when mirroring the product and verification test view from a high-level perspective, it is apparent from a product point of view, that FE_4 and FE_5 is realized by DE_6 and DE_4, DE_5 and DE_6, respectively. When analyzing the test view, design element DE_4 has been included in the test for the properties of FE_4, which misalign with the product view. The same correlation is found when looking at the design elements that have been included for the properties of FE_5, here DE_2 has been included, although this does not align with the product architecture view. These delta-elements and their relations are unfolded in a detailed ΔDMM model for the identification of the underlying models revealing the dependencies (Fig. 6.44).



Tab. 6.44: Quantification of discrepancies across the product and test view of the medical device program: Analysis of the underlying property and test models

As the illustration shows, by unfolding the underlying property (downstream) and verification test models (upstream), the delta-elements (DE_4 and DE_2) have gone into multiple tests. First, when analyzing the property model of FE_4 to design element DE_6, it is revealed (as described earlier on filling out the product architecture) that DE_6 has three structural characteristics affecting the functional property $FP_{1,FE4}$ of FE_4, namely its surface ($SC_{1,DE6}$), flow rate ($SC_{2,DE6}$) and depth ($SC_{3,DE6}$). Both $SC_{2,DE6}$ and $SC_{3,DE6}$ are relatively highly sensitive towards changes,

which means that if changed, they will have a high impact on the functional property of FE_4. While looking at the verification test view, DE_6 has correctly been included, but so has DE_4 although this design elements is not assumed to influence the functional property of FE_4. By unfolding the views, evaluating the tests and related documentation, it is found that DE_4 has been included in two tests, i.e. VET=0219 and VET=0220. Further, it is found that these tests are rated relatively high on both time and resources. The same goes for the mirroring of FE_5. Here, from a product point of view, DE_4, DE_5 and DE_6 are influencing the functionality of FE_5 through the structural characteristics of these design elements. Meanwhile, when analyzing the verification test view, it is found that DE_2 has been included in two of the tests for $FP_{1,FE5}$, namely VET=0023 and VET=0912, where the latter have high resources and have taken relatively long time to conduct, which misaligns with the product realization.

The same methodology is applied for the product portfolio to validation test view. Here, the understanding of how customer needs entailing its use activities, intended use, and risk classification, are realized by the functional elements, and how this have been validated mirroring the upper-level product and test view. Also, here a discrepancy is found through the ΔDMM modelling. Hence, customer need CN_1 should be satisfied through functional element FE_4, which have been validated. This testing is confirmed from a validation test point of view, but the test view also reveals that FE_2 has been included in one or more of the underlying tests. As earlier stated, one cannot separately test functional elements against customers' needs – the physical realization must be included – but this just further constrains the design downstream the product view.

In general, the discrepancies (or deltas) drive complexity when future product variants are to be created based on the existing composition of the product program. Especially this is the case if medical device manufacturers pursue reusing both the design elements and their related tests in new commercial variants (for more info see next section). Therefore, these deltas are subject for further investigation as the aim of applying the ΔDMM with its unfolded views is to analyze the relations for potential decoupling creating a one-to-one mapping between the two views, which will result in a more flexible foundation for creating new product variants. Elimination of deltas should be pursued so that each property model is verified by a test with related documentation only considering the design elements that are included in the property models of the product architecture.

In the case where the product architecture view reveal relations between functional and design elements that are not identified in the verification test view, or the product portfolio view show relations that have not been tested mirroring the validation test view, immediate actions must be taken by the design team. Such discrepancies are showing non-compliance and will be subject to nonconformities potentially resulting in public warnings stated by the regulatory authorities,

which will have enormous impact on the business going forward. Such cases should be taken very seriously by the medical manufacturer.

Applying the mirroring technique in the ΔDMM model to the holistic architecture approach reveals the delta between relations across product and compliance test and documentation views. By mirroring the architectures, it is found that more design elements are included in multiple verification tests regardless of their influence on the given function of the product. The same has been revealed in the functional testing against the customer domain validating the products shown in the product portfolio design. Here functional elements have been included in tests although these do not align with the customer need, neither do they support the use activity. These deltas drive complexity when tests are to be reused across the product program. For example, if a new design element is to be added or an existing design element is to be redesigned in order to enable new product functionality or enhance an existing one, the company cannot exchange these physical entities as they are constrained from a test perspective. It is therefore recommended to act on these in order to enable flexibility of the program developing new product variants.

6.4.3 Module-based Platform Design: Applications of the Driver for Compliance Testing and Documentation Reuse

Compliance is essential to medical device companies. Meanwhile, it is found that compliance (V&V) testing and documentation drives medical device complexity, whilst it predominantly consumes the R&D resources and highly affect time-to-market as compliance-related work extensively adds to the lead time of new products. Further, medical companies are challenged with ever tightening regulations, which complicates the maintenance of devices already brought to market. Thus, two external drivers for change are found to be of high importance to medical device manufacturers:

1) New or changes to customer needs require the company to introduce new product variants or enhance the performance of existing products, hence redesign of existing design elements.
2) Changes to the regulatory requirements force the company to investigate compliance documentation and potentially re-test existing products in order to comply with new regulatory enforcements.

In the first case, the company's ability to bring product to market at a certain lead time is highly affected by the time-to-approval (TTA), hence the lead time is influenced by the time spend testing and documenting the performance of the products prior to applying for market clearance. In the latter case, the company has a certain timeframe within which it is to bring its

products and documentation in compliance with the new regulatory requirements. The time it takes a medical device manufacturer to get in compliance with new regulations is here referred to as time-to-compliance (TTC) and is vital for medical companies as it can cause catastrophic effects on market presence if new requirements are not met by the company within the settled timeframe. TTC, which we define as the time by which it takes a manufacturer to reach compliance with present regulatory frameworks by means of building the required test documentation, plays an important role in the process of bringing new medical devices to market within cost and at time and within scope, which is seen as the ultimate obstacle delivering new medical devices to market.

It is essential for a company to shorten both TTA and TTC driving its competitiveness forward. Shorter TTA obviously strengthens a company's competitiveness, as new products can be launched at a faster pace. TTC can be turned around from being a burden to a competitive strength, as the company can choose to investigate regulatory trends and tendencies and incorporate these bringing it into the compliance frontier. Modularization is found to be a key enabler when meeting these challenges of the industry, hence the subject of compliance driven modularization. Focus will be on which changes to make and how this is done in order to reach the objective of developing medical device programs based on modular platform architectures (Fig. 6.45).

Meeting these challenges of the medical industry, one of the key driving forces for modularization of the product program is the driver for compliance testing and/or documentation reuse, hence the catalyst for compliance driven modularization. This brings higher flexibility towards market changes (customer needs and regulatory requirements), since these changes can be isolated to only affect delimited areas of the product program. Meanwhile, it can bring shorter time-to-approval and time-to-compliance as it enables parallel testing of modules instead of testing the entire device when the design has finished. Further, when tightening of regulations are announced, the traceability and thereby depiction of the affected areas of the product, its related testing and documentation, which is encapsulated into modules, can easily be identified.

The new requirements, its testing and documentation related to these modules can be re-examined based on the new legislative enforcements without affecting the other areas of the product program. Hence, using the MDM-based CACE modelling tool applying this compliance related catalyst for modularization creating a modular platform architecture for the medical device program can bring multiple benefits to a medical company.

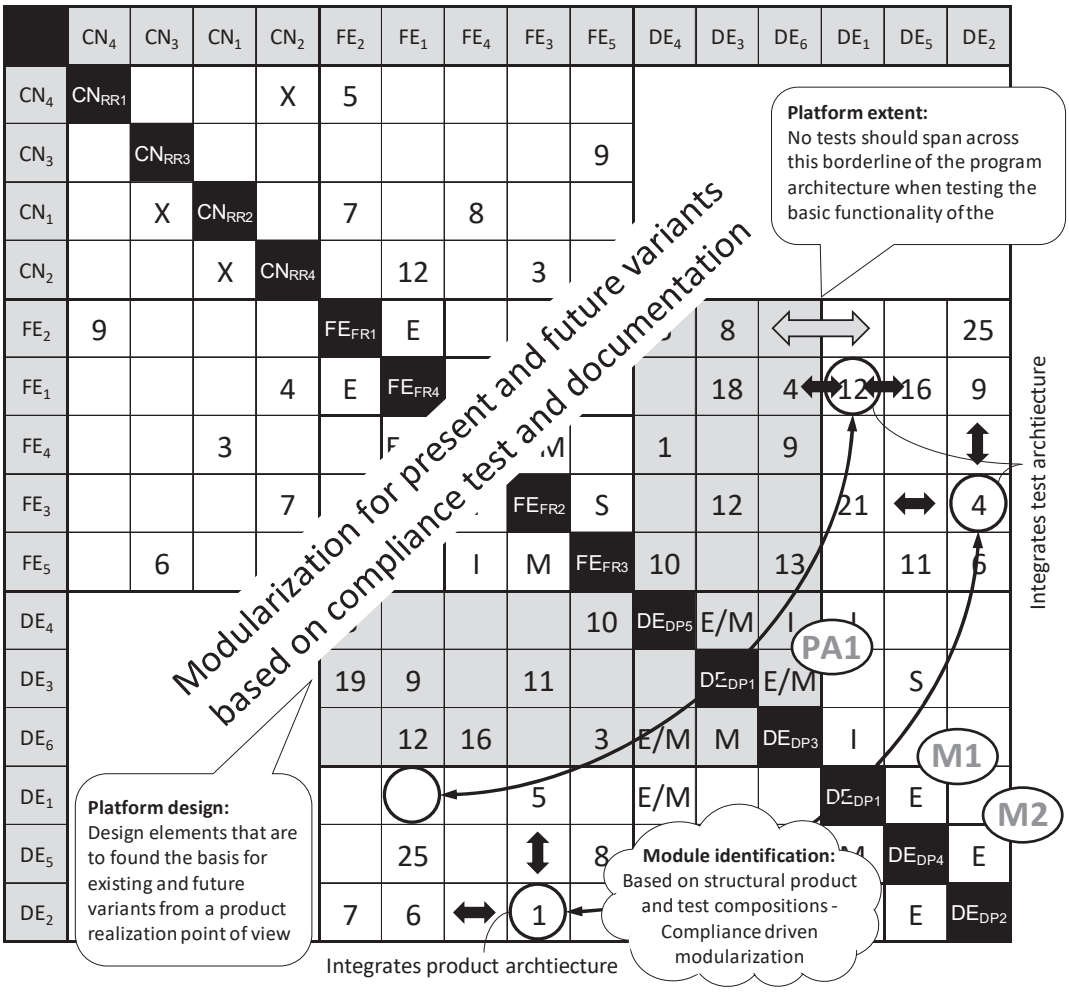


Fig. 6.45: Module-based platform architecture design: Identification of common and unique design elements for present and future variants, and potential upcoming changes in regulations

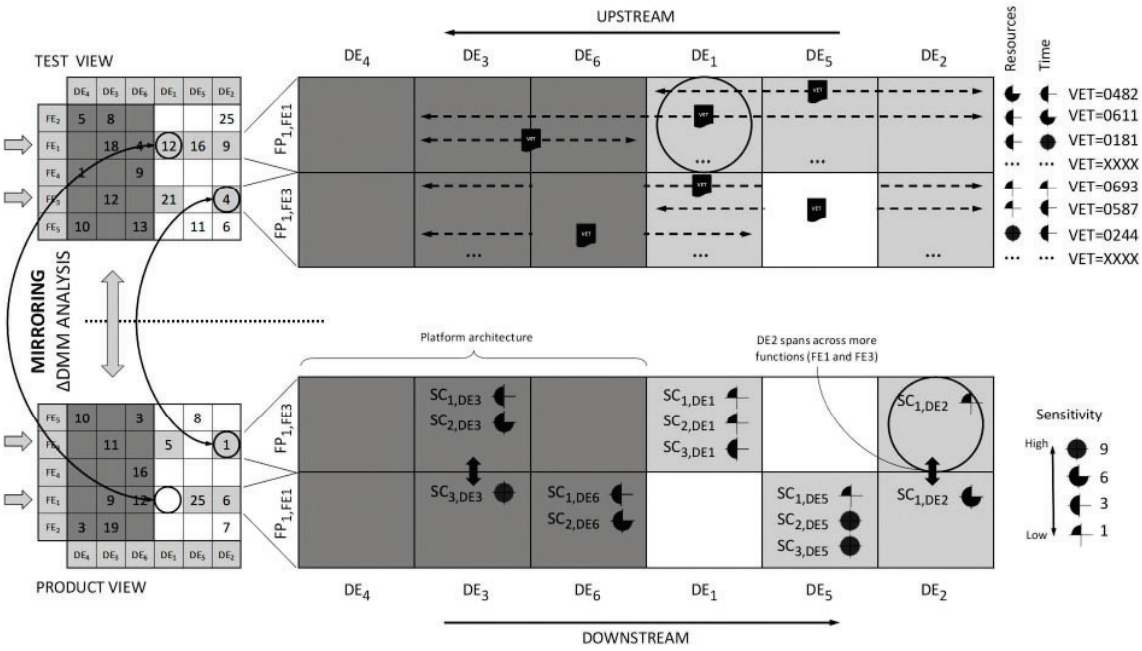
Before entering the compliance driven modularization with support using the CACE modelling tool and achieving its potential benefits, it is recommended that the design team has finalized the integration analysis and thereby have identified potential discrepancies across the views before initiating the module-based platforming of the product architecture. Though, the team should not necessarily have taken initiatives to solve possible identified issues, streamline the views by creating a one-to-one mapping, as this can be done following the modularization of the architecture.

When modularizing the product program, the design team should establish a roadmap for future variants that is believed to be launched. It is highly recommended that this roadmap entails an underlying technology roadmap that describes the needed technical solutions (modules) bringing the product variants to market. The design team should thereby be able to analyze for

common and unique design elements considering both existing and future product and technology differentiations. As the program layout (i.e. the foundation on which the design team is to create new product variants) is highly affected by the test and documentation view, the design team should not only, when modularizing the program, examine the product realization from a product point of view. They should investigate tests and documentation from a commonality and variety aspect just as with the product view, because the compliance material (V&V test and documentation) is the driving force for modularizing the medical architecture. Hence, it is not the engineering effort required designing new products, it is the test and documentation that drives the complexity and thereby time and resources of a medical device company.

As illustrated above (Fig. 6.45), the program has been modularized for test and/or documentation reuse. A modular platform architecture (PA1) has been designed based on present and future product variety looking into both product realization domains and V&V test domains. What constitutes the platform are those design elements (DE_3, DE_4 and DE_6) that are and continuously will be founding the basis for differentiated offerings to the marketplace. These are the design elements common to the products based on their commonality to product variants based on product and test analysis. It is important here, to look at long leads, as the platform design strategy should retain over a longer time span and across multiple product spin-offs in order to achieve full benefits of the efforts put into designing the platform. Besides the platform, modules (M1 and M2) have been identified based on present and future product and compliance work. Based on these considerations, when applying modularization to a medical device program, as illustrated above (Fig. 6.45), a few challenges surfaces leading to initiations of the following recommended corrective actions:

First, by analyzing the situation using the approach introduced in the previous section, one discrepancy is found to have high impact on the modularity of the product program, namely the test for the functional property of FE_1. Here, the design element DE_1 has been included in at least two tests (VET=0482 and VET=0611) although it does not have any influence on this function given its structural characteristics (Fig. 6.46). This discrepancy should be eliminated due to its constraining nature, i.e. the design team cannot redesign the identified modules, neither can they exchange modules for the purpose of creating product variety, which is the purpose of establishing the compliance-based modular platform architecture. Remember, one must include this design element in the tests that it is already a part of, whenever the medical market changes and new requirements are to be met, regardless if these are regulation- or customer-related.



Tab. 6.46: Quantification of discrepancies across the product and test view of the medical device program: Analysis based on the compliance-based modularization and modular platform architecture design

Second, as illustrated above, it is found that the underlying property model of the relation between FE_3 and DE_2 integrates both the product and test view of the medical device program. First, the structural characteristic $SC_{1,DE2}$ both influence the functional property $FP_{1,FE1}$ of FE_1 and the functional property $FP_{1,FE3}$ of FE_3. Second, this $SC_{1,DE2}$ of design element DE_2 influences the functional property of FE_3, although its relation is rated to have very little impact. This forces the company to execute verification tests to verify this cross-domain relation, which further constrains the architecture. The design team should pursue to circumvent such relations in order to raise the degree of modularity providing the intended flexibility of the program.

Thus, the design team should, based on the top-layer identification of discrepancies as a result of the modular platform architecture design, examine the underlying property and test models of product and V&V view of the product program. Critical property models and its related tests spanning across common and unique design elements should be unfolded as shown above. Here, it is identified that more tests span across both the platform and the design elements that form the modules. For example, verification test VET=0244 includes both DE_1 and DE_3, which should be avoided. Naturally integration tests are needed when design has finished ensuring the performance of the complete system (emergent behavior), but tests for basic functionality should be limited to those that are either common or unique, not spanning across both common and unique design elements.

Given that not all design elements and their structural characteristics affect a given functional property equally, it is of interest to highlight those tests where both unique and common components take part and where the unique components' level of impact on the property is low, as it is the case with $SC_{1,DE2}$ to $FP_{1,FE3}$. Elimination of these deltas should be pursued so that each property model is documented by a verification test only considering the design elements included in the property model. Thus, two classes of design elements should attract the design team's attention:

1) Those common and/or unique design elements that seem to have high impact on the functions (functional properties) if changed and in the same time take part in many and comprehensive tests. If these functional elements in addition are critical to patient or operator safety (following the risk profile) we may want to protect or at least fully understand these critical design elements.

2) Those unique design elements that only have minor impact on a function (functional property) if changed that spans common and unique components, but which are extensively tested in the V&V view. There may be a potential to scope these components out of the tests by intensively scrutinizing the relation and documenting it properly and if necessary, make a design change to minimize or eliminate the impact completely.

Verification tests are intended to prove the correctness (performance) of the conceived property models, i.e. how structural characteristics of design elements meet the functional properties of the functional elements. Compliance driven modularization developing medical device programs based modular platform architectures is intended to form a set of common elements that are shared across the range of products of the program, i.e. the platform.

Modularization of the medical device architecture is reached by means of encapsulating one or more design elements of the program while complying with the catalyst for compliance testing and documentation reuse. This is reached when the design team has: 1) a one-to-one mapping between product and test view, 2) identified the platform considering the commonality of the program, and 3) encapsulated strongly connected elements and decoupled these from other groupings of elements based on the compliance aspect of the medical device program.

In order to decouple verification tests, the design team should, following the description above, examine the physical realization of the products on the level of the property models. Meanwhile, the team should investigate the underlying test models. These property and test models should be examined with the objective to decouple design elements based on these views. Following this, two principles for decoupling is recommended:

1) Perform explorative testing and gain ample insight into the behavior (output) of the modular platform architecture by varying the inputs. The platform and modules that

have been identified based on the program layout, should play a central part of the explorative tests, so that the design team can make thorough rationales for the behavior of these elements of the system.

2) Apply design changes to the design elements aiming at manipulating the property models so that dependencies are eliminated. Design changes should ensure that interfaces to both the platform and among modules are decoupled to an extend where only integration tests are needed to ensure overall performance – no tests of basic functionality should be necessary, as these spanning across common and unique design elements will integrate the design of the product to test program architecture.

Whilst decoupling principles should be applied by means of exploration and redesign, the design team could apply robust design principles to vary input-output to elements ensuring rigid control of structural characteristics interference with functional properties reaching the accepted performance of the medical device variants. As a result of this, complete interface and interaction requirements to the platform and modules are documented based on input from the property models with unambiguous acceptance criteria. Although, this seem to be a meaningful step to take, it is out of scope of this research and therefore, it will not be treated further in this thesis.

The interface and interaction requirements metaphorically represent the “fence” protecting the platform and the defined modules from outside changes of the current and future program layout. The justification for reusing a test thus relies on proving whether the unique component complies with this set of requirements, which are founded on rationales that again are based on explorative tests for robustness.

Thus, compliance driven modularization is about encapsulating product to test and/or documentation elements for the reuse of compliance-related work (the effort required testing and documenting the product design). Correct decoupling using the driver for compliance test and/or documentation reuse, taking both the product and compliance view into account, enables reconfiguration of product variants and is an approach by which medical manufacturers can reuse compliance testing by adding and removing technical modules and related test and/or documentation packages.

This compliance driven modularization encapsulating variety for the carry-over of compliance test and/or documentation reuse, creating a one-to-one mapping across views with modules identification based on cross-domain dependencies both reduces TTA and TTC. It provides the required agility of the medical device program to meet new customer needs bringing new medical device variants to market at a shorter lead time, while it provides the possibility for the design team to plan the required test and documentation efforts and thereby set narrowed targets for product launches.

It is found that compliance driven modularization can bring robustness to a medical company. By applying the CACE modelling tool creating a modular platform architecture on which the medical device program builds, will create a more robust program towards changes in the regulatory environment. Not only because it will be possible to trace how such changes will affect the program, but because modularization for compliance testing and/or documentation reuse encapsulates design elements. Hereby, regulations that are likely to change and thereby affect the medical device program will be delimited to a module that is decoupled from others so that it will not propagate out in the system creating ripple effects. Thereby, the impact of change is reduced radically – less resource and shorter time is needed when getting in compliance with new regulations.

6.4.4 Architecture Concept Exploration: Evaluating new Medical Device Design based on the Compliance Aspect

New medical device development is a complex endeavor. Not only should medical manufacturers cope with the inherent complexity of their products, they should also be in control of tests and documentation in order to continuously comply with the regulatory frameworks.

Design concept evaluation plays a critical role in the early phases of new medical device development as it has significant impact on the downstream development processes. Within the medical domain, such decisions have substantial effects on the compliance test and documentation, which is critical to the success rate of bringing new medical devices to market. Essentially, design concept evaluation is a complex multi-criteria decision-making process involving large amount of data.

Quite some researchers have been working on quantifying the product realization of new product designs. These often are based on translating customer requirements into engineering metrics, which then are appointed the design elements of the system. Interaction and interface analysis then found the basis for creating product variety to meet the new market demands. That said, it has been found that little to no research have been done quantifying conceptual designs based on the compliance work of the development.

Meanwhile, it has been found that exactly compliance testing and documentation drives complexity and thereby extensively consumes R&D time and resources in medical device manufacturing companies, not the engineering effort needed to design the product itself. The CACE modelling tool enables first glance quantification of new variant design based on the compliance aspect (Fig. 6.47).

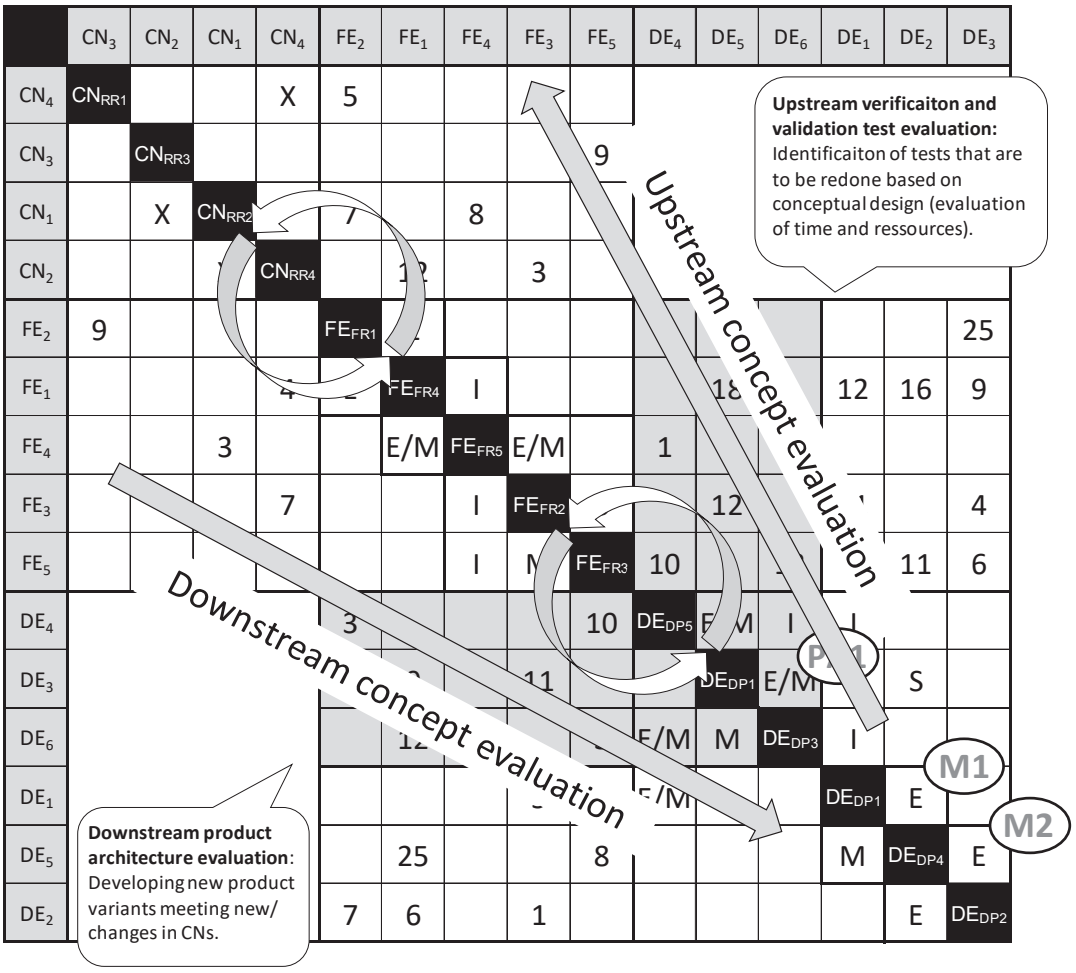


Fig. 6.47: Exploration of new conceptual architectures based on product and compliance realizations: Downstream and upstream architecture concept evaluation

Using the CACE modelling tool, it is possible to forecast test and documentation time and resource consumption when new medical devices are to be developed and launched to market and thereby the tool adds to the basis for making qualified decisions in the front-end. Further, it provides inputs to product, test and documentation planning as applying the tool makes it possible to better predict test cycle times and thereby improve the forecast for time-to-market. Naturally, such decisions should be made on a thorough foundation when meeting external drivers for change, e.g. customer needs, cost reduction, regulations, etc., which is what the CACE modelling tool can bring to the designers' table. Thus, the proposed tool supports two aspects of the front-end medical device development:

1) The ability to evaluate a design change based on the compliance burden related to bringing the design to market and evaluate different conceptual designs against each

other bringing a certain product (functional and physical realization) to market based on the test and documentation burden.

2) The ability to forecast the effort needed reaching compliance with regulations during the front-end of the medical device development process and systematically plan the tests (resources and time) needed in order to apply for market clearance of the new medical device design.

The application of the architecture concept exploration, like the previous applications of the CACE modelling tool, heavily builds on combining the two views of MDM-model. It provides an approach to evaluate the designs based on the architectural layout. From the product view, it is possible to review a given conceptual design from a product realization point of view. Whilst from the test and documentation view, it is possible to evaluate the conceptual design from a compliance point of view.

The CACE modelling tool is about investigating the conceptual design solution within the product domain (functional and physical view, hence the realization of the product design) and then mirror this solution into the compliance domain (verification and validation test and document) evaluating the effects from a compliance point of view. The tool thereby provides a systematic approach to the evaluation of compliance architecture-based designs during new medical device development.

When changes are to be made, either if these are caused by one or the other request, the design team should consider the product realization view using the traceability routing from market over functional to the physical domain. This enables the designer to get an overview of how the change requests dripple downstream the medical device program, i.e. analyzing the system change propagation and effects. Often such propagations will end up pointing at more design elements of the physical domain, which realizes a function that supports the given market requirements. Here, within the product architecture, the structural characteristics of the design elements have different impact on the functional domain; hence the functional properties to structural characteristics mapping.

Thus, if one or the other design elements are to be redesigned caused by a change in the market, this can be traced based on the product view. Upon this product analysis and detection of relevant/critical design elements, which can be redesigned, the design team can mirror that downstream trail into the upstream compliance view. By this, the design team is able to evaluate the change impact to the related test and documentation and thereby the required compliance-related effort in terms of time and resources changing one or the other design element meeting the new market requirement (Fig. 6.48).

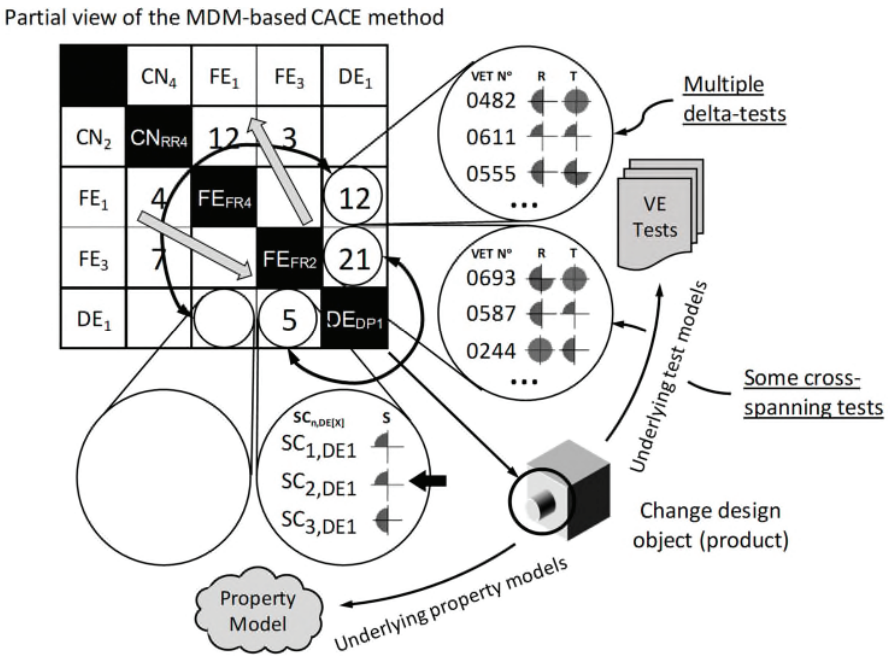


Fig. 6.48: Principle for changing a design element of the program: Change propagation analysis evaluating the effect from the product and test point of view

Depending on the initiatives taken prior to changing a design element, the consequence in terms of compliance-related resource and time consumption will vary. As the above figure illustrates, by example, if design element DE_1 is to be redesigned, three structural characteristics apply to the functional property of functional element FE_3. Looking into the upstream compliance view of the program, DE_1 has been tested for both FE_1 and FE_3. If none of the previous initiatives have been taken, two possibilities exist; one is to retest and redocument against both functional elements. This will raise the efforts testing and documenting the design change in order to stay in compliance.

Another possibility is to use the CACE modelling tool to make design rationales trying to scope out these tests when verifying performance of the redesigned DE_1. Although, the design team should be concerned with the fact that the company already has tested the element, which might raise concerns with the public authorities proving that this no more applies to the compliance view of the program. Therefore, it is recommended that the design team take initiative to analyse the program integration of the two views using the delta-domain mapping matrix and rationalize the product-to-compliance discrepancies prior to making design changes and developing new products.

Furthermore, some of the tests that have been carried out for FE3 also span across various design elements, i.e. DE1, DE2 and DE3 (Fig. 6.46 and Fig. 6.47). This additionally increases the effort required when testing and documenting FE3 relative to what could have been the case, if

the design team had established a modular platform architecture and designed the modules for compliance testing and documentation reuse (see 'Module-based Platform Design: Applications of the Driver for Compliance Testing and Documentation Reuse'). An important point is, if the designer had chosen to encapsulate the design elements, ensuring inputs and outputs with rigorous interface and interaction clarification, testing and documentation could have been isolated. Then, these would only take part on that new module with subsequent integration test ensuring the emergent behaviour and possible derivative effect of the system when combined into the desired medical device offering. As shown, compliance driven modularization of the medical device program can bring valuable assistance to the compliance effectiveness and efficiency of a medical company.

As already mentioned, market driven change requests may affect the program layout in such a way that more design elements are appointed meeting the changed use and/or need situation, as more design elements can realize the same functional element (Fig. 6.47). Thus, by means of mirroring the product view into the compliance view, the design team can evaluate whether one or the other change is the most profitable when it comes to complying with given regulations.

Thus, it might be possible to change the structural characteristics of another design element then DE_1 in order to reach the same performance of functional element FE_3 given the functionality of the device. This might require less testing and documentation by the R&D department, whilst it provides the same achievements both when it comes to performance (quality attributes) of the device and customer satisfaction. This predominantly is a result of the architectural composition of both the product and compliance view of the medical device program. Hence, the design team should take actions to modularize the medical device program driven by the compliance testing and documentation.

Not only can modularization for tests and documentation reuse lower the compliance burden of a medical company, it can quite drastically reduce the time by which a medical device manufacturer is able to compile the required compliance work establishing the application for market clearance to the public authorities. The current practice to compliance work is to initiate the test process late in the development cycle. With little control over the alignment of the product and test view, the underlying property models that influence the overall performance and the underlying test models verifying the performance, result in heavy testing and high uncertainties in the success rate of the compliance work (Fig. 6.49).

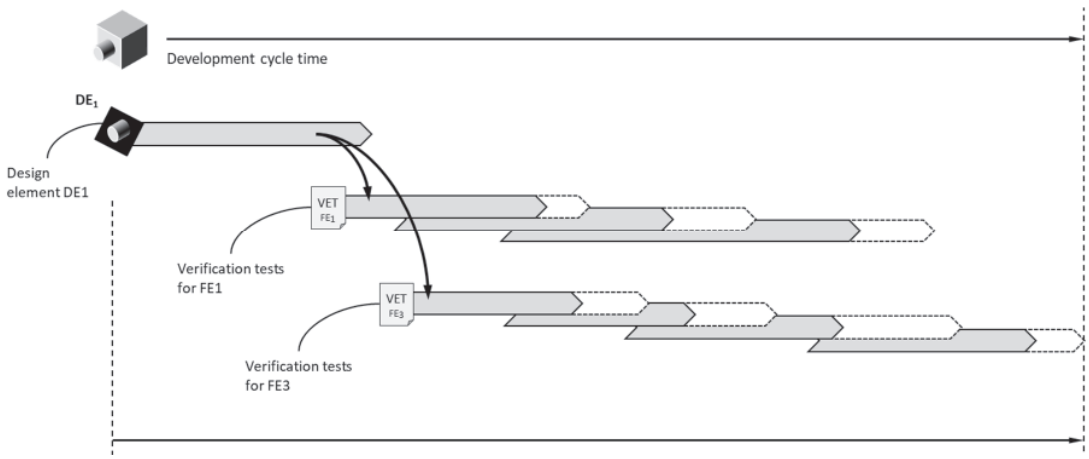


Fig. 6.49: Changing a design element based on the pre-modularized medical device program: Integrated product and test architecture require multiple re-verification tests

Having an overview of both the product and compliance aspects of the program enables more accurate technology and test road-mapping and potentially can shorten time-to-market for new medical device designs (Fig. 6.50).

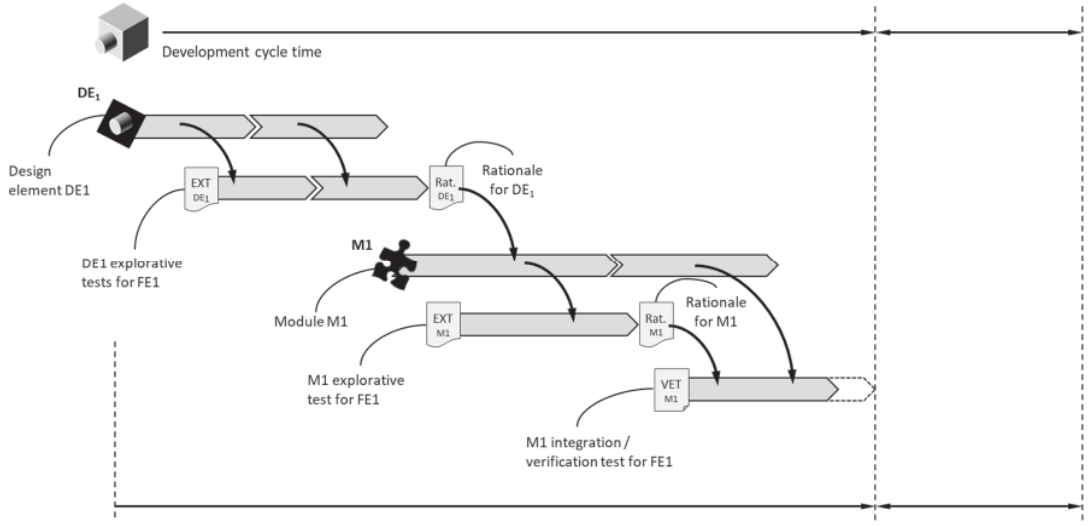


Fig. 6.50: Changing a design element based on the modular platform architecture: New explorative tests, rationales, integration tests and verification tests. Reduced resources and development cycle time

As the above illustrations indicate, the secret lies not only within the direct derivatives of the modularization for compliance testing and documentation reuse as described earlier. It also lies within the fact that modularization establishing a modular platform architecture for the medical device program can enable better explorative testing. Thereby it helps creating more rigorous rationales, which provides higher probability of success and less uncertainties in new

technology and test road-mapping. Further, it enables the design team to initiate both explorative and verification testing earlier than what is found to be today's practice. The designers can split the development task up into smaller chunks equivalent to the modules, which isolated can be exploratively tested upon which rationales can be made when designing the product and performance can be ensured gradually during the development process. The design team can thereby progressively build the compliance evidence, which both ensures that test results are achieved as expected and codification is initiated from the front-end of the design process, so compliance documentation is compiled and matured along the development of the new medical device variants.

6.5 Conclusions on the CACE Modelling Tool

The coherence of the product and compliance view depends on the manufacturers' ability to align the elements of the domains captured in the MDM-based CACE modelling tool. This potentially increases the efficiency handling the required test and documentation when developing new medical devices. The coherence of the critical domains to new medical device design can be controlled and managed by using the proposed CACE tool.

The functionality of the products must meet the voice of customer, while the performance of the product must comply with the regulatory requirements. Depending on customer needs, the use activities related to the need statements given the intended use and thereby the posed risk towards the human health and safety, classifies the products and thereby affect the test and documentation requirements modelled in the compliance view of the medical device program. This influences the level of required verification and validation tests needed to prove compliance with regulation. Further, the verification tests are experiments of the property models outlined in the product architecture, thus these relations go across the functional and physical domain (the product design), and these relations are mirrored in the compliance architecture.

Coherency supports the company in balancing the different elements and their complex pattern of relations to control meeting with customer need with its situated regulatory requirements: That the product variants of the program have the required performance level according to regulation, that the product variants are tested and documented properly, and that the cross-domain knowledge is properly captured and controlled with the purpose of insuring the human health and safety.

The CACE modelling tool provides a systematic approach to trace cross-domain complexities of the medical device program and thereby can be used as input to both the design history file (DHF) and medical device records (MDR) of the company. These are of high importance to the medical manufacturers as they prove control of the development and maintenance of the various

product variants to the regulatory authorities. By mapping cross-domain dependencies, the design team prove vigilance towards external drivers for change, they get in control of downstream product realization caused by market requirement fluctuations, and finally get in control of verification and validation tests that are to ensure correct performance (quality, reliability, safety, etc.) of the product variants within the program. Thus, the proposed tool provides enhanced traceability of product to test history of the development while it supports building solid medical device records for the fabrication of products.

The CACE modelling tool provides a structured way to follow the systems engineering V-model, as the MDM reflects this methodology. The tool applies quantitative measures evaluating the downstream product realization while relating this to the upstream verification and validation test/documentation. Further, this systematic way of relating elements of interest supports the design team in evaluating different conceptual designs meeting new market requirements. It helps identifying the translation of requirements throughout the development process and reveal which elements that are to be changed as a result of changes to the market. Because the regulatory frameworks set tight requirements for medical manufacturers that are to launch new products and maintain products already offered to the marketplace, manufacturers are under constant pressure to show compliance.

The CACE modelling tool provides the ability to systematically identify which elements that are to be affected by tightening regulation while it provides the ability to evaluate new product designs based on compliance capabilities. Thereby, the modelling tool support the medical manufacturer in being more proactive to changes in the external environment and potentially can harvest great competitive advantages driving its program design forward meeting new customer needs and changes to the regulatory environment.

Indisputable, establishing the domains entailed in the CACE modelling tool require resource and time investments, but as Paul McNulty once said: *"If you think compliance is expensive – try non-compliance"*. The CACE modelling tool covers four areas, namely: (1) prioritization and traceability analysis, (2) integration and discrepancy analysis, (3) platform and module design, and (4) new variant creation based on architecture concept exploration. These are sequentially introduced gradually extending the application meaning that a company can decide only to carry through e.g. the first and second part without initiating the module-based platform architecture design and the variant creation based on concept exploration. It depends on the company's situation and aim using the proposed tool. Although, if a company is to execute the latter parts, it is recommended that all parts are carried through following the order by which they have been introduced to reach the full benefits using the modelling tool.

Manufacturers that develop product programs subject to restrictive regulatory requirements and thereby are forced heavily to invest in compliance work, can harvest great benefits being in

control of its program. The CACE modelling tool is provided to support manufacturers facing the challenge of keeping track on the compliance aspect of developing new product variants while maintaining the product variety already brought to market. The tool is provided contributing to the modelling of modular platform architectures and extends the current body of knowledge by incorporating the compliance view to the modelling of product programs.

"If knowledge is not put into practice, it does not benefit one."
– Muhammad Tahir-ul-Qadri

Chapter 7

INDUSTRIAL APPLICATIONS OF THE COMPLIANCE ARCHITECTURE CONCEPT EXPLORATION MODELLING TOOL

The objective of this chapter is to show how the concept of Compliance Driven Modularization and especially how the proposed Compliance Architecture Concept Exploration (CACE) modelling tool can be applied in practice. The industrial case, which frames the applicability testing of the CACE tool, heavily builds upon the description of the tool in the previous chapter. Thus, the aim of this chapter is solely to shed light on the usefulness of the tool through exemplification, hereunder to show: (1) how the MDM-based tool is filled out by executing the prescribed analytical exercises, (2) how the tool can support the front-end development and maintenance work of the design team, namely the four areas of support provided by the CACE tool: (a) traceability, (b) mirroring, (c) modularization, and (d) concept evaluation. Finally, this chapter is to show (3) how the CACE tool can support the design team in navigating the front-end multi-product development of medical devices – hence, the development and maintenance of medical device program designs. The chapter closes by outlining the economic effects of applying the modelling tool.

7.1 INTRODUCTION TO THE INDUSTRIAL APPLICATIONS

This chapter is to bring the theoretical contribution of the CACE modelling tool into practice and thereby illustrate how the tool can be applied in an industrial setting while it seeks to show how the tool can bring competitive advantages to a medical device manufacturer. The case presented as exemplification of applying the CACE tool is based on an empirical case study. The case results

build on a three-and-a-half-year study of one multinational manufacturer of advanced medical devices within the business area of life sciences and diagnostics. Preliminary results during of the case study were first revealed by Jensen (2013) and later enhanced by Jensen et. al (2015). In this chapter, the results using the CACE tool will be described. The results shown in this chapter are based on data obtained within the real-world. As described in chapter 2, multiple case studies have been carried out supporting the research study. They have been used throughout the research study and thereby have supported both the development and testing of the CACE modelling tool. The case company chosen for illustrating applicability has been used for testing of the tool and thus has been acting as the backbone of the research V&V process, and therefore has been chosen to illustrate the capabilities of the CACE tool. The chapter will provide:

- *An introduction to the industrial case setting*: First, the scope and objective of the case study will be introduced. Next, the case company will be presented, where an introduction to both the market application and the product program will be provided. Upon this, a description of the business case will be provided. This collectively is to set the context within which the tool has been applied and tested.
- *Description of how to bring the tool into industrial practice*: Second, it is described how to fill out the CACE modelling tool based on the formalisms introduced in the previous chapter. Here, the focus will be on the three predominant views provided by the tool, i.e. market, product and compliance. The description will sporadically provide insight to the analytical exercises recommended to be carried out by the design team during the establishment of the CACE tool. The description will not cover all aspects of each view, but instead it will provide an overall description of how the different domains of the CACE have been established.
- *Description of how to use the tool for analytical and synthesis purposes*: Third, a description is provided on how the case company has been using the CACE tool for both analytical and synthesis purposes. Analytical, as the tool has been applied to provide the design team with an overview of how the current situation is; hence, the performance of the medical device program from a market, product and compliance point of view. Namely, the tool has been applied for traceability and discrepancy analysis. And synthesis, because the company has used the tool to explore how they should navigate the front-end development landscape based on its situational awareness, which has been provided by the CACE modelling tool. Here, the description will touch upon the elements that the tool is able to enhance, i.e. modularization for compliance reuse and architecture concept exploration.
- *An overview of the effects of applying the CACE tool in industrial practice*: Last, the effects the case company has gained will be described. Here, emphasis is put on how the CACE modelling tool has provided the design team with a rigid decision basis for selecting its

inroads towards new markets while it has provided the design team with a fundamental understanding of how changes to one element of the program affect others, namely the product-to-compliance view of the medical device program. Meanwhile, it will conclude on how the tool have brought additional competitive advantages to the company, which will lead to the thesis to its closure.

These four areas collectively aim at describing the utilization of the CACE method while it aims to test and thereby justify the provision of the new proposed tool as a result of this research.

7.1.1 The Case Study: Research Scope and Objective

The objective of this chapter is to answer research question RQ3.1: *"How can modularization of a product architecture be applied to address a medical device company's dependence of regulatory compliance?"*. Thus, this chapter is to provide insights into the applications of the Compliance Driven Modularization research contributions hereunder particularly to show the utilization of the CACE tool proposed, both as an analytical tool for rationalization of medical device programs and show its applicability in the front-end synthesis of new medical devices.

The scope of the practical contribution, the utilization and testing of the CACE modelling tool, will focus on the architectural composition (functional and physical domain) of the product view to the verification test and documentation of the compliance view of the program. There are two reasons for this: (1) the lower part of the CACE model relates to the engineering view of the program and thereby is of highest accordance to the offset of this thesis, namely the 'Copenhagen School' of engineering design and product development, and meanwhile, (2) the verification test and documentation domain is found to be the most resource and time consuming part of the compliance aspect when maintaining a medical device program and developing new medical devices. Thus, in this chapter showing the applicability of the CACE tool, the product portfolio and validation testing and documentation is scoped out.

The case study presented has been conducted in one case company within which the focus has been on one central product program to the company neglecting other product assortment offerings. Namely, the focus has been on the arterial blood gas (ABG) sampler product program. The reason is that the company with its ABG sampler program has been found to pose core characteristics. Namely, the company with its current product program is subject to: (1) specific changes to the regulatory environment, hence tightening of requirements, (2) manifold demands from customers, hence new product offerings, and (3) a general raise of test and documentation, which burdens core units of the company. Last, when applying the CACE tool analyzing the chosen product program for maintenance and synthetization, the scope will largely be on the mechanical aspects of the engineering domain. Thus, the manufacturer faces great challenges maintaining its current product program while it lacks insight into the effects of choosing one

product development project over another. Meanwhile, the product variants are simple enough to grasp but still very complex in its product-to-compliance setup. Therefore, this case study seems to be fit for presenting the applicability of the CACE tool.

7.1.2 The Case Company: A Medical Device Manufacturer

The case company is a leading manufacturer of medical devices for testing and measuring of blood gases and provides high technologically advanced acute care solutions, which aims at simplifying and automating the phases of acute blood gas testing. The company's brand relies heavily on high quality, and in order to remain the leading provider of high technologically advanced acute care solutions, and to gain market share at both established and emerging markets, it is of great importance to the company that it continuous to stay in compliance with products already at market and improves its ability to bring new commercial variants to market, while concurrently reduce resource-related costs maintaining its program while reducing time-to-market for new product designs.

The company is continuously faced with the challenge of maintaining its medical device program. Due to tightening regulatory requirements, the product variety is demanding heavy compliance-related time and resources. New market needs and wants forces the company to launch new commercial variants, which due to complex intra- and inter-related couplings across the product and compliance view of the product, between components and subassemblies and verification test and documentation, increases time-to-compliance (TTC) meeting new regulatory requirements while it rises product time-to-approval (TTA), which heavily affect time-to-market and substantially consume research & development (R&D), regulatory affairs (RA), and quality assurance (QA) related resources.

7.1.3 Product Application Area: Arterial Blood Sampling

Arterial blood gas (ABG) sampling is a medical technique used for blood gas analysis and is utilized in order to monitor the physiological condition of a patient. Arteries are high-pressure vessels that transport blood from the heart and carries oxygenated blood, hence it carries over twice the amount of $pO2$ than a vein and therefore is the best type of blood for blood gas analysis providing the best information about the oxygen status, which is of primarily concern in ABG sampling. The purpose of arterial blood gas sampling is to clarify the patient's respiratory condition and acid-base balance, and therefore is commonly used on patients whose breathing is either controlled mechanically or who have respiratory challenges. Thus, this type of monitoring through blood gas sampling is mainly for serious ill patients.

There exist various methods by which it is possible to obtain arterial blood samples, i.e. by arterial puncturing, arterial line or capillary samplers. Most of all samples for blood gas testing

are collected with syringe-type samplers. Arterial blood sampling will typically be taken from a patient in any department where blood gas is standard. Sampling techniques are characterized by either arterial line (A-line) or arterial puncture (A-puncture) sampling (Fig. 7.1).

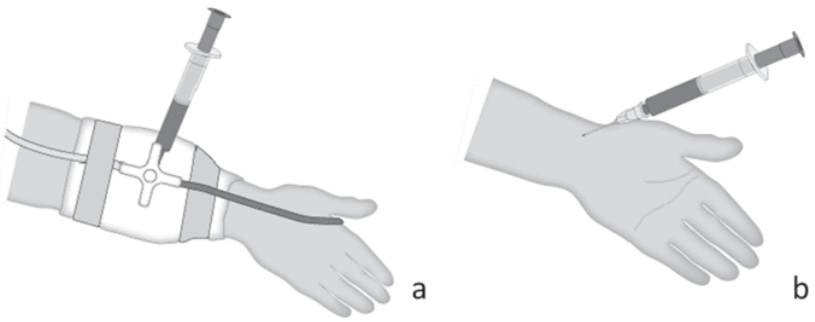


Fig. 7.1: Sampling procedures: A-line samples are collected with an aspirating (ASP) or self-filling (VENT) syringe from a catheter (a) and A-puncture samples are collected ONLY with self-filling (VENT) syringes with an attached needle.

A-line sampling (Fig. 7.1, a) is used on patients who are admitted to hospitals in an intensive care unit for a longer period. The patients are often anesthetized, ventilated and highly medicated, and must be under constant surveillance. Therefore, they may have taken several arterial samples, and in order to avoid puncturing the artery each time a sample is required, an arterial catheter will be placed, from which the sample can be obtained. In order to take a sample, first the saline must be removed from the A-line. The blood is afterwards obtained using either the self-filling (VENT) or aspirating (ASP) technique. Like in the case of A-puncture, after filling the sampler, all possible air in the sample must be expelled in order not to bias the pO_2 results, and finally the syringe must be sealed and mixed with anticoagulant.

A-puncture samples (Fig. 7.1, b) are currently collected ONLY with self-filling (VENT) syringes with an attached needle. A-puncture sampling is used on patients who are admitted to hospitals in an emergency care unit and is recommended to be taken once or twice a day in order to get the overall status of the patient. A-puncture is more demanding than a venous puncture, thus only trained professionals can perform an arterial puncture. The puncture site by which the sample is obtained depends on type of syringe and patient, though in either way the syringe should be positioned in a 45º angle in respect to the plane of artery. A self-filling sampler will allow the blood to flow automatically into the syringe as soon as the needle punctures the artery wall by the means of the capillary forces. Whereas, an aspirating sampler requires the operator to manually draw the blood into the syringe, by pulling the plunger after artery penetration.

The influence of pre-analytical errors has reached significant attention over the last decade. Basically, there are two reasons for this: (1) pre-analytical errors affect accuracy in specimen analysis and thereby customer care and (2) pre-analytical errors directly translates to sampler

performance, or issues herewith, in the eyes of the customers and thereby influence company reputation and market positioning. Pre-analytical errors play a significant role in the shaping of medical devices that are to target this business area. The reason is that pre-analytical errors are subject to bias, which affect the human health and safety, and these are related to both the use activities and technical performance of the arterial blood gas samplers.

Thus, pre-analytical errors are of importance because of two reasons: (1) they arise from misuse of samplers, which relates to the market view of the CACE model and is to be proved minimized through thorough product validation test and documentation, and (2) they relate to the technical performance of the products, which should be proved compliant through critical product verification test and documentation. Therefore, the subject of pre-analytical errors plays a significant role in the shaping of the medical device program and thus is a central underlying aspect when modelling the medical device program and testing the applicability of the CACE tool.

7.1.4 THE PRODUCT PROGRAM: 27 ABG SAMPLER VARIANTS

The ABG sampler program, which is to be modeled using the CACE tool, consists of several medical device variants (referred to as ABG samplers). The product variants can be grouped according to familiarity (shared functionality, structures and technologies), while yet they possess specific features meeting specific customer requirements of different markets (Tab. 7.1).

ABG Family A (ASP)	**ABG Family B** (ASP*plus*)	**ABG Family C** (VENT)	**ABG Family D** (VENT*plus*)
This basic product family consists of aspirating samplers for aspiration of sample volumes in the range of 0.5-2.0 mL and is for arterial line (A-line) use only.	The family consists of more advanced aspirating variants of the ABG Family A. The samplers are for A-line use only with a volume range of 0.7-1.7 mL	This family consists of self-filling samplers for either A-puncture or A-line use, and allow the obtainment of sample volumes in the range of 0.3-1.5 mL	The family consist of highly advanced samplers based on the C family. They are self-filling for both A-line and A-puncture sampling and has a volume of 0.7-1.5 mL

Tab. 7.1: The ABG sampler families currently making up the case company's medical device program

The product variants are divided into four families based on the level by which the variant supports the customer requirements mitigating pre-analytical sources of error in arterial blood

sampling process, use activities and technical solution, relating to the views of the CACE model. These four families target specific market segments, while each family member (product variant) addresses specific subsets of customer needs within market segments. The ABG "Family A" represents the basic sampler target at the lower end of the cost-conscious segment, whereas ABG "Family B" represents the more advanced variant targeting the premium customer segment, with mixing ball, barcode and vented tip cap, though build on the ABG Family A sampler foundation. The ABG "Family C" on the other hand target the cost-conscious segment and the upper end of the cost-conscious segment while the ABG "Family D" targets the premium customer segment.

7.1.5 The Company Business Case: Changes to the Regulatory Environment and an Increasing Demand for New Variants

Due to increasing regulatory requirements, the product variety is demanding heavy resource efforts maintaining the current medical device program offered by the company. The ABG sampler program currently consist of 27 variants launched to the global marketplace which stretches a manifold of regulatory requirements set at different risk classes, which the products are subject to. Meanwhile, these requirements are at change, constantly tightening and therefore the company continuously must clarify how these changes affect the individual variants placed on those different markets. Namely, the company seeks to get a better understanding of how changes to a specific regulation affect the maintenance work keeping the variant within compliance given the regulatory framework.

Thus, momentarily the company is experiencing challenges tracing the specific effect of the individual regulatory changes, which is critical to the success of staying in compliance with current regulatory frameworks. Namely, the company is challenged with foreseeing how specific regulatory change require changes to the verification test and documentation domain and thereby lack sufficient knowledge evaluating the change effects in order to stay in compliance with the current regulatory frameworks, which in this research is found to be a direct result of tracing structural dependencies among the domains and finally the product program architecture design. Therefore, the company is in need for structural support evaluating regulatory changes and its effects to the product program at hand.

Meanwhile, the company wish to establish a solid foundation on which the company will be able to develop and market new product variants. Currently, it is found that the medical device program's underlying architecture does not provide ample flexibility towards bringing new products to market based on the existing architectural composition. The company is in need for a tool that visualizes the product program compositions and that offer insight into possible

modularizations taking compliance into account. Hence, the theme of this research: Compliance Driven Modularization.

Finally, the company experience difficulties making solid and propriate decisions regarding new product introductions. This is because the company lacks insight into one of the most important life-phase disciplines of the medical domain, namely the regulatory compliance and how this affect new product designs when it comes to probability of succeeding with the design while bringing the time and resource consumption spend on the regulatory aspect of bringing new products to market into account.

Thus, currently the company it is in need for a structural approach to gain insight into how changes to the marketplace and especially the regulatory side of it affect the company through its current product program design. Meanwhile, it is in need of a structural approach to evaluate current and possible future architectures, enabling the company to evaluate new product designs from the compliance test and documentation point of view, and how this might change the overall evaluation and add to the foundation on which the company decide to pipeline and execute new product development projects.

New Strategical Company Targets

New market requirements force the company to launch new commercial variants, which due to complex intra- and inter-related couplings rise product time-to-market and substantially require resources. In order to meet new business opportunities, the company needs to build a robust foundation that ensures high performing products, that enables the company to bring new product variants to market and lower the cost of developing new product variants with regards to compliance work.

According to the strategic plan, the company has set the goal to double the overall sampler revenue within the next five years. This surplus in revenue should be generated based to an increase of overall syringe sampler sales (the existing product program) and by introducing new product variants, or arch types (foundation for a family of products). To reach the strategic goal of growing sampler revenue, the case company is going to pursue the following:

1) Enhance existing variant performances by launching “Product A”
2) Penetrate emerging markets by introducing “Product B”
3) Introduce “Product C” to gain share at high safety demanding markets
4) Introduce “Product D” sampler to attack high-end emerging markets
5) Launch “Product F” for minimal invasive treatment at established markets

Although, pursuing to reach these strategic targets, the case company is challenged within different fields. Whilst the company must introduce new product variants in order to raise market share and overall sampler revenue, the current sampler product structure or program architecture is complex and currently offer little to no re-use of both design elements and compliance material. This leads to high cost (resource expenditures) and long lead time for new product introductions.

From a new front-end product introduction point of view, the synthesis application part of the CACE modelling tool will focus on "Product B", while the analytical application of the CACE modelling tool focus on abilities of the company's current program exemplified by specifically chosen findings. Thus, the description will not reveal in detail, how the company has acted upon all findings of the study. Based on this analysis, the case will illustrate how the CACE tool has provided the company with the ability to create a more modularized compliance centered architecture upon which the design team can develop new medical device variants at less resources and shorter time-to-market.

As described, five new arch-type device variants are to be developed and launched. For ease, only one new product variant will be considered exemplifying the synthesis part of the CACE modelling tool. Although, all variants are considered analyzing the current situation modelling the foundation and improve this by modularization for the ease of new variant creation. All five variants will be considered in the final evaluation of the tool as they all have taken part in the case study.

In the following, the CACE modelling tool is applied to show the benefits of using the tool, both for analytical and synthesis purposes handling complex medical device programs in a heavy regulated environment as is with the case company chosen for illustration.

7.2 Modelling the ABG Sampler Program using the Proposed CACE Tool

The modelling of the ABG sampler program will focus on the three views provided by the CACE tool. Namely, it will describe the medical device from a market perspective including customer needs and thereby describe the program from a variety point of view. Further, the market view will include regulatory substances relevant to the program and thereby offer a practical description of the analytical exercises that are to be carried out in order to establish the customer domain of the CACE modelling tool. Next, a description of the concrete product view is provided establishing the downstream view of the CACE tool. Here, functional elements and its materialization will be described filling out the functional and physical domain of the modelling tool. Further, the description will touch upon filling out the downstream view, which lies in

between the two domains entailed in the product view. Last, the compliance view offered by the CACE tool will be treated. Here, primarily the verification test and documentation design will be described. The section ends by summarizing how the CACE model looks for the current ABG sampler program. Thus, the section will focus on describing how to fill out the CACE tool carrying out selected analytical exercises. The section will not cover all aspects but aims to provide the reader with an understanding how the tool can be brought into practice by concrete exemplification.

7.2.1 Market View: Customer Needs and Regulations

The following will describe the market view as illustrated by the CACE tool. The section will walk through depicted analytical exercises that led to establishing the final customer domain for the ABG sampler program. The market view will entail the two predominant aspects of the market as prescribed by the tool, i.e. the customer needs and the regulations, as external factors that drive the changes to the medical device program. The section will in short walk through key outcome of analyzing the market trends and tendencies, its segmentation and differentiation, while looking into customer needs, its use activities and the intended use, which lead to describing the regulatory aspects, i.e. relevant risk classes and its regulatory requirements. This leads to the combined customer domain for the analyzed ABG sampler program, which was later used as input to the CACE modelling tool.

Market Tendencies, Its Segmentation and Differentiation

The ABG sampler market of the case company can geographically, on a global basis, be divided into two main segments, i.e. established markets and emerging markets. The established markets cover the European countries, USA and Japan, whereas the emerging market covers Brazil, Russia, India, China, and Middle East. Further, the geographical segmentation can be divided into hospital units, i.e. point of care (POC) and laboratories (LAB), which have very different attributes depending on their aim of medical treatment. These units with their different environments and purpose lead to diverse customer demands.

When carrying out the market segmentation grid following the proposed tool, the segments represent business units, here POC and LAB, and tiers represent the risk classes in order to gain insight into the complexity of the market dispersion. In this study it was found that tiers can be separated into two categories, namely IVD, which represent less risk-sensitive products and MDD, which representative high-risk products.

During the analysis, it was found that progressively more hospitals at emerging markets require high-end products, which the case company offers, but still the products must meet special regional needs, e.g. LAB needs MDD products in order to carry out procedural ABG processes.

Meanwhile, these markets were found to become highly regulated by public authorities who tend to tighten their control of both the companies that manufacture and bring medical devices to market, and the hospitals executing the medical treatment. In order to get an overview of these market conditions, a market grid has been established (Fig. 7.2).

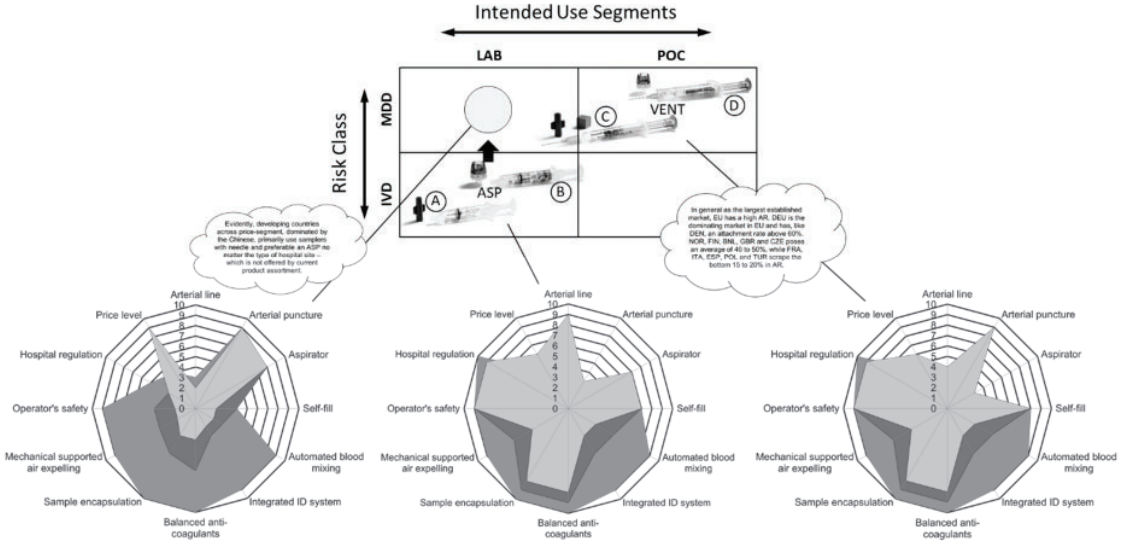


Fig. 7.2: ABG market segmentation grid: Showing the leverage across LAB and POC (use context) applying the risk classification (regulatory graduation) as market tiers while showing the customer preferences across eight different value generators (performance parameters) on a global basis

The radar diagrams reveal that there exists no diversity across the POC and LAB segment at the emerging markets, in terms of customer demands. At established markets, customer demand diverse types of sampler functionality, which is linked to the usability during the use activity of the product offerings:

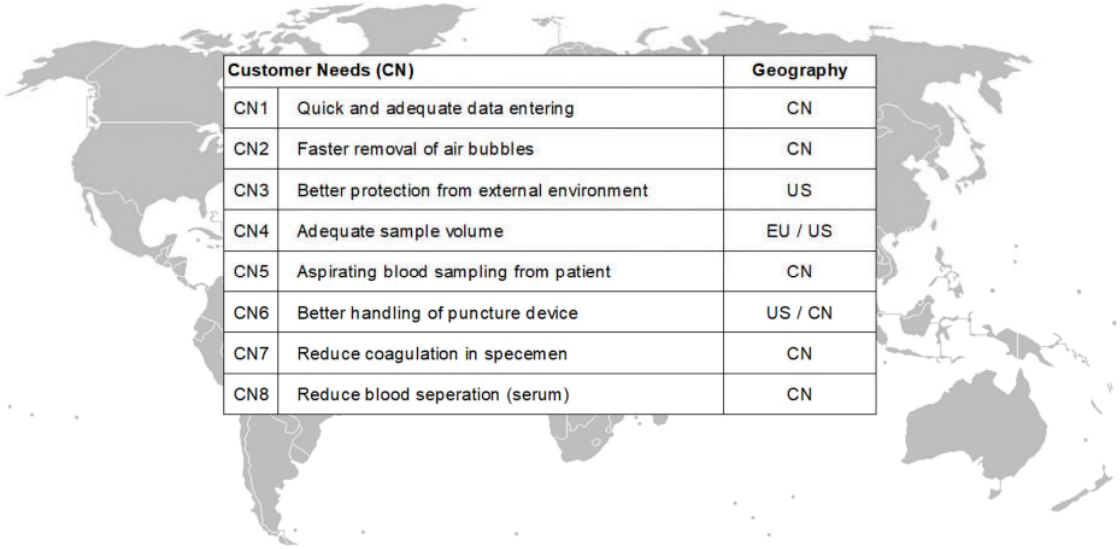
- At emerging markets, both POC and LAB units demand aspirating arterial puncturing devices (MDD classified samplers). Although, the case company does not “Product B”.
- High-end samplers, as those offered by the company’ program, is at increasing demand at emerging markets. Meanwhile, price points remain very important to customers.
- At established markets, POC segment demands A-line and do not distinguish between ASP and VENT samplers. LAB demands A-puncture samplers and only use VENT devices when puncturing arteries.

Meanwhile, the regulatory situation is to change in the emerging markets, namely China is to base new medical device regulations based on the FDA approach in the US, which heavily will change the regulatory environment affecting both products already launched to these markets and the process of getting market clearance for new products.

Conclusively, during the VOC process, it was found that the company does not on a large scale meet the customer requirements in emerging markets. As the above illustration shows, the company momentarily lack high-risk offerings at the LAB market, which is due to changes in emerging markets. The company is to pay attention to these raising markets, which differentiate in customer needs and wants. Further, the case company does not offer specific solutions that are needed in order to further penetrate established markets.

Voice of the Customer: Setting the Customer Needs

During the voice of the customer process, eight customer needs have been gathered covering the global arterial blood gas market relevant to the company (Fig. 7.3). Please note that the gathered VOC is based on the global market spread at which the company is currently present and thereby fluctuate across market segments.



Customer Needs (CN)		Geography
CN1	Quick and adequate data entering	CN
CN2	Faster removal of air bubbles	CN
CN3	Better protection from external environment	US
CN4	Adequate sample volume	EU / US
CN5	Aspirating blood sampling from patient	CN
CN6	Better handling of puncture device	US / CN
CN7	Reduce coagulation in specemen	CN
CN8	Reduce blood seperation (serum)	CN

Fig. 7.3: Customer need statements gather through voice of the customer process. Three major markets to require new product improvements, i.e. US, EU and CN. Four of the five statements by CN is momentarily covered by the program offerings.

As the illustration shows, emerging markets are requiring more advanced samplers, which the company currently offers to the more established markets, i.e. by the ASP*plus* and VENT*plus* family. This concerns the quick and adequate data entering (CN1), faster removal of air bubbles (CN2), reduce coagulation in specimen (CN7), and reduce blood separation (CN8). Meanwhile, it was found that e.g. China requires high-end samplers for aspirating blood sampling from patient (CN5), which is currently not offered by the medical device program (c.f. the earlier description of the ABG sampler program). Meanwhile, during the analysis, it was found that established markets, such as the EU and US, is requiring more adequate sample volume (CN4) and better

handling of the puncturing devices (CN6), which also applies the emerging markets. Further, it was found that the US market is great need of a high-end sampler that pose better protection from the external environment (CN3), which is currently not offered by the company's ABG sampler program. Thus, when looking at the gathered customer needs, the company is to enhance its product portfolio while it must penetrate new markets with products already offered by the current medical device program.

Use Activities and Intended Use

When the customer needs have been gathered, following the prescribed steps of filling out the CACE modelling tool, the next step is to investigate the use activities and map these against the customer needs, as this in combination create the basis for the intended use and thereby the characterization of the medical ABG market (Fig. 7.4).

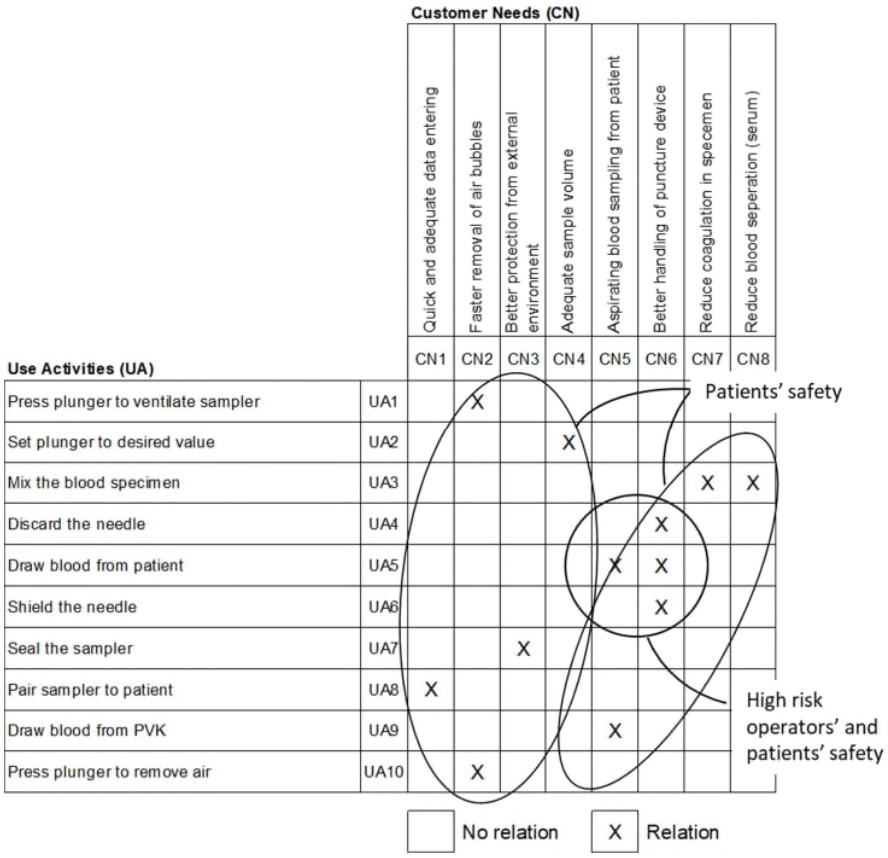


Fig. 7.4: Mapping customer needs against use activities establishing an overview of how the VOC is realized during operational procedures undertaken by the operator

As shown in the above illustration, during the analysis it was found that the different customer needs apply to a wide-spread spectrum of use activities. In total, ten activities were identified,

which can be separated into two categories of marketing products "for the human health and safety" stated by the public authorities, i.e. patients' safety and operators' safety. All activities apply to the theme of pre-analytical errors and therefore is of great importance to the market. By establishing the CN-to-UA matrix, the team got to discuss varies aspects of the possible forthcoming development projects. E.g. it was found that UA5, to which both CN5 and CN6 apply, concerns both patients' and operators' safety. Thereby, this gives rise to concern when it comes to risks meeting these customer needs. This is because new product launches are required in order to meet CN5 stated by new entry markets, which should be further treated in the modelling using the CACE tool.

In order to further feed the discussions following the CACE tool, based on the knowledge obtained and in order to raise discussions among the marketing and development departments, a holistic view was created in collaboration with the teams providing a common understanding of how the market is looking mapping the use activities and product offerings based on current family compositions (Fig. 7.5).

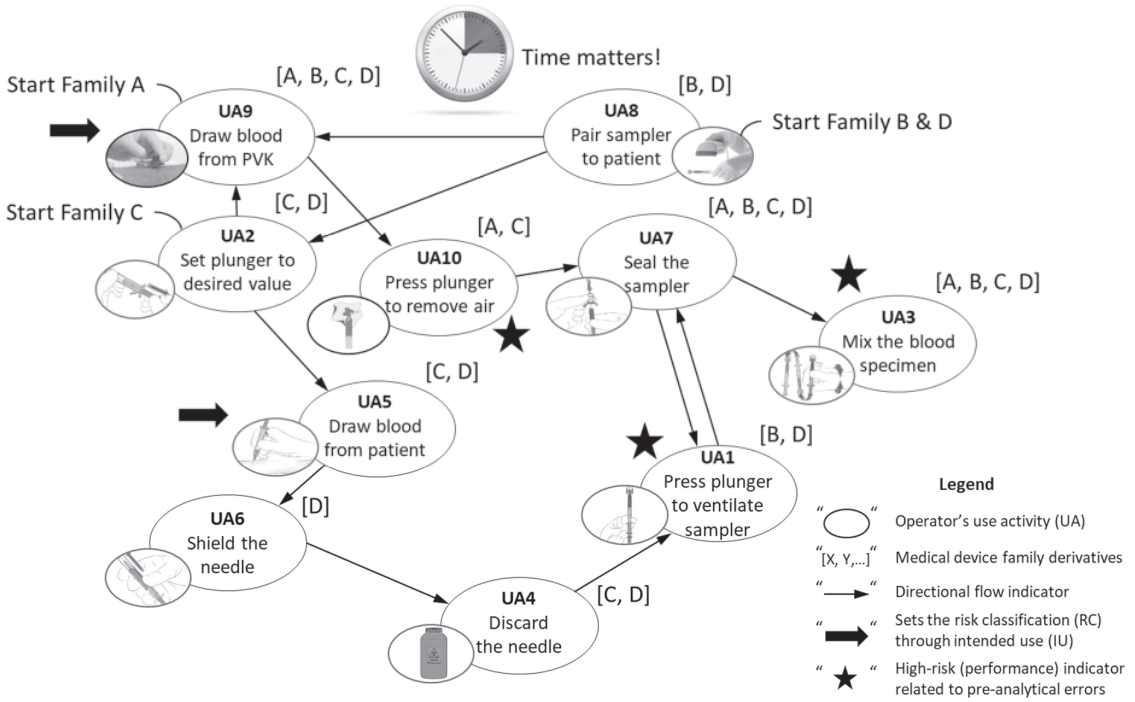


Fig. 7.5: Use activity flow chart presenting the predominant sequential steps during the ABG sampling process indicating all four medical device families

As shown, the illustration depicts required directional flow of activities to be carried out during the operational procedures. As written in the top of the illustration: "time matters!". Not only must activities be carried out in the right sequence, they also must be executed in the shortest

time possible. This is a core deliverable of the high-end "*plus*" variants of the ABG sampler program. These are critical to the pre-analytical errors and in general the purpose of marking medical devices, namely, to support the human health and safety. By investigating the use activities (based on Fig. 7.4), the teams were able to grasp the complexity of current market constellations and comprehend the company's current situation looking in to current and new markets. By this simple analytical exercise, it was revealed that UA1, UA3 and UA10 pose the highest risk. The reason for this is that these have the highest effect on pre-analytical errors and thereby is of great concern to both customers and the public authorities.

Risk Classifications and It´s Regulatory Requirements

Risk classes are, as earlier described, of critical importance to the compliance work needed in order to launch new products to the medical market while staying at these markets. Meanwhile, these are of great importance to products already launched to the marketplace. Therefore, it is crucial to investigate how the current product program with its market spread are being subject to legal requirements. For this reason, these constellations were mapped for the team to get an overview of how such market conditions are (Fig. 7.6).

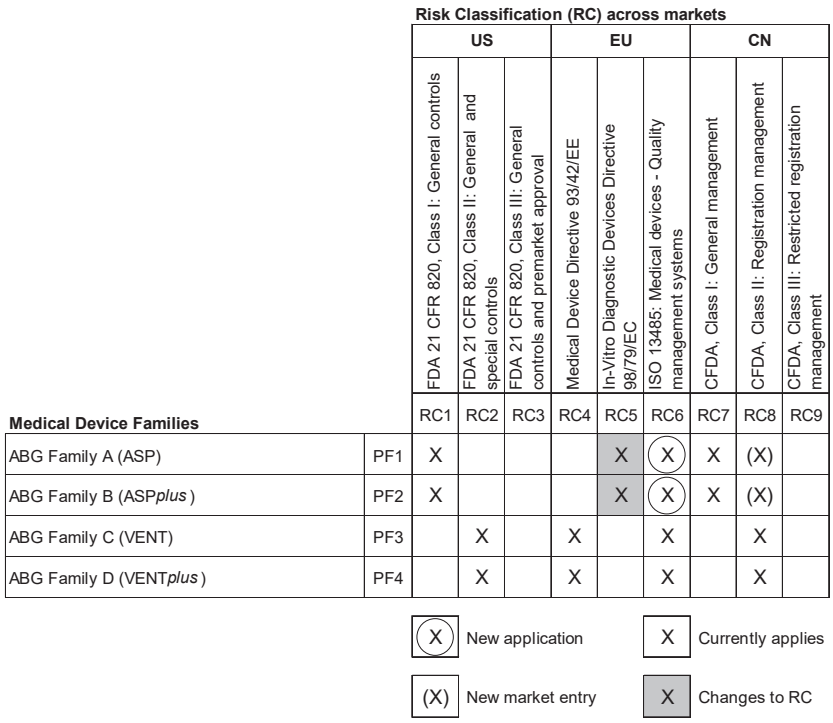


Fig. 7.6: Mapping of the current product program by family offerings against risk classes regulated by different markets of interest to the company

The above modelling provides insight not only into the current situation, but also it visualizes the foundation upon which future variants are to be build. As the illustration shows, if the company proceeds, not only does new risk classes apply at the EU market, but new unexperienced markets such as the CN, which is to be penetrated following the company strategy is a great risk, which the company is to face.

As indicated by the illustration, new variants based on the existing ABG sampler program must be re-classified in order to reach market acceptance at the attractive emerging markets. Here, especially CN is of interest to the company, where a new aspirating A-puncture sampler is required. In order to get further insight into these constellations, the risk classes were mapped against the regulatory requirements. Thus, having modelled the relevant risk classes, the next step was to take a deeper look into the specific regulatory requirements set within the risk classes (Fig. 7.7).

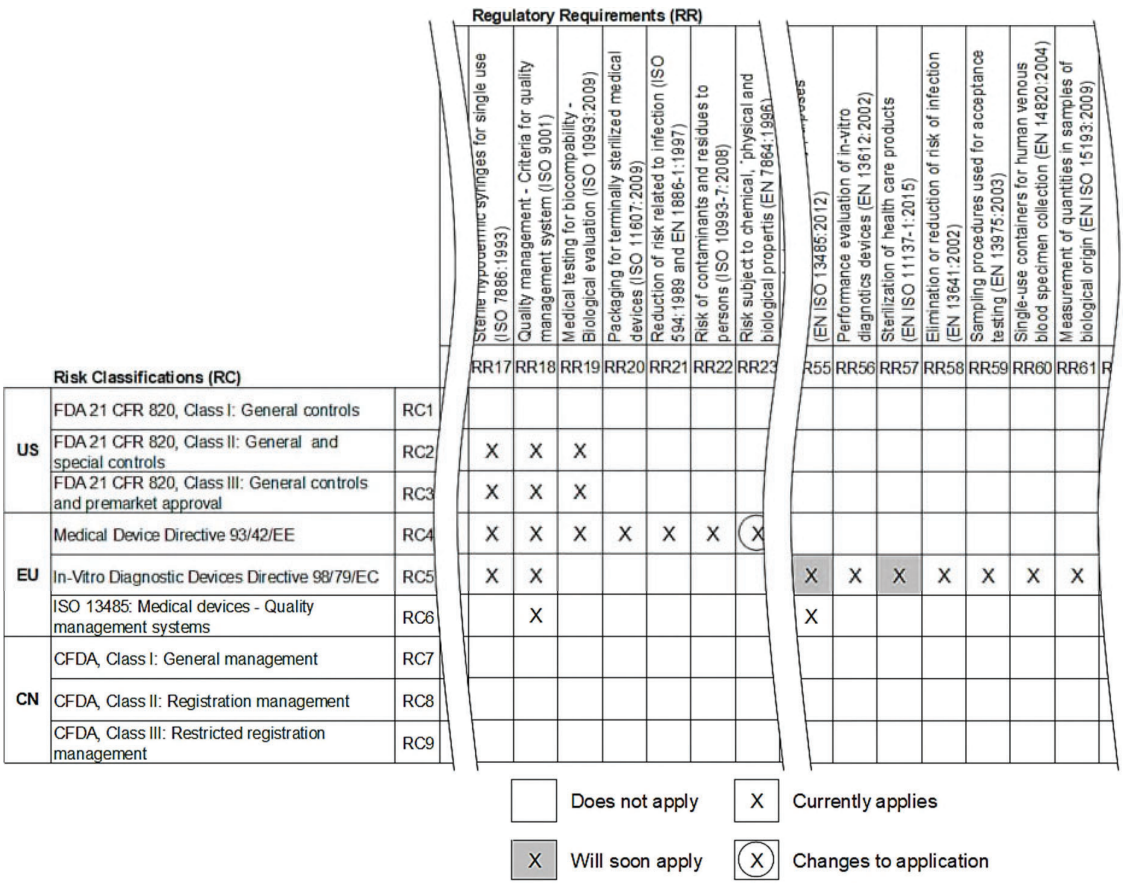


Fig. 7.7: Mapping the current risk classes against regulatory requirements stated by authorities of interest depicting changes critical to current and future product offerings

As the above illustrates, at existing market, products classified within IVD will be subject to new legislative requirements. Granularity might be applied for the clarification of individual risk classes, e.g. A, B. C, D within IVD and I, II, III within MDD of each of these larger group of classes (IVD and MDD). Namely, the performance evaluation set by ISO 13485 and sterilization procedures and measures set by EN 11137 will apply to these products, which changes the current state of compliance. New regulations are to be met, where especially ISO 13485 is of interest, which means that the company is to accelerate the compliance work on products being currently risk classified as IVD products. This finding is a subject for further investigation using the CACE modelling tool.

The Combined Market View of the Medical Device Program

Based on the market analysis, investigating both the market from a customer point of view and a regulatory point of view, the company gained insight into the current market situation, upon which, it then was possible to establish the customer domain relevant to the ABG sampler program. Combining the data, while evaluating the prioritization of customer needs to be meet, it was possible to establish a preliminary view on the customer domain (Fig. 7.8).

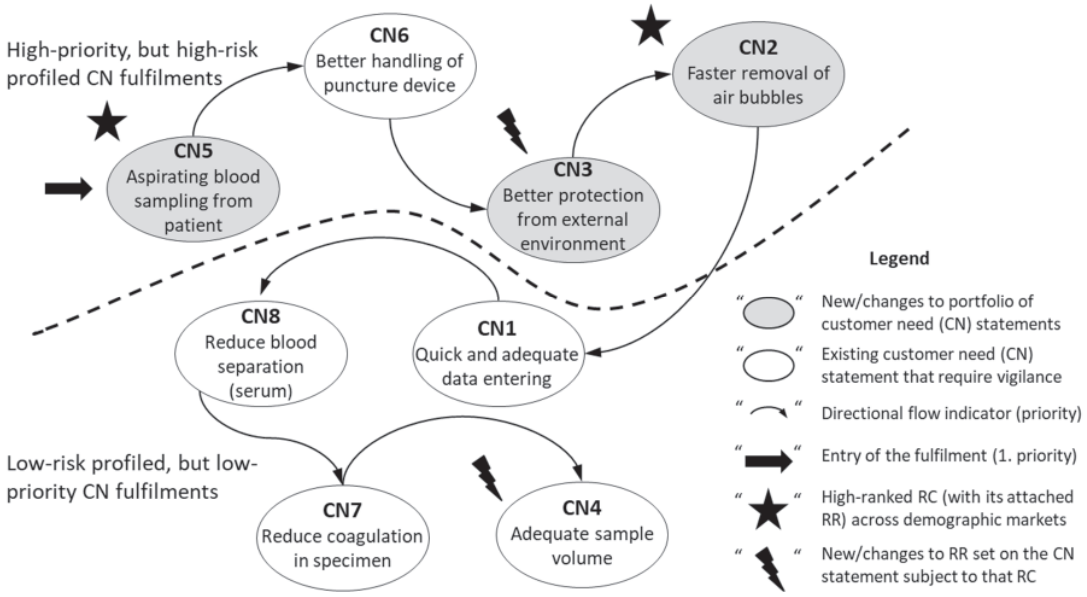


Fig. 7.8: Customer needs prioritization based on ABG market conditions, i.e. indicating focus areas and influencing factors of the regulatory environment

As the figure shows, not only is the customer needs modelled, but also the knowledge gained through the investigation of the legislative side of the medical market is included, providing the cross-organizational teams with a common understanding of the current situation and the desired new development projects seen from a marketing perspective.

As illustrated, the company has set CN5 as the highest priority to fulfill. Meanwhile, this is labeled as a high-ranked RC and requires new/changes to the current product program. Next, the company would like to meet CN6 and after that CN3, which entail better protection from the external environment. This is subject to new/changes to the RR directed towards the CN, which is subject to a certain RC given its use activity and thereby intended use. As the illustration shows, this is also the case with the lowest prioritized need, i.e. the need for adequate sample volume. In general, as the figure shows, the four of the eight highest ranked customer needs are the highest risk-profiled needs in the market. This provides the teams with an in-depth understanding of the challenges to be faced in the forthcoming future, if the overall business strategy for new product development is to be fulfilled successfully. The knowledge gained through the prescribed analytical exercises was then mapped into the customer domain modelling matrix, which constitute the first of the three main domains of the CACE tool (Fig. 7.9).

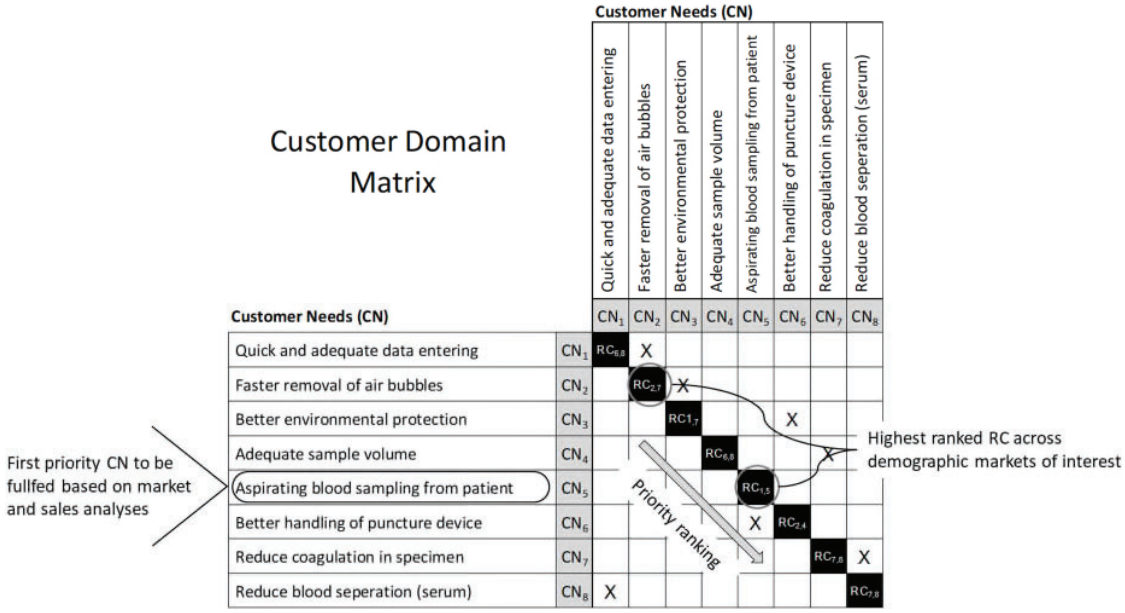


Fig. 7.9: The finalized customer domain matrix considering the ABG sampler market conditions including customers and regulations

The customer domain modelling matrix shows how the different customer needs have been prioritized, to which risk classes they belong based on the use activity analysis while it offer the possibility to indicate those risk classes that are currently at change due to new/changes in regulatory requirements. Thus, in this case example, it was decided to mark the regulatory influencers by their respective regulatory risk classes ($RC_{1...n}$), which offer the possibility of simplifying the customer domain matrix. Although, these risk classes simplify the view, it still connects or inter-relate the customer need statements to the regulatory environment at provide

the traceability needed when both evaluating the market options and clarity how changes to the regulatory environment might change the medical device program moving down the downstream view and up again the upstream view of the CACE modelling tool.

The customer domain with its underlying analytics has provided the company's teams across functions with insight into the market data while is has been modelled for ease of accessibility and representation in the company. Meanwhile, this domain creates an offset for establishing the downstream view of the CACE modelling tool, which offers better understanding of cross-domain dependencies facing new market changes that are to be met by or at least based on the product program. The customer domain captures the market influencing factors, which may require changes to the ABG sampler program. Hence, as earlier described, new/changes to regulatory requirements to risk classes by which product variants currently takes part and new/changes to customer needs to which the company must act in order to sustain its market position.

7.2.2 Downstream Product View: The ABG Portolio Design, Program Functions, Design and the Architecture

The aim of establishing the downstream product view of the program is to reveal how the ABG sampler program is realized from an engineering design and product development perspective. Thus, the predominant objective was to find out how the different customer needs or preferences are met by functions offered by the program revealing the current sampler portfolio design. Further, the functional domain was analysed in order to get insight into how functional elements are coupled together by means of interactions. Here, the aim was to understand how modular or integral the functional domain is and how the different functional properties of the elements support the portfolio. Further, the physical domain is important to map. This too was done by carrying out different analytical exercises to understand the nature of that domain. Last, but not leas the current architecture were modelled, looking into how the different design elements realize the functions of the program.

Product Variety: The Current Product Portfolio

Based on the market analysis, customer needs are in focus in order together with the functional variety of the product program, to map the current ABG sampler portfolio design. The aim is to get insight into the disposition of the functions and grasp the meetings with the customer needs found earlier on, as the functional elements of the program are to satisfy the customer needs in order to provide a value generating portfolio of products offered to the marketplace.

A list was established with the functions provided by the current ABG sampler program and customer needs were put on posters. The marketing and new product development teams then

mapped the customer needs against the functions to establish the first downstream product view of the CACE model (Fig. 7.10).

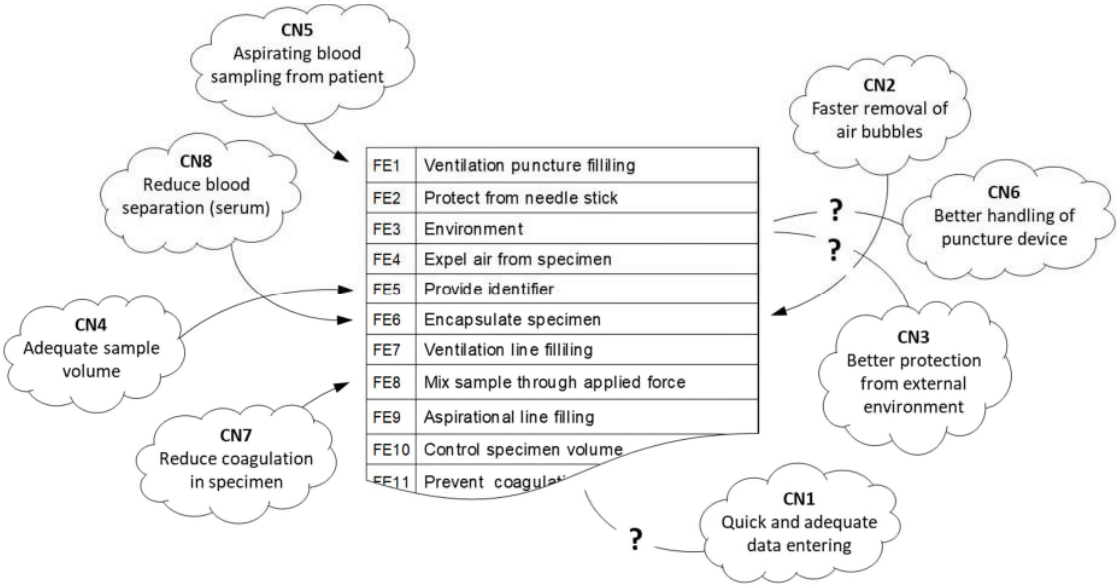


Fig. 7.10: List of functional elements provided by the ABG sampler product program

As the illustration shows, most of the customer needs could be directly linked to functional elements of the program. Meanwhile, a few, e.g. the aspirating blood sampling from patient (CN5), could not be directly interlinked to existing functional offerings of the program, which has to do with the fact that this is not a current offering.

As found during the market analysis, more of the customer needs, e.g. better protection from external environment (CN3), are at change and therefore those functional elements of those specific offerings do not perfectly fit the need statements. Thus, it was found that more changes are required for the company to meet its strategical targets. As insinuated, this exercise mapping the product portfolio, gives rise to discussing the current state of the program, which then found a basis for creating a common understanding across functional units of the company.

Based on the exercise and by applying the system impact index (Tab. 6.1), the product portfolio design matrix could then be established (Fig. 7.11). Based on rating the integration points between market and functions, the design team could evaluate the current status. Through analysis of the functional properties (see “Product Functionality Analysis”), the interest for the customer is the one perceived using the product, hence the use activity laid out in the market analysis.

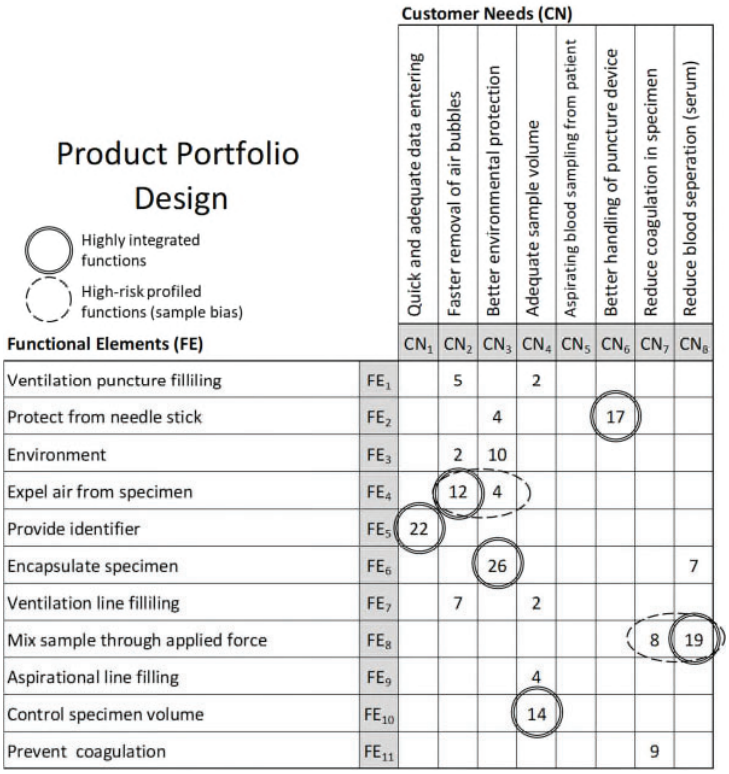


Fig. 7.11: The functional variety to customer needs fit creating an overview of the current ABG sampler portfolio design

As illustrated, quite a few meetings between function variants and customer needs are highly integrated. Meanwhile, more of these highly integrated functions support customer needs that directly relate to the prevention of bias on blood specimen, which is a predominant topic to the public authorities affecting hospital procedures and protocols. As shown, the functional element mix sample through applied force (FE8) and expel air from specimen (FE4) are highly affecting customer need for reducing blood separation (CN8) and faster removal of air bubbles (CN2), respectively. Meanwhile, these meetings are high-risk profiled, as they are highly influencing the bias on the blood specimen and thereby errors reducing the human health and safety of applying the medical product. Finally, these elements are offered by a variety of the products of the current program, namely it is offered by both the ASP*plus* and VENT*plus* sampler families. As evaluated by the team, changes to the mixing of the sample through applied force, will highly affect the need for reducing blood separation. Meanwhile, this functional element of the program has a mediate impact on reducing blood coagulation, which then is to be considered if this functional element is to change. The same goes for expel air from specimen, which will both affect the need for faster removal of air bubbles and better protection from the external environment.

Thus, the mapping of the ABG sampler portfolio has revealed how certain functional elements of the program lead to customer satisfaction, the perceived goodness of the function and creates a solid foundation for evaluating the change effect of altering an existing function or how the changes to the market will affect the current functional domain. Hence, such considerations are key in modelling the ABG sampler program and constitute the first domain of the product downstream view of the CACE model.

Product Functionality Analysis

As earlier described, the sampler program spans a variety of functions offered to the ABG market. In the functionality analysis, core functions of the most advanced product family, i.e. the VENT*plus* family, act as exemplification of the analytical exercises that were carried out during the case study of the ABG sampler program (Fig. 7.12). Please note, more of the design elements will be introduced during the description (for more information on the design elements (see the "Physical Design Analysis").

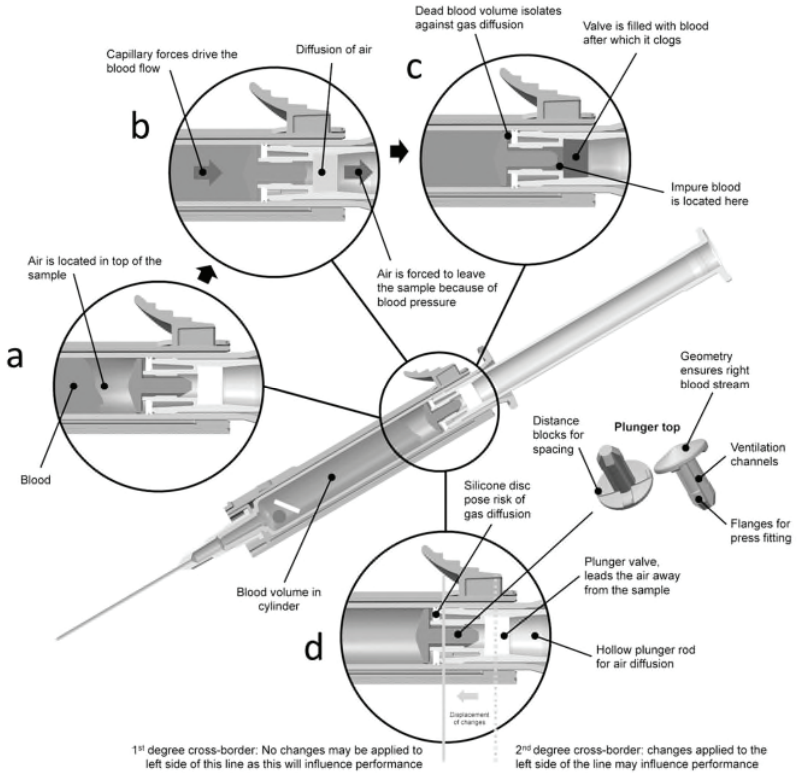


Fig. 7.12: Depicted functionality of the VENT*plus* sampler family: Shows the functionality (step-by-step) of the product. Further, it shows the identified cross-borders indicating which part(s) of the products that can undergo design changes without interfering with the performance of the product (Jensen 2013)

The above figure illustrates how different steps of the blood sampling process, varies functional elements come into play. At first, when either the artery is punctured or the catheter is opened, with the means of capillary forces, the blood fills up the cylinder starting at the blood inlet (Fig. 7.12, a). This constitute the first step and depending on the operational procedure revealed during the use activity analysis (Fig. 7.5), more functional elements come into play, i.e. ventilated puncture filling (FE1) and ventilated line filling (FE7). The sampler filling is possible since the capillary forces are more powerful than the resistance in sampler, and because the resistance in the sampler is lower than in the artery the blood is forced to flow into the sampler. This functionality is founded in the construction of design, the arrangement of design elements and the interface among these elements of the system (Fig. 7.23). When the cylinder is filled with blood (Fig. 7.12, b to c), at first the air in top of the sampler enters the spacing between the silicone disc and the top of the plunger head, after which it streams into the ventilation channels formed by the cross-cut in the plunger top and the mating interface between this design element and the plunger rod. During this step of the procedure, the functional element of expelling air from the blood specimen (FE4) is activated. After the air has passed the ventilation channels, it diffuses through the valve and out through the hollow plunger rod (Fig 7.12, b). The blood then follows the air and runs through the same arrangement of functional elements with its design units. During the analysis, a schematic representation of how the functional elements interact with each other was created (Fig. 7.13).

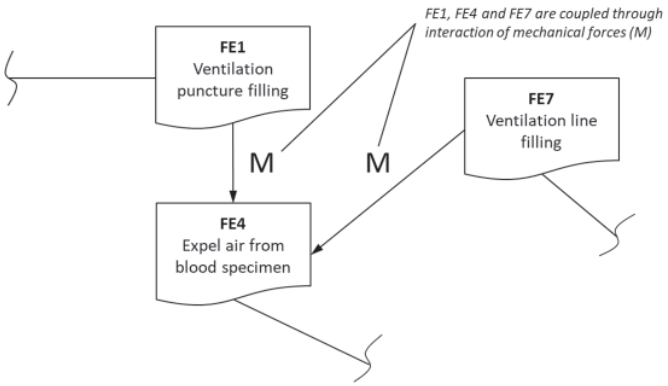


Fig. 7.13: A schematic representation of how functional elements interact with each other following the operational procedures during the first part of the sample process

Based on the above analysis of the functionality of the plunger, it is anticipated that changes should not under any circumstances be applied to the left side of the 1st degree cross-border, indicated by the line (Fig. 7.12, d). During the analysis it was found this this part of the sampler system should be locked from changes. Changes applied to this left side are assumed to change the performance of the blood gas sampler. Further, a 2nd degree cross-border was established. When moving from right to left in the sampler construction, this line, indicated by a stippled line

(Fig. 7.12, d), shows that the design team is getting close to the core functionality of the VENT-based sampler. Changes may be applied to the right side of the line, but at the left side, the changes may begin to influence performance parameters (see "Physical Design Analysis). No changes should be applied to functional elements that influence the performance of the sampler.

After obtaining the blood, the air in the sample is expelled using a vented tip cap (Fig. 7.14). During the air expelling of the sample, the air and blood is pushed towards the vented tip cap (VTC) located in the top of the cylinder luer. This is done by pushing the plunger in direction of the VTC. During this process, the air flows up in the cylindrical shaped VTC bottom, and through the lamellas, after which it flows around the rubber disc, through the filter paper and out the VTC top (Fig. 7.14, d). After the air, the blood follows the same process, but when it interacts with the filter, it clogs, and no further expelling is required, and the sampler has been sealed.

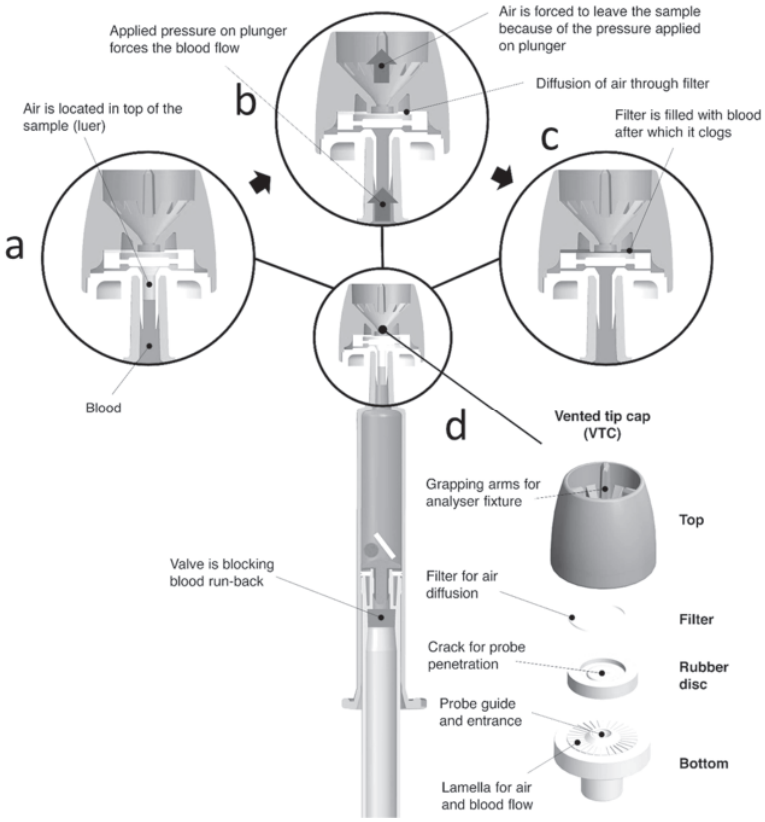


Fig. 7.14: VENT*plus* sampler with attached vented tip cap: Shows the functionality of VTC and its interplay with the rest of the sampler system during air expel and encapsulation (Jensen 2013)

As indicated, during this use activity, more functional elements interplay, i.e. expelling the air from the specimen (FE4) and encapsulating the sampler (FE6). After end air expelling, the sampler system interacts with the blood gas analyzer, the queue function and analyzer inlet. This

indicates another functional element, namely the environment (FE3), which is an important element of getting an adequate sample. Prior to aspiration of the blood into the analyzer, the sampler is being mixed for 7 second, i.e. mix sample through applied force (FE8). During this process the mixing ball is rotating because of the magnetic field created by the rotating magnet in the analyzer. After properly mixing, the sample is being aspirated by the inlet of the blood gas analyzer (FE3). The schematic representation of the functions and their interaction can be seen below (Fig. 7.15).

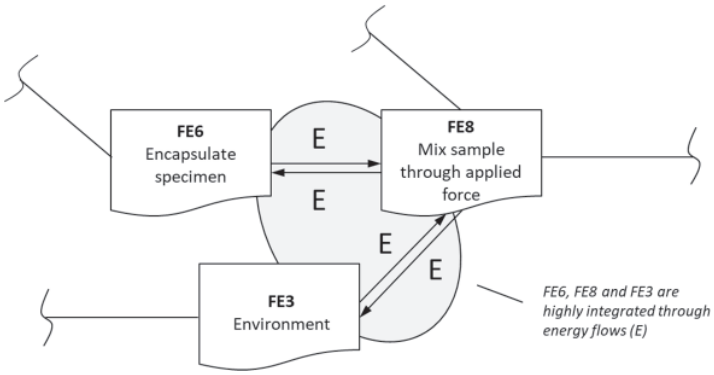


Fig. 7.15: A schematic representation of how functional elements interact with each other following the operational procedures during the latter part of the sample process

Based on the combined analysis, the complete overview of the depicted functionality of the VENT*plus* family can be established (Fig. 7.16). As it shows, the elements interact and thereby is coupled to each other and there cannot just be changed without affecting each other.

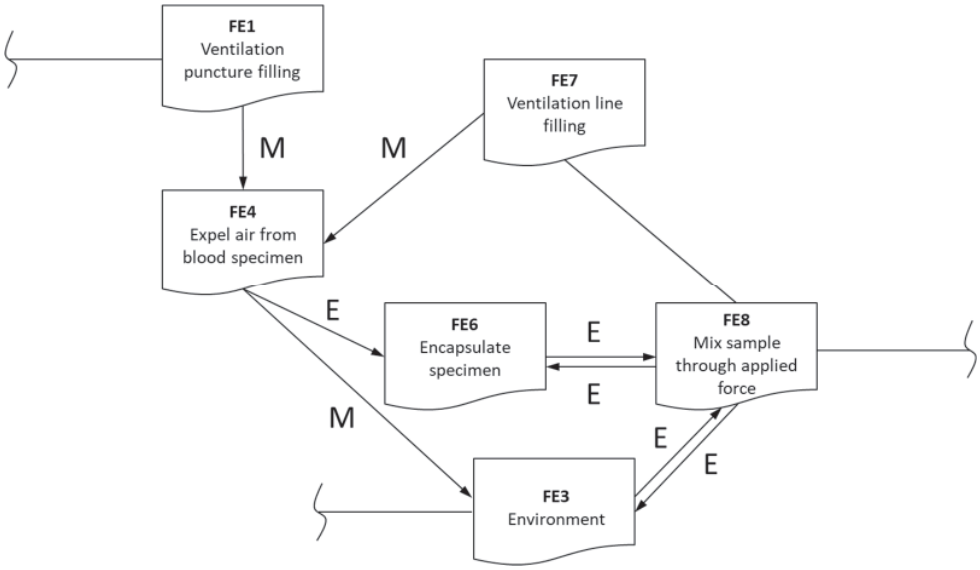


Fig. 7.16: A partial view of the functional domain based on depicted analyses of the VENT*plus* family

These overviews identifying the interactions among functional elements was created based on discussing the concrete functions of the products. Hence, such translations are important establishing the functional domain of the CACE model. Hereby, the teams get a clear picture of how the products' functions interact and depend on each other.

Besides having a close look at the functionality of the different product variants of the ABG sampler program, the functional requirements was noted and mapped against the functions to get an overview of how the requirements within the functional domain currently flow (Fig. 7.17).

		Functional Requirements (FR)							
		Sampler must be easy to identify with little to no risk of misaligning IDs	Sampler must pose little to no risk of bias on blood specimen	Sampler must not harm the operator during operational procedures	Blood specimen should be easy to control when under pressure	Risk towards operator handling blood specimen should be minimized	Sampler should pose as little harm to patient as possible	Device should be easily connected to other devices in the life cycle	Device should pose litte to no risk of
Functional Elements (FE)		FR1	FR2	FR3	FR4	FR5	FR6	FR7	FR
Ventilation puncture filliling	FE1		X	X			X		
Protect from needle stick	FE2			X					
Environment	FE3			X			X	X	
Expel air from specimen	FE4		X			X			
Provide identifier	FE5	X							
Encapsulate specimen	FE6		X			X			
Ventilation line filliling	FE7							X	
Mix sample through applied force	FE8		X						
Aspirational line filling	FE9							X	
Control specimen volume	FE10		X		X		X		
Prevent coagulation	FE11		X						

Fig. 7.17: Mapping the functional requirements (FR) to functional elements (FE) of the ABG sampler program

As the illustration shows, functional requirements are quite widespread across the functional elements. Please not that requirements are high-level and therefore apply to more functional elements. Nevertheless, namely the requirement stating that sampler should little to no risk of blood specimen, applies to more functional elements.

As the matrix reveals, many of the functions have direct impact on the bias and therefore is under control of that requirement. Further, requirements about operators' safety apply to varies

functional elements and therefore should be carefully surveilled during design changes. Thus, as it has earlier been revealed, patients' and operators' safety are at stack when carrying out the operational procedures using the ABG samplers and therefore requirements reflect these regulatory conditions.

Based on these analyses of the functions provided by the different products, the functional domain matrix could be established (Fig. 7.18). Note that functions have been analyzed across the entire program of ABG samplers considering all relevant functions across the program.

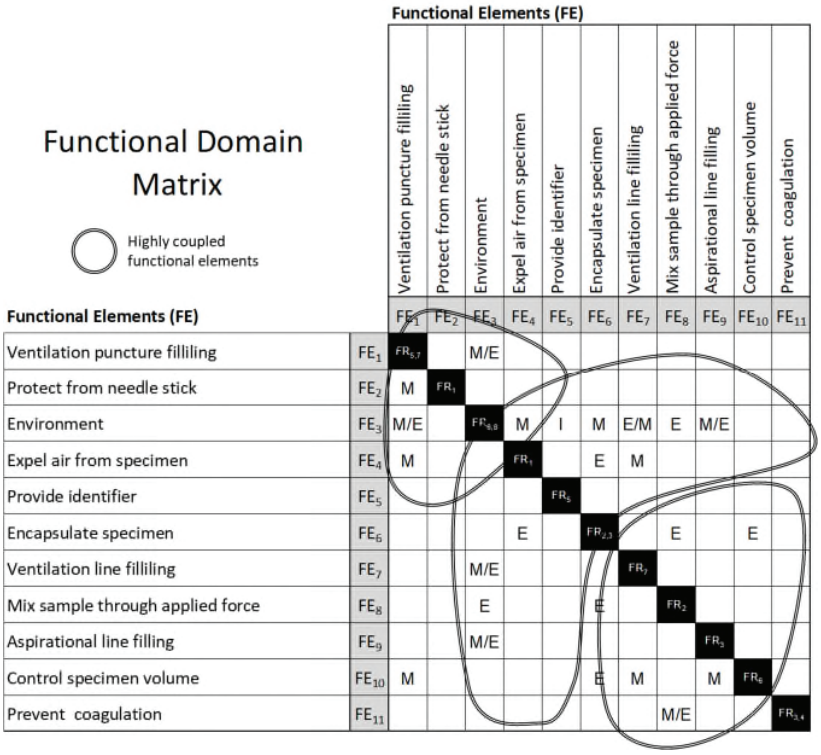


Fig. 7.18: The complete functional domain of the CACE tool. Functional elements have been modularized according to interactions of the functions coupling them together

As the compiled functional domain for the ABG sampler program shows, more functional elements are highly integrated. Here, functions are highly integrated based on interaction (couplings) among functional elements. Further, the domain reflects the functional requirements set on those elements of the program. Hereby, it has been possible for especially the design team to comprehend functional structures (elements, their couplings and arrangement). These functional structures have a high impact on the ability to change or develop new ABG sampler devices based on the program layout, which should be considered when new offerings are desired based on the market conditions investigated earlier on.

Physical Design Analysis

A wide variety of design elements found the basis for the functionality provided by the ABG sampler program (Tab. 7.1). As earlier described in introduction to the chapter, four families of products exist. The ASP family variants are for aspirating line sampling and consist of a cylinder, a solid plunger, heparin discs and a tip cap (Fig. 7.19, a). For the high-end ASP family, i.e. ASP*plus*, more advanced features and offerings are available. Here, the variants are offered with vented tip cap (VTC), a barcode for automated identification and a mixing ball for automated mixing of the device (Fig. 7.19, b).

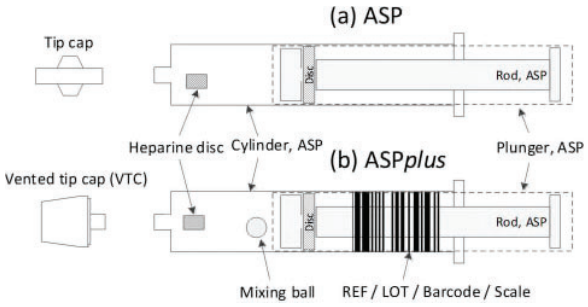


Fig. 7.19: The aspirating sampler families, i.e. the basic ASP family and the more advanced ASP*plus* family: Member variants are for arterial line sampling only

Besides the ASP-based families, two VENT-based families are currently launched to the global marketplace, which core functionality is to automatically fill the sampler with blood during sampling procedure. The VENT-based family (Fig. 7.20, c), is the basic ventilated sampler family and as with the ASP samplers, a more advanced family is offered to the market (Fig. 7.20, d).

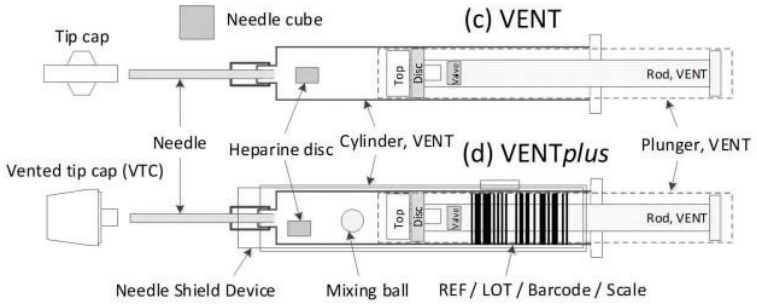
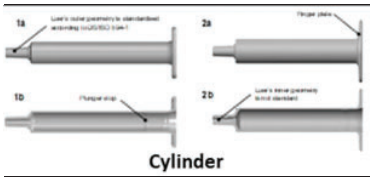
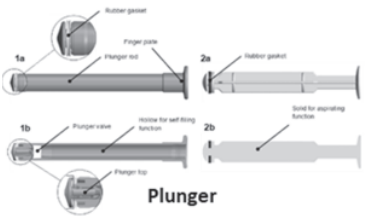
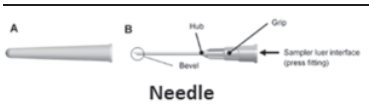
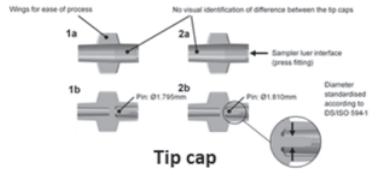
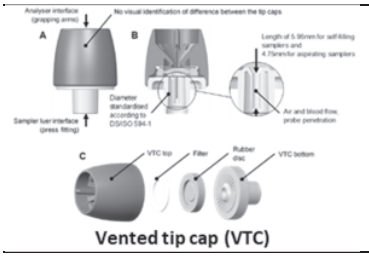
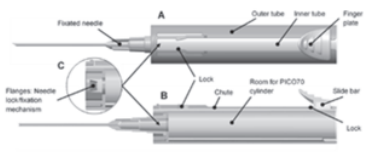


Fig. 7.20: The ventilated/self-filling sampler families, i.e. the basic family VENT and the advanced VENT*plus* family: Member variants of the two families are for both arterial line and puncture sampling

Along with the above schematics, a list of the predominant design elements was established creating an overview of the current elements realizing the ABG sampler program (Tab. 7.1).

Technical illustration	Description
 Cylinder	Two variants of the cylinder cover the product program. The VENT cylinder (1a and 1b) is a 2mL barrel molded in naturally transparent polypropylene (PP) with no use of regrind material. 0.25% to 0.3% amide E (polyamide) is used as release agent. The outer geometry of the luer is standardized according to ISO 594-1. The ASP cylinder (2a and 2b) has the same volume with standardized luer, though the geometry is different from the VENT.
 Plunger	Two kind-off plungers exist, one for VENT (1a and 1b) and one for ASP (2a and 2b), which creates the foundation for the function of samplers, i.e. the ventilating and aspirating function. In case of the VENT plunger, a rod, valve, gasket and a top construct the plunger and founds the functionality of VENT variants. The aspirating plunger, where the operator manually drags the blood into the cylinder, is constituted by two components, i.e. a solid plunger rod and a rubber gasket. The working principles of the VENT plunger is much more complex compared to the aspirating plunger, and so are the design elements, their structure and internal interfaces.
Heparin disc	The heparin inside VENT- and ASP-based samplers is coated onto a fiber disc made by chromatography paper; it measures 6 x 3mm and its thickness varies in proportion to the heparin concentration. Heparin is a very important anticoagulant, naturally occurring in the human body. Concentrations of 80IU and 60IU are used. The two different heparin discs are, like the cylinder and plunger, variant specific designs.
 Needle	Needles are applied for the purpose of arterial puncture, and therefore momentarily are of relevance to only the VENT-based families. The needles are thin walled in order to increase the speed by which the sampler is filled with blood and comes in a variety of sizes to fit patients' physiology.
 Tip cap	The tip caps are small tubes with two wings and have the purpose of encapsulating the sampler after blood fill. there exist two variants of tip cap, one for VENT (1a and 1b) and one for ASP (2a and 2b). The reason for this is that the inner geometry of the luer, is not standardized. Thus, in order to accomplish appropriate sealing of the samplers, two tip caps with varying pin diameters is required. The differentiation on cylinders leads to further variety of the design elements of the program.
 Vented tip cap (VTC)	The vented tip cap (VTC) basically aims at the same as the tip cap but offers a maximum of sample integrity and operators' safety, posing a triple functionality: (1) air expel, (2) encapsulating the sample, and (3) integrates with the analyzer. The VTC consist of a top, filter, rubber disc and a bottom allowing the functionality of the device. The VTC fit both the VENT- and ASP-based sampler variants, but with different bottom parts. There is a major drawback to this component variety; not only is it recognized as a non-value adding variance, it does also reduce the performance of the aspirating sampler.
 Needle shield device (NSD)	The needle shield device (NSD) is a one-hand operational safety device developed to support the VENT*plus*-based variants. It is constructed by two parts, an inner tube and an outer tube. The inner tube slides freely within the outer tube. The needle which is assembled to the cylinder is secured in the end of the outer tube using four flanges as fixation mechanism (C). The inner tube is slid towards the needle where it is locked using two flanges (A), and will thereby cover the exposed needle, preventing needle stick injuries.
Needle cube	The needle plug is another safety device that facilitates safely disposal of the needle. It is standard as it may be applied to any sampler variant within the product assortment, though the device is no longer accepted by the European council as a proper safety device as it is not safe enough to operators.
Mixing ball	The mixing ball is made by martensitic stainless steel and is coated with a gold. The mixing ball is standard that may be applied to any sampler variant in the product program.
Barcode label	The barcode facilitates a maximum of data accuracy in arterial blood gas testing. The barcode automatically links the patient ID with the sample ID and thereby supports the mitigation of pre-analytical errors.

Tab. 7.1: An overview of core design elements founding the materialization of the ABG sampler program

The parts constructing the design elements and its interfaces, all together found the functionality of the commercial ABG samplers constituting the program. As the above description of the design elements reveals, the variety among elements is quite high. In order to get a clearer picture of how the different design elements interfaces, an analysis was carried out. Using the CACE tool, modelling the ABG sampler program, the design elements are used for integration analysis. The different design elements were written on post-its, and the design team was to rearrange these and draw the interfaces among the elements (Fig. 7.21).

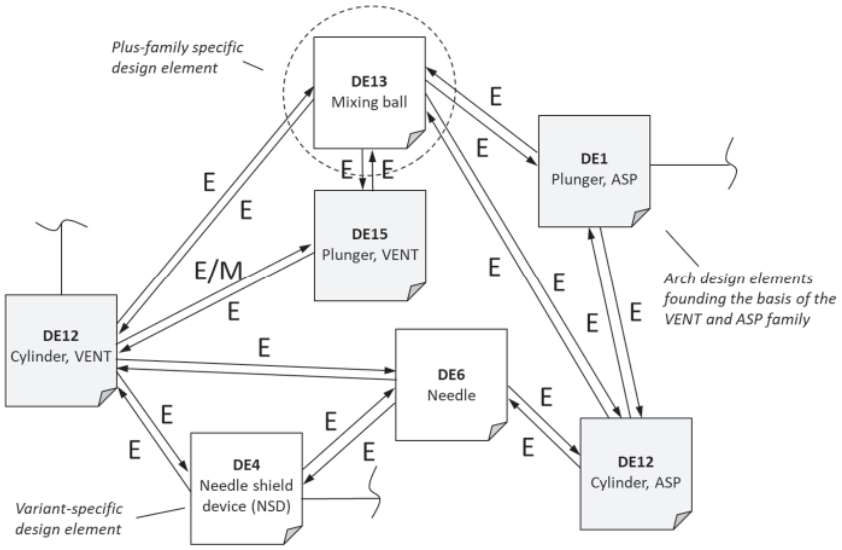


Fig. 7.21: A schematic representation of how design elements interface (intra-relate) with each other following the physical design analysis (only a partial view)

During the analysis, it became clear that the non-standardized interface of sampler luer creates non-productive variance. The variety of design elements offer common usable functions, but the interface to the different elements are not identical across more diverse product families, which evidently reveals lower performance, higher complexity, cost and lead time of the product development. It is found that the geometrical difference of the luer is highly connected to the creation of physical design variance (Fig. 7.21).

Thus, it during the analysis bringing the design team to the table, it was found that the functionality of a sampler variants is highly linked to this coupling between design elements; a change in one element, either cylinder or VTC bottom, will require a change in the other component. What is more to the outcome of the analysis is that the blood specimen interlocks the different design elements; hence, elements do not necessarily have to be directly connected in order for them to be coupled together, which adds another of complexity to the physical establishment of the ABG sampler program.

Further, the design parameters set on the design elements was mapped in order to get insight into the flow of nonfunctional requirements within the physical domain of the program (Fig. 7.22)

Design Elements (DE)		Design Parameter (DP)											
		No undesired material should enter the blood specimen (ISO 788-1)	The volume should not change during operational procedures (use activities)	Plunger force during movement must be < 3N, as (P_{mid}+2.5*S_D)/$F_{mid,tot}$ < 8N	Air in sampler should be, spread for pO2 approx. 40 mm HG (±10 mm Hg)	No analytical affect on sample size (between min. and max volume - pO2, 15g/dL)	Needle attachment should be 2pl > 18N / 2pl < 12 Ncm to work	Check sum and eadability should be suffecient	Adhesiveness should reach satisfaction and no rubbing throuhg of label	Start force plunger movement should be > 1.5N under normal conditions	Ball should be < 3.6mm so that the propbe can	Air flow should be min. 50 mL/min. at a pressure of 1 bar	Heparin activity should be 63 IU ± 20IU and at least IU/mL heparin after 20 sec mixing
		DP1	DP2	DP3	DP4	DP5	DP6	DP7	DP8	DP9	DP10	DP11	DP12
Plunger, ASP	DE1		X	X		X				X			
Cylinder, VENT	DE2	X	X	X	X	X	X	X	X	X			
Heparine disc, ASP	DE3												X
Needle shield device (NSD)	DE4						X	X					
Tip cap, ASP	DE5				X								
Needle	DE6						X						
Tip cap, VENT	DE7				X								
Vented tip cap, VENT	DE8				X							X	
Heparine disc, VENT	DE9												X
Needle cube	DE10						X						
Barcode label	DE11							X	X				
Cylinder, ASP	DE12	X	X	X	X	X	X	X	X	X			
Mixing ball	DE13	X	X		X						X		
Vented tip cap, ASP	DE14				X							X	
Plunger, VENT	DE15		X	X	X	X				X			

Fig. 7.22: Mapping the design parameters (DP), or nonfunctional requirements, to the design elements (DE) of the ABG sampler program

The overview shown above is important for the team to understand its current restriction within the design space. Further, these requirements establish the foundation for the tests that are to be carried out verifying that the design meets its criteria. During the analysis, it was found that many of the requirements involve the cylinders and plungers, further, the mixing ball and heparin discs are heavily restricted by design parameters.

Based on the analytical exercises carried out, the physical domain matrix was established showing the design elements, its interfaces and the requirements set on the different design elements (Fig. 7.23).

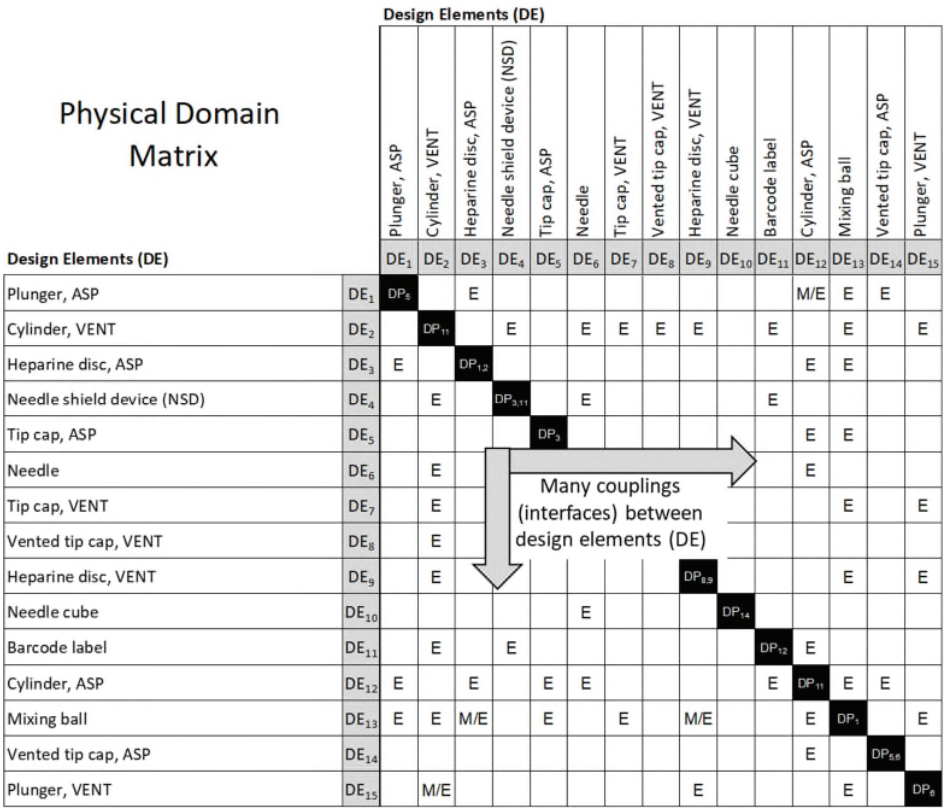


Fig. 7.23: The physical domain matrix showing the design elements and their interfaces

As shown by the illustration, the mapping of design elements and their interfaces reveal that many elements are coupled together through especially mechanical energy. Especially cylinders, plungers, and heparin discs, both for ASP and VENT families are highly integrated by the current setup. Further, the mixing ball is highly integrated. The reason is that cylinders, plungers and heparin discs take part in every variant of their respected families while the mixing ball goes across the *plus*-families. Meanwhile, not all design elements are coupled together, some are even loosely coupled, and therefore, clustering mechanisms should be applied to understand this.

The ABG Sampler Program Architecture Design

Following the analysis of the physical domain of the ABG sampler program, the underlying product architecture was mapped (Fig. 7.24). When looking into the architecture, it is found that there are five clusters of highly integrated meetings between the functional and physical design elements. Please remember that the view visualizes the meeting between the functional properties of the functional elements and the structural characteristics of the design elements; hence, the property models underlying that establishes the architecture. In the above product architecture domain matrix, the dependencies have been evaluated based on the system impact index (Tab. 6.3).

Product Architecture Design		Functional Elements (FE)										
		Ventilation puncture filliling	Protect from needle stick	Environment	Expel air from specimen	Provide identifier	Encapsulate specimen	Ventilation line filliling	Mix sample through applied force	Aspirational line filling	Control specimen volume	Prevent coagulation
Design Elements (DE)		FE_1	FE_2	FE_3	FE_4	FE_5	FE_6	FE_7	FE_8	FE_9	FE_{10}	FE_{11}
Plunger, ASP	DE_1			4	11		12		1	24	17	2
Cylinder, VENT	DE_2	13		12	11	4	20	11	11		19	7
Heparine disc, ASP	DE_3			1	4		2		3	8		18
Needle shield device (NSD)	DE_4		17								12	
Tip cap, ASP	DE_5						11					
Needle	DE_6	4										2
Tip cap, VENT	DE_7						21					
Vented tip cap, VENT	DE_8			13			19				4	2
Heparine disc, VENT	DE_9	4		3	5		2	4	3			16
Needle cube	DE_{10}		9									
Barcode label	DE_{11}			11		20					19	
Cylinder, ASP	DE_{12}			14	7	5	18		9	7	12	4
Mixing ball	DE_{13}	5		23	6		7	14	27	11	1	7
Vented tip cap, ASP	DE_{14}				19		14					3
Plunger, VENT	DE_{15}	15		2	7		21	16	3		9	1

VENT

VENT

ASP

Fig. 7.24: The product architecture domain matrix. Showing how the different functional elements are realized by means of varies design elements

Thus, by applying the proposed quantitative measures, the design team has been able to quantify the inter-relations connecting the functional and physical domain. To get a better understanding of the underlying architectural complexities, namely how and by which means the architecture design is, a complete picture of the couplings has been calculated (Fig. 7.25).

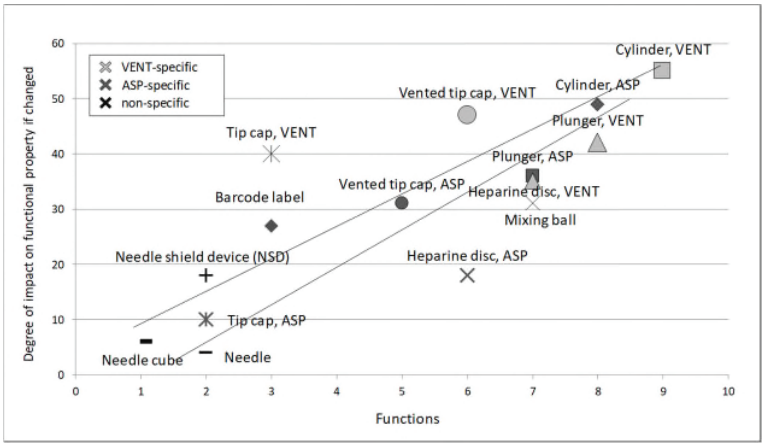


Fig. 7.25: The integration level of design elements as function of the degree of impact on the functional domain if changed

As the above graph shows, by using the system impact index (SII) to rate the impact of design elements changes to the samplers' functional properties, it was found that the cylinders, plungers and heparin discs are highly functionally integrated (x-axis) and have a high probability of affecting the samplers' functional properties if changed (y-axis). This is knowledge further adds to the foundation, with the current setup, to have two platforms, one for ASP and one for VENT, as discussed during the analysis of the physical domain layout. Hence, highly integrated design elements should be encapsulated from changes, as these have high degree of affecting the properties (performance) of the affected samplers, if changed.

7.2.3 COMPLIANCE VIEW: V&V TESTS AND DOCUMENTATION

In the compliance view, the verification and validation test and documentation is mapped. Though, the scope in this study has been on the verification view. The V&V views was investigated based on analytical exercises while looking into the compliance documentation available to understand how elements of the program have been tested.

Physical Designs and Their Verification Test Couplings

To gain insight into the upstream compliance view of the CACE tool, the design team should consider the functional, physical domain and its inter-relation, namely the product architecture. An exercise was carried out mapping physical design elements of the ABG sampler program against each other, with couplings representing test dependencies (Fig. 7.26).

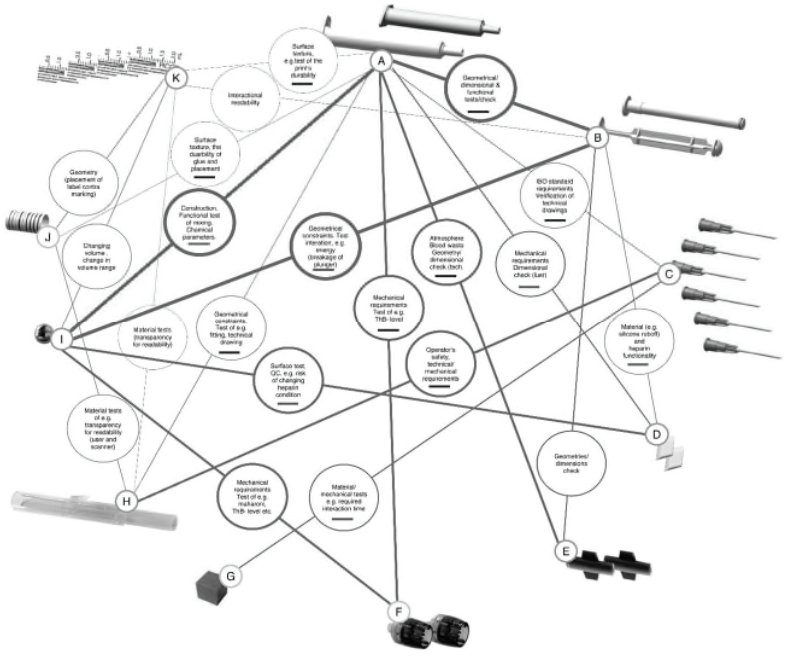


Fig. 7.26: Mapping of couplings between physical design elements by means of verification test and documentation using the proposed test impact index (TII)

The above mapping was carried out to get cross-functional teams to get to the same understanding of the complexities mapping cross-domain inter-relations, namely, to have physicals designs that are coupled together by means of verification test and documentation dependencies. Here, the mapping revealed how much testing should be done if a physical design element was to be changed. The mapping reveals how the designs are interlocked by means of testing and documentation. One design element cannot be changed without affecting compliance work done on both that design element, but also the once it relates to through its structural characteristics providing the functional property needed in order to make the product work as desired. The thickness of the nodes indicates the density of test and documentation. This exercise brought cross-functional teams together to get to the same understanding of the current sampler product program form a test and documentation complexity perspective given the current physical design. It came as no surprise, that the cylinders and plungers are highly integrated, but an important finding was that more less obvious physical designs are highly integrated, when it comes to verification test and documentation. Namely, tip caps, vented tip caps (VTC) and the mixing ball require burdening compliance work if changed. Thus, with a first glans, these elements of the program are interlocked from a compliance point of view.

The Verification Test and Documentation Design

After conducting a preliminary workshop, looking into the how the different physical design elements inter-relate from a compliance perspective, as described above, the verification test and documentation modelling matrix was established (Fig. 7.27).

Verification Test and Documentation

Functional Elements (FE)		Design Elements (DE)															
		Plunger, ASP	Cylinder, VENT	Heparine disc, ASP	Needle shield device (NSD)	Tip cap, ASP	Needle	Tip cap, VENT	Vented tip cap, VENT	Heparine disc, VENT	Needle cube	Barcode label	Cylinder, ASP	Mixing ball	Vented tip cap, ASP	Plunger, VENT
		DE_1	DE_2	DE_3	DE_4	DE_5	DE_6	DE_7	DE_8	DE_9	DE_{10}	DE_{11}	DE_{12}	DE_{13}	DE_{14}	DE_{15}
Ventilation puncture fillliling	FE_1		12		3		9		1	9		1		4		10
Protect from needle stick	FE_2				12		3				9			5		
Environment	FE_3	2	9	4	3	2			11	2		10	5	20	2	9
Expel air from specimen	FE_4	16	13	4					8	3			11	17	10	6
Provide identifier	FE_5		2									16	3			
Encapsulate specimen	FE_6	17	11	7		7		9	3	4		2	10	10	8	18
Ventilation line fillliling	FE_7		15		1				1	11		3		1		15
Mix sample through applied force	FE_8	8	10	7				6	11	12		4	10	12	5	10
Aspirational line filling	FE_9	12		9	2							2	11	4	6	
Control specimen volume	FE_{10}	9	10	5					7	3			10	3		7
Prevent coagulation	FE_{11}	10	14	8	4	2	6	1	7	8	1	3	15	8	5	11

VENT ASP VENT

Fig. 7.27: The verification test and documentation domain based on quantitative evaluation using the test impact index (TII)

As shown, in order to quantitatively evaluate the dependencies of the verification view, the test impact index (TII) was applied measuring the inter-relations within the domain. In this domain, the it is evaluated how the different physical design elements of the program have been tested against the functional elements; hence, it how the performance have been evaluated, which is the definition of verification testing.

Like with the architecture design, the compliance view, i.e. the verification test and documentation complexities have been calculated (Fig. 7.28).

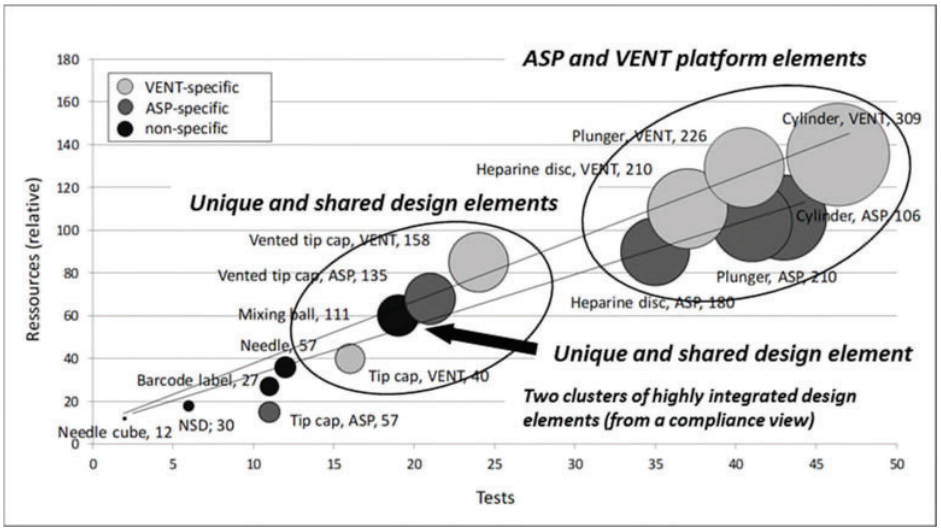


Fig. 7.28: Test impact index of physical design elements as a function of accumulated compliance-related resource consumption

As shown by the illustration, during the modelling of this domain it was found that the functionally integrated design elements, i.e. cylinders, plungers and heparin discs, are the design elements that have been taken part in most test (x-axis). Meanwhile, these tests have required heavy use of resources (y-axis) while they have been the most time consuming (bubble size). Because of this, and since these design elements are all common across the ASP and VENT families, these will be a part of the platform, which was identified during the establishment of the physical domain matrix, and therefore these should be protected against changes.

Further, it was found that the mixing ball is the second most resource- and time-consuming unique, while shared, design element from a verification test and documentation point of view. To get a deeper understanding of these correlations, the design team should take action to investigate this working with the CACE modelling. These findings should be carried over to the later modelling using the CACE tool.

The Validation Test and Documentation Design

After having established the verification test and documentation view on the product program, the validation view was established (fig. 7.29). Here, the aim has been to highlight validation testing aspect of the program design, namely if the design reach customer satisfaction.

Validation Test and Documentation

Customer Needs (CN)		Ventilation puncture fillling (FE_1)	Protect from needle stick (FE_2)	Environment (FE_3)	Expel air from specimen (FE_4)	Provide identifier (FE_5)	Encapsulate specimen (FE_6)	Ventilation line fillling (FE_7)	Mix sample through applied force (FE_8)	Aspirational line filling (FE_9)	Control specimen volume (FE_{10})	Prevent coagulation (FE_{11})
		Functional Elements (FE)										
Quick and adequate data entering	CN_1					19						
Faster removal of air bubbles	CN_2				16		33	7				
Better environmental protection	CN_3		5	13	2		13					
Adequate sample volume	CN_4							3		3	12	
Aspirating blood sampling from patient	CN_5											
Better handling of puncture device	CN_6	11	12									
Reduce coagulation in specimen	CN_7								8			9
Reduce blood seperation (serum)	CN_8	1							21	8		

Fig. 7.29: The validation test and documentation domain based on quantitative evaluation using the test impact index (TII)

As the illustration shows, the validation testing is less integrated, which offers more flexibility towards this compliance view of the program. As the matrix shows, more of the functional elements have been tested against one customer need statement, e.g. the "provide identifier" (FE_5) has been tested against the need for quick and adequate data entering (CN_1). The same goes for "control specimen volume" (FE_{10}), "prevent coagulation" (FE_{11}), and "mix sample through applied force" (FE_8), which has been tested against the need for adequate sample volume (CN_4), the reduction of coagulation in specimen (CN_7), and the reduction of coagulation in specimen (CN_7), respectively.

Meanwhile, as indicated, this also shows how more functional elements provides to the satisfactory of one or few customer needs. Thereby, it has been found that more customer needs are affected by more than one functional element provided by the program. As already revealed, this goes for the need which is concerned with the reduction of coagulation in specimen. Here, both FE_8 and FE_{11} is affecting the need. This is because both anti-coagulants, but also the mixing unit of the sampler together provide less coagulation. Thus, although quite a few one-to-one mappings of this domain have been identified, several functional elements together affect

specific customer needs revealing a more-to-one mapping when observing the program upstream the validation view of the program. This is an important finding, when customer needs are to change or physical elements of the program are to be redesigned, these might in combination affect customer needs. This is because more functional elements have a wide-spread influence on customer needs. Thus, these finding should be considered if changes are to be made or if changes are realized at the marketplace.

7.2.4 COMPLETE CACE SETUP FOR THE ABG SAMPLER PROGRAM

Based on the exploration of the relevant domains to the CACE tool, the complete overview could be established illustrating how the domains inter-relate while indicating how the model is read downstream the product view and upstream the compliance view (Fig. 7.30).

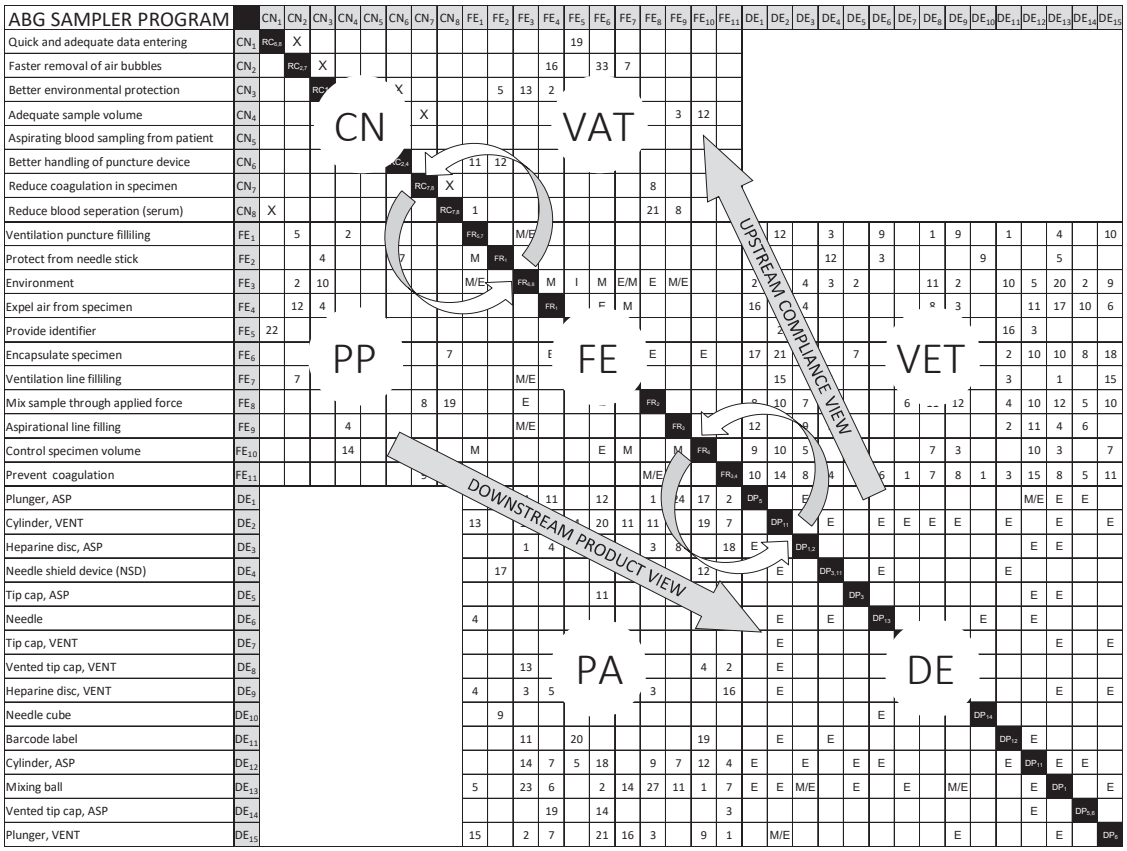


Fig. 7.30: The modularized platform architecture for the ABG sampler program

As illustrated, the three central domains, i.e. the customer, functional and physical domain, have been modeled by means of design structure matrices (DSM), the downstream product view showing the product portfolio design and the product architecture design has been modeled by

applying domain modeling matrices (DMM), and last the upstream compliance view revealing the correlating validation and verification test and documentation view. By this, the design team has been able to grasp how these relevant domains to new medical device development and product maintenance are inter-related based on the three predominant views on the ABG sampler program, namely the market, product and compliance view of the program. As the complete picture shows,

7.2.5 MODELLING THE ABG SAMPLER DEVICE PROGRAM

After establishing the CACE model, this was used for the purpose of tracing change and effects, understand discrepancies, moving towards creating a modular platform architecture and evaluate the different product development projects set by the strategical targets.

Tracing Program Change and Effects based on Identified New Requirements

To better understand the down- and upstream effects of these changes, the CACE modelling tool was used to trace the change propagation (Fig. 7.31).

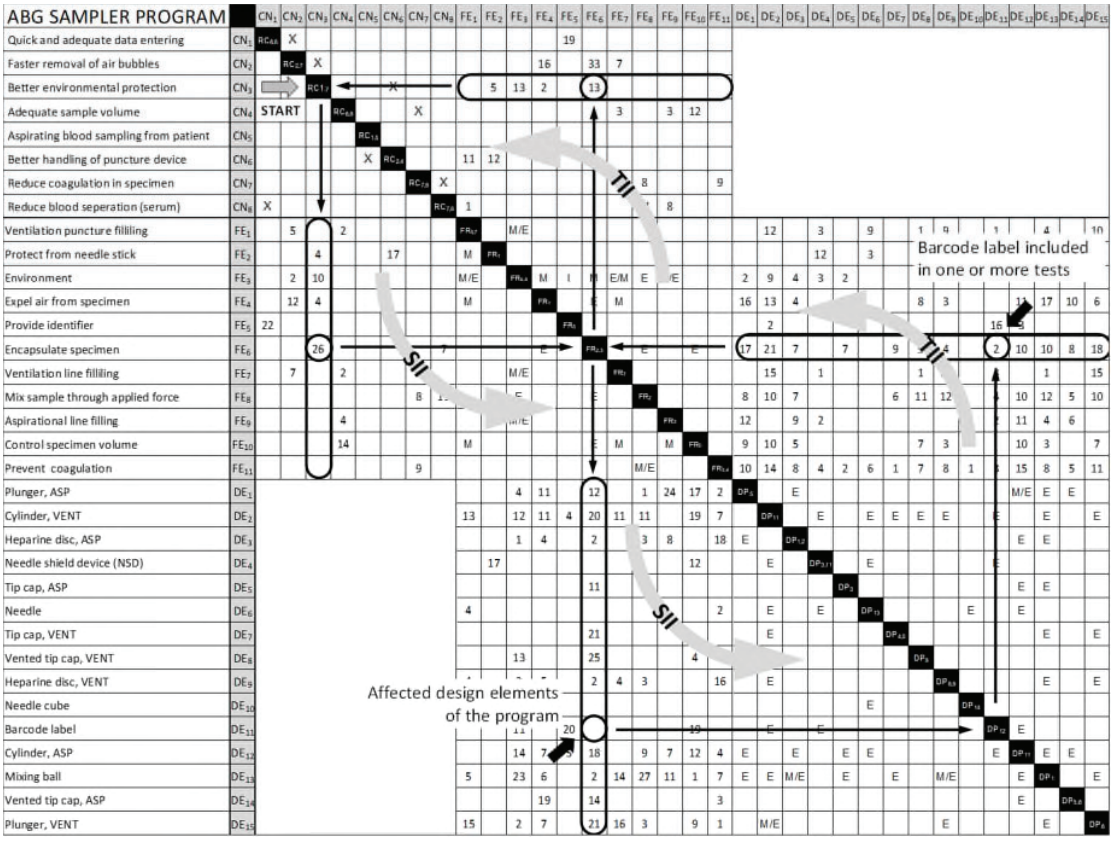


Fig. 7.31: Change effect analysis revealing the change propagation down- and upstream the views of the ABG sampler program

As revealed during the market analysis and especially through the investigation of the risk classes (Fig. 7.6), the regulatory requirements influencing these classes (Fig. 7.7), and its effects on current customer needs (Fig. 7.8), it was found that more changes to the regulatory environment to which the current ABG sampler program takes part, is soon to apply. Namely, it was found that changes will impact CN3 and CN6, which are a part of market view on the program.

By example, the need concerning better protection against the external environment (CN_3) was mapped using the CACE modelling tool. As the illustration shows, the changes to the market view was mapped downstream the product view to reveal which functional elements and physical design element of the program that would potentially be affected by these market changes. Upon this analysis, the upstream compliance view was investigated to get insight into the effects on the current V&V test and documentation setup. Based on using the traceability application provided by the CACE tool, it was possible to get an overview of how this change affect the ABG sampler program design.

Analyzing the downstream view, at first by investigating the product portfolio design, it was found that the functional element providing encapsulation of blood specimen (FE_6) is having the highest influence on the customer satisfaction of the need. This is because the element carries a functional property directly related to encapsulation, i.e. the ability to enclose the blood specimen and thereby protect it from the external environment. Naturally, the environment itself has a high impact. Namely because the environment as function pose specific properties that changes the condition for protection. Continuing down the model analyzing the product architecture, it was found that most of the design elements contribute to this functionality of encapsulating the blood. It was found that the function is the most integrated one, as the architecture reveals a one-to-many mapping between this function and the design elements. This is because encapsulation requires a united effort by the different design elements during the use activity, in which the function comes into play, in order to enclose the blood specimen. The cylinders and plungers, for example, creates a chamber for the blood to be carried, while the tip caps and vented tip caps (VTC) seal the sampler. Thus, these three design elements are highly coupled to the function. Meanwhile, these design elements carry varies structural characteristics, i.e. wall thickness, material, surface roughness etc., which all affect the functional property of that functional element, namely the ability to enclose the blood and thereby protect it from the external environment.

Analyzing the program from an upstream compliance point of view, first investigating the verification test and documentation domain, it was found that a high level of test and related documentation has been executed proving that the physical design elements of the program provide the functionality to a satisfactory level given by the acceptance criteria stated by the functional requirements. This means, that the design elements, additionally to what was found

analyzing the product view, are interlocked from a compliance point of view. Thus, not only do these design elements materialize the functional element measured by the system impact index (SII), they have also been heavily tested and documented as such applying the test impact index (TII). Thus, in this case analyzing the product program from the two predominant views, most of the design elements are equally integrated from both a product and verification point of view. Meanwhile, when analyzing the verification test and documentation domain, it was found that an additional design element, i.e. the barcode label (DE_{11}), has been included in one or more test, although this element does not contribute to the functional property of encapsulating the specimen (FE_6). Thus, this design element will be interlocked the group of elements that are to be tested when changes are made to this functional element. This finding was later evaluated during the discrepancy analysis.

Conclusively, the traceability analysis revealed how the changes to the marketplace, which as described is two-folded by means of customers and authorities, was to impact the program. The traceability provided by the CACE tool gave rise to well-founded decisions based on identifying exactly in which way the change to a risk class (RC_5) by which a the regulation (RR_{55}) applied to that risk class lead to an effect on the use activity (UA7) to which the customer need (CN_3) took part. In this chosen example, where an upcoming change to a regulatory requirement affecting the risk class by which more arterial blood gas samplers are subject, the CACE tool created a solid foundation upon which employees within both research and development (R&D), quality assurance (QA), and regulatory affairs (RA) got to a common understanding upon which they were able to plan the activities getting in compliance with the new regulatory situation. As the description reveals, the CACE tool offered the possibility to read the program up and down the down- and upstream views of the program. This is because the CACE modeling is based on causal relations. Thus, the downstream view provides the ability to move down the program view, but as important, it simultaneously provides the possibility to move up the product view, which support iterative processes. This is important when design teams are to discuss, as one can go down the product view to see how a certain functional element is realized, but concurrently one can move up the downstream product view to find a functional element to which that specific design element contribute. During the traceability analysis, this has clearly contributed to the satisfactory of the decisions made.

Analyzing the Current Product Program for Discrepancies Between Views

Following the analytical exercises establishing the domains relevant to the CACE tool, where the varies intra- and inter-relations are mapped, and thereby, as prescribed by the tool, the discrepancies between the views of the program has been identified. Here, the downstream and upstream view of the program, with their evaluated relations was mirrored using the delta-domain mapping matrix (ΔDMM) as provided by the CACE tool (Fig. 7.32).

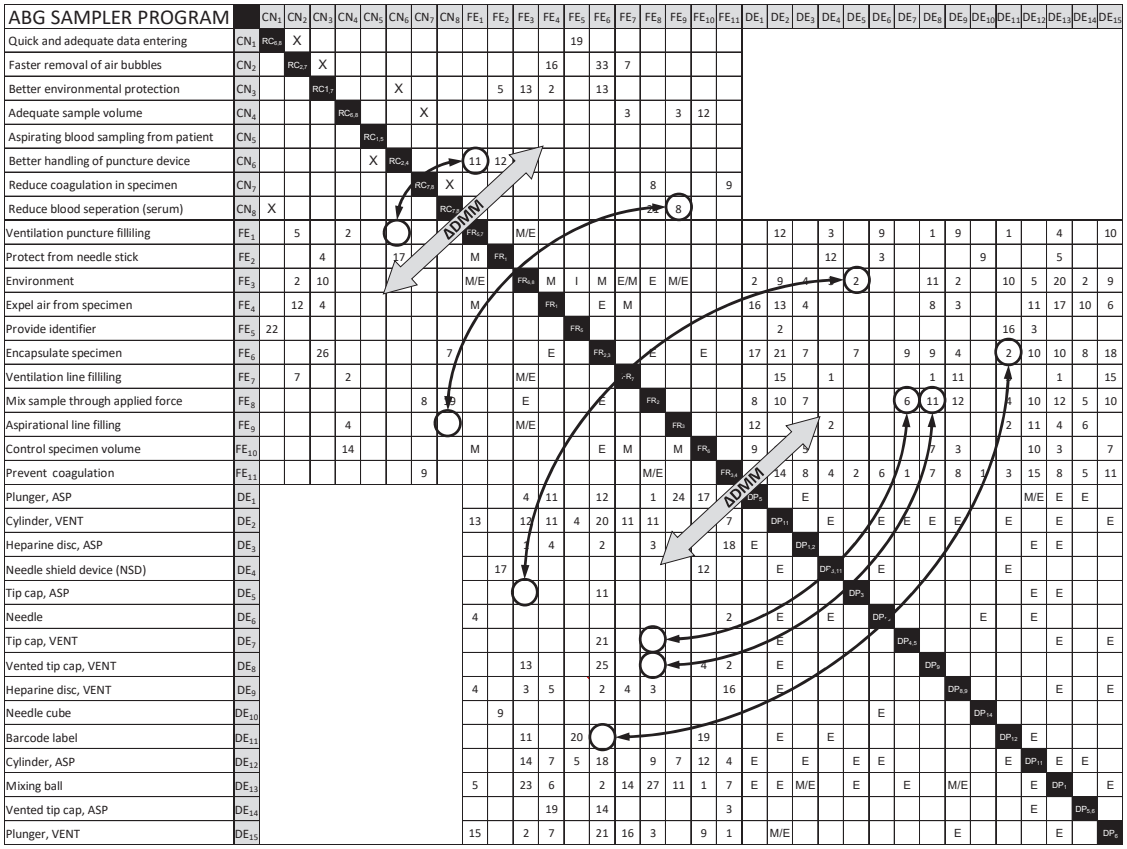


Fig. 7.32: Modeling the discrepancies across the product and compliance views of the ABG sampler program applying the delta-domain mapping matrix (ΔDMM) offered by the CACE modelling tool

As the illustration shows, when mirroring the product and verification test view from a high-level perspective, it was found that more discrepancies exist between views. Hence, the product view and the test and documentation views are out of sync or misaligned. As an example of what was found, the analysis revealed more design elements, i.e. the tip cap (DE_7) and vented tip cap (DE_8), not having an impact on the functional property of the functional element considering mixing the blood sample through applied force (FE_8) was tested for this functionality in the verification view. Thus, on one side, these design element does not realize the functional property of the functional element, but when analyzing the test view, the design elements were tested and thereby inconsistency between the product and test architecture is currently present in the ABG sampler program. Meanwhile, when analyzing the product architecture, it was found that this functional is highly integrated into the physical realization, and therefore quite a few design elements support the function and have been tested for such influence. In order to get a deeper understanding of the discrepancies found, the delta-elements and their relations were unfolded using the detailed ΔDMM model for the identification of the underlying models revealing the dependencies (Fig. 7.33)

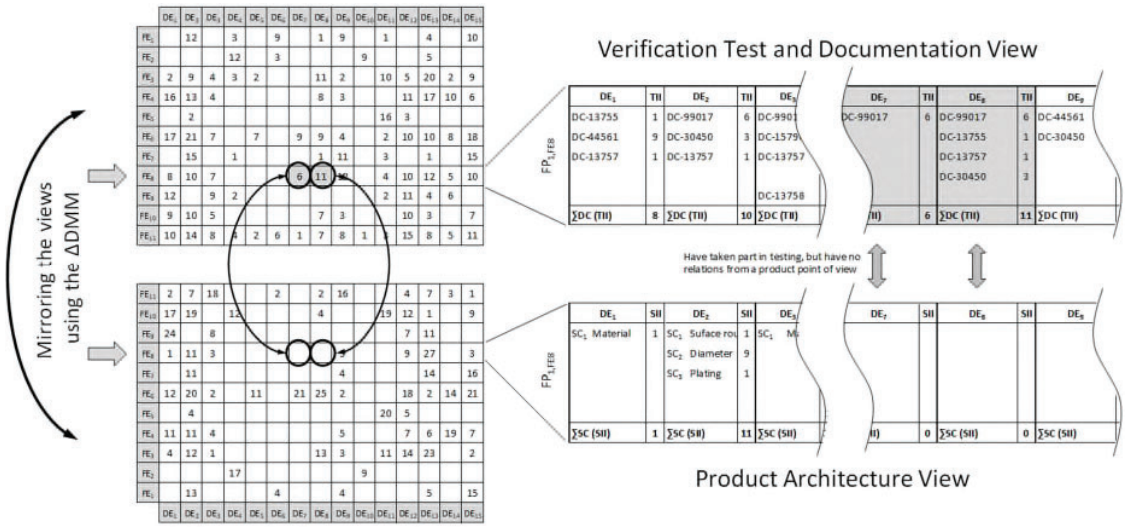


Fig. 7.33: Delta-domain mapping of the current ABG sampler program revealing current discrepancies between the product and compliance view on the program with detailed view on depicted discrepancies

The above illustration shows how the unfolded view reveals the underlying functional property to structural characteristics relations. The functional element of mix blood sample through applied force (FE_8) got a functional property, namely the effective mixing property ($FP_{1,FE8}$), which is affected by the structural characteristics of DE_1, DE_2, and DE_3. Here, the material ($SC_{1,DE1}$) of the plunger has a minor influence on that property, rated 1 according to the system impact index (SII). Here, SII is evaluated on combined resources and time consumption. The cylinder (DE_2) has three different characteristics, which influence the effective mixing property, i.e. surface roughness ($SC_{1,DE2}$), diameter ($SC_{2,DE2}$) and plating ($SC_{3,DE2}$), rated with 1, 9, and 1, respectively giving a total impact of SII = 11. Thus, the cylinder has a quite an influence on the ability for the function to effectively mix the blood specimen. The heparin disc (DE_3) affects the function by its material ($SC_{1,DE3}$). When looking at the verification view, these different design elements have taken part in tests that had the purpose to prove the performance of the sampler, namely here, the functional element FE_8 and its ability to effectively mix the sample. Moving to the left of the unfolded view, it is evident that the DE_7 and DE_8 do not have any influence. Meanwhile, when looking into the test view, it is found that these elements took part in the DC-99017 testing, which is a test that is rated relatively high in terms of resource and time consumption using the test impact index (TII). Further, the model reveals how DE_8 has taken part in multiple additional test, though not rated as high, but still adding up to a total of TII = 11.

As it has earlier been described, these deltas drive complexity when tests are to be reused across the product program. Here, if a new physical element is to be design based on the existing program layout, the test and documentation view interlock the design flexibility. If, one is the

design team is to change either tip cap or the vented tip cap (VTC), this has been tested for a mixing functionality on which they not necessarily influence. This means that the design team must undertake inappropriate testing and documentation work, for the program to stay in compliance with current regulations. Therefore, the design team was recommended to take action on the current situation. In order not to overburden the new product development department, actions could be scoped to design elements found to be interlocking the program, while planned for upgrade. In this way, the design team is cleaning up the discrepancies in a value adding order for the company to reach its strategical targets. Hence, a smart rationalization of the program based on the revealed during comparison and review of the product and test view on the current ABG sampler program.

Creating a Modular Platform Architecture for the ABG sampler Program

After reviewing the ABG sampler program from a traceability and discrepancy point of view, the program was evaluated with the focus on establishing a modular platform architecture for the sampler variants (Fig. 7.34).

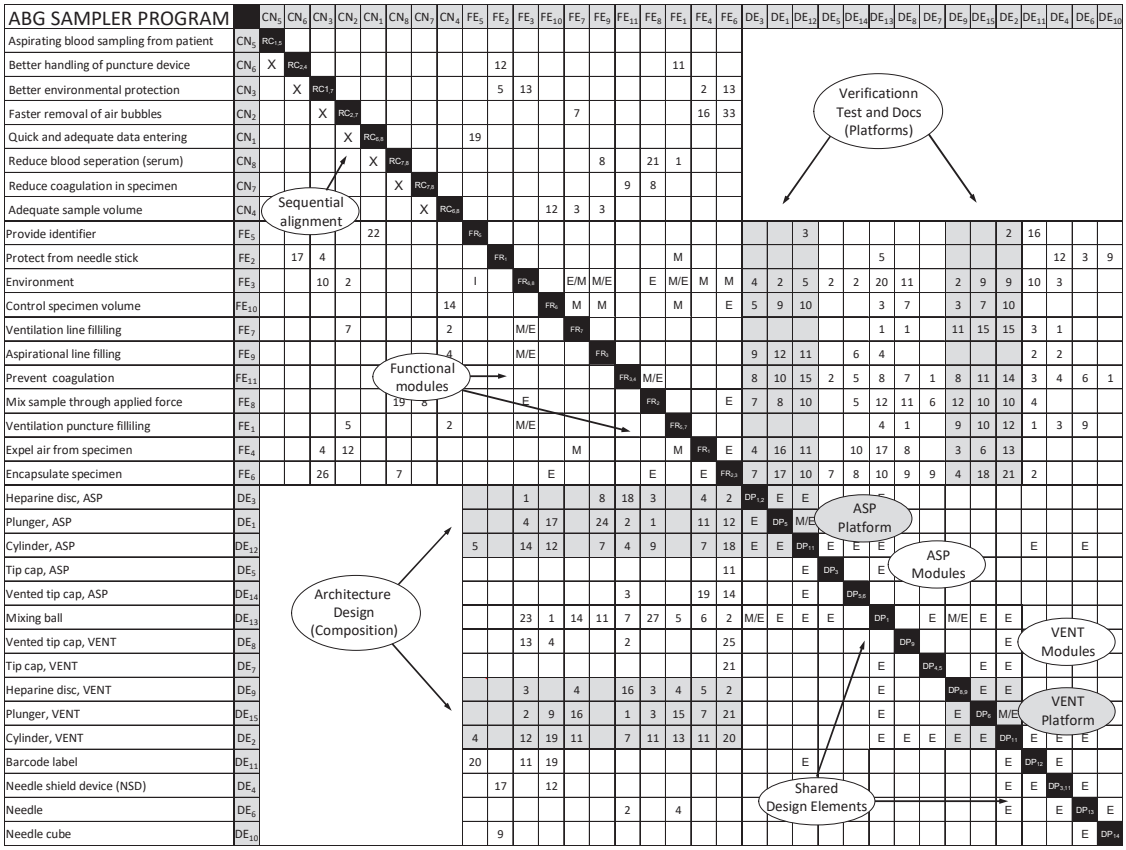


Fig. 7.34: The modular platform architecture for the ABG sampler program revealing the flows of the current situation and providing insight into the way forward

As the above illustrates, the ABG sampler program has been modularized, and platforms have been identified. Here, the customer domain was manipulated for sequential alignment. Hence, the customer needs were ranked according to prioritized fulfilment of the given customer preferences. The functional domain was the clustered for integrity, to reveal which and in what way the different functional elements are interacting based on interaction couplings. Here, it was found that the environment (FE_3), that is the context in which the functional elements interact and the control blood specimen (FE_{10}) are highly integrated into the functional structure of the program. Moreover, mix blood sample through applied force (FE_8), ventilation puncture filling (FE_1), expel air from specimen (FE_4), and encapsulate specimen (FE_6) are interacting with each other. Please bear in mind, that these functions also are the once posing some of the most important capabilities towards patients' and operators' safety, cf. the earlier market analysis. Further, the physical domain was modularized for carry over and here, platforms were identified based on integrality of the design elements – what founds a sampler. Three aspects were important, and are when using the CACE tool for creating a modular platform architecture: (1) the physical domain and its current interface dependencies coupling the design elements together, (2) the product architecture, showing how different design elements of the program currently supports the functionally provided, and last but not least (3) the verification test and documentation view showing in which tests the different design have taken part and thereby how design elements are integrated into the test view of the program. This last point is important to emphasize, when the program is to undergo compliance driven modularization. Thus, first the modules were identified based on the three predominant aspects of modularizing the program for compliance. When looking at the program from a verification point of view, it was evident that specific design elements were highly integrated in terms of test and documentation. Especially the cylinders (DE_{12} and DE_2), plungers (DE_1 and DE_{15}), and heparin discs (DE_3 and DE_9), which represents the ASP and VENT families, respectively and thus can be seen as the foundation for the sampler variety offered by the program, were identified as being highly integrated into the verification view. Further, the mixing ball (DE_{13}) was identified as being a highly integrated design element. When looking into the product architecture provided by the product view, these design elements are highly integrated into the functional domain. Here, especially the cylinders have high impact on functional properties of the design elements. Finally, looking into the physical domain, that the cylinders, plungers, heparin disc and the mixing ball are highly coupled through interfaces, especially mechanical energy is represented.

Thus, two platforms have been identified based on clustering. These consider the cylinder, plunger and heparin disc for both a ASP group of products and a VENT group of products, which together cover the entire ABG sampler program. As shown by matrix, modules have been identified based on their level of integration. These follow the platforms, so that modules fitting the ASP platform are clustered around these design elements founding the ASP platform and likewise for the VENT platform.

Further, a group of design elements were identified as being very integrated with each other, but not necessarily connected to the platforms. These we call “shared design elements” that can be combined with different other modules but are not required as product offering. During the earlier analysis, in total fifteen design elements were identified being integrated with each other. As the illustration shows, many interfaces have been identified as being energy (E) because many of the design elements interfaces with each other through mechanical energy. Meanwhile, it was revealed during the exercises investigating the physical domain of the ABG sampler program that the blood act as ab amorphous medium, which integrates the functionality in a complex mapping to the design elements, e.g. the blood acts as a force transmitting medium and thereby functionally integrates the components that are in contact with the blood (Jensen et al. 2015).

Based on the outcome of this analysis, the views were unfolded to evaluate the conceptual layout of the platform architecture and modules identified (Fig. 7.35).

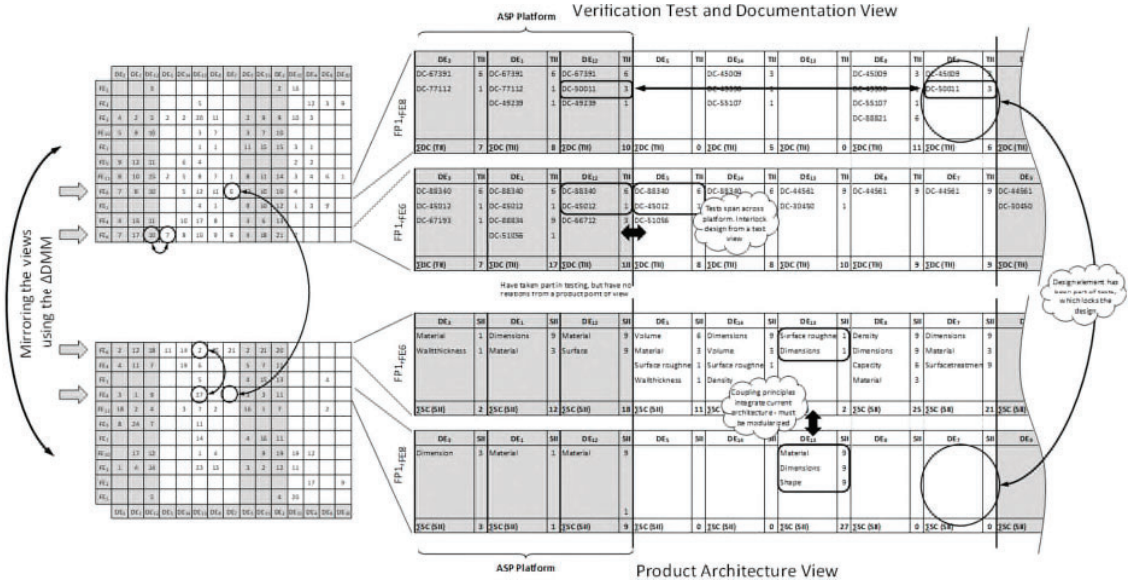


Fig. 7.35: Quantification of current discrepancies obstructing the future product designs based on the new modular sampler platform program

During the exploration of the architecture concept, it was found that a few intra- and inter-relations currently obstruct the modular platform architecture design proposal analyzing the unfolded ΔDMM exploring the platform extend. The following exemplifies types of findings when exploring a modular platform architecture concept using the CACE modelling tool:

First, it was found the tip cap (DE_7) has no impact on the mix sample through applied force (FE_8), but when looking at the verification test and documentation view, the design element has taken

part in more test. This was also found during the discrepancy analysis. Here, additionally it was found that one of these tests, the DC-50011, is a part of the platform. Namely, this test is has tested the cylinder (DE_{12}) against the effective mixing property ($FP_{1,FE8}$), which the vented tip cap should not be part of. This showed how the compliance view locks the design flexibility. In this way, the vented tip cap (DE_7) cannot be changed without interfering with the identified platform. Hence, it is crucial for the modular platform architecture to work properly, that it is encapsulated from changes both from a product and test point of view. Here, the design team could choose to change the tip cap without interfering with the platform from a product point of view, but from a test view, the design element cannot be changed without retesting it for the effective mixing property ($FP_{1,FE8}$), which tip cap (DE_7) has nothing to do with.

Second, the analysis revealed that not only has the entire ASP platform been verified through DC-45012 for gas diffusion property ($FP_{1,FE6}$), also the tip cap (DE_5) has been included in that test. Here, the test is spanning across platform elements and design elements unique to the program. In principle one could argue that this makes sense, as the tip cap has a high influence on the ability to encapsulate the blood specimen, but in this research, it is argued that the design team should seek to decouple the tests. When mirroring the views, it is the objective to have a one-to-one mapping, and when establishing a modular platform architecture, this should be modular from both the viewpoints. Meaning that tests should be scoped according the platforms and modules. In this case, it was recommended to split the test in two, one for the platform elements and one for the combined view. The reason is that in this way, it would then be possible to decouple both the product and the test view. Then, it would be possible to isolate change and effects and calculate impacts for a given design change to element and upon that carry out the test, also referred to as explorative testing.

Third, it was found that when looking into the product architecture view, the mixing ball integrates into two very different functional elements. The mixing ball (DE_{13}) has a high impact on the functional property the functional element mix sample through applied force (FE_8), which has the functional property of effective blood mixing ($FP_{1,FE8}$). This, correlation is evident as the structural characteristics of the mixing ball reach SII=27, which should be no surprise. Meanwhile it is found that the mixing ball has a relatively low impact, rated SII=1, on the gas diffusion property ($FP_{1,FE6}$) of the functional element encapsulate blood specimen (FE_6). Thus, the unfolded ΔMDM view showed how such identified delta, during the high-level analysis of the CACE model, spans across. Meanwhile, such a relatively little impact rises the potential for decoupling. Namely, that $SC_{1,DE13}$ which concerns the mixing ball's surface roughness could be eliminated by redesign in order to create a more modular architecture, when then could provide the potential of easier upgrade of the product variants.

Thus, based on exploring the modular platform architecture concept, a few actions were to be taken for the new architecture to pose sufficient modularity capability from both a product and test point of view while having the strategical targets in mind:

First, the design team should take action to create a one-to-one mapping between the downstream product view and the upstream test and documentation view. The company should ensure that executed tests follows the embodiment of the products, so that only those design elements that contribute to the given function, is included in the test, giving its properties and related requirements. Here, the design team was asked to rationalize the views of the program, so that maximum flexibility is enabled. Hence, the test view should not additionally lock the program and thereby restrict design, which was found to be the case during the analysis. This should be done by carrying out explorative tests revealing the performance of the program, i.e. by looking into the product view, and test the functional elements for their functional properties taking the right design elements into account.

Second, the design team was asked to act decoupling the design elements that drives the complexity from a product point of view. During the analysis, it was found that the structural characteristics of the mixing ball was integrating the product architecture. Therefore, the design team should analyze the surface roughness of the design element and redesign the element. As found (Jensen et. al 2015), reducing the surface the surface would decouple the mixing ball from the gas diffusion property of the encapsulating blood specimen function. The design team should carry out explorative testing where the functional property is tested for the influence of the structural characteristics of the mixing balls by varying the surface qualities to understand the impact of variation. By this, an acceptance criterion stating an acceptable range of surface qualities guarantying the properties of the modular platform architecture and thereby protect or decouple the platform from being impacted by outside variations.

Last, the design team should take action to decouple the identified platforms from a test and documentation viewpoint, as it should be avoided to have unnecessary tests spanning across common (platform) design elements and unique (variant specific) design elements. This is a matter of cleaning up the test view. Based on the analysis, a few tests with low TII was identified spanning across the identified platforms and the rest of the program elements. Here, the design team was asked to redo the tests only considering the design elements that do influence the performance of the functional properties being tested. By this, the platforms will be decoupled protected or decoupled from outside variations. Remember that tests spanning across will lock the program from new product development point of view, when changes occur in the market, either by changes to customer preferences or regulatory substances.

With the above initiatives, the program will pose the desired capabilities, i.e. to reduce time-to-compliance (TTC) and time-to-approval (TTC), which highly affect market launch capabilities.

Evaluating New Product Variant Development Projects

Based on the strategical targets, the company wishes to launch five new product variants over the years to come. Varies engineering design initiative revealing different conceptual designs were discussed and evaluated. In the following, only one example will be provided, and the unfolded views of the medical device program will not be disclosed – the principles of unfolding views of the CACE modelling tool with its established views, have already been described earlier. Thus, the following provides limited insight into the use of the tool. To provide exemplification, the conceptual design for "Product B", creating an aspirational puncture sampler, was evaluated based on the current situation (Fig. 7.36).

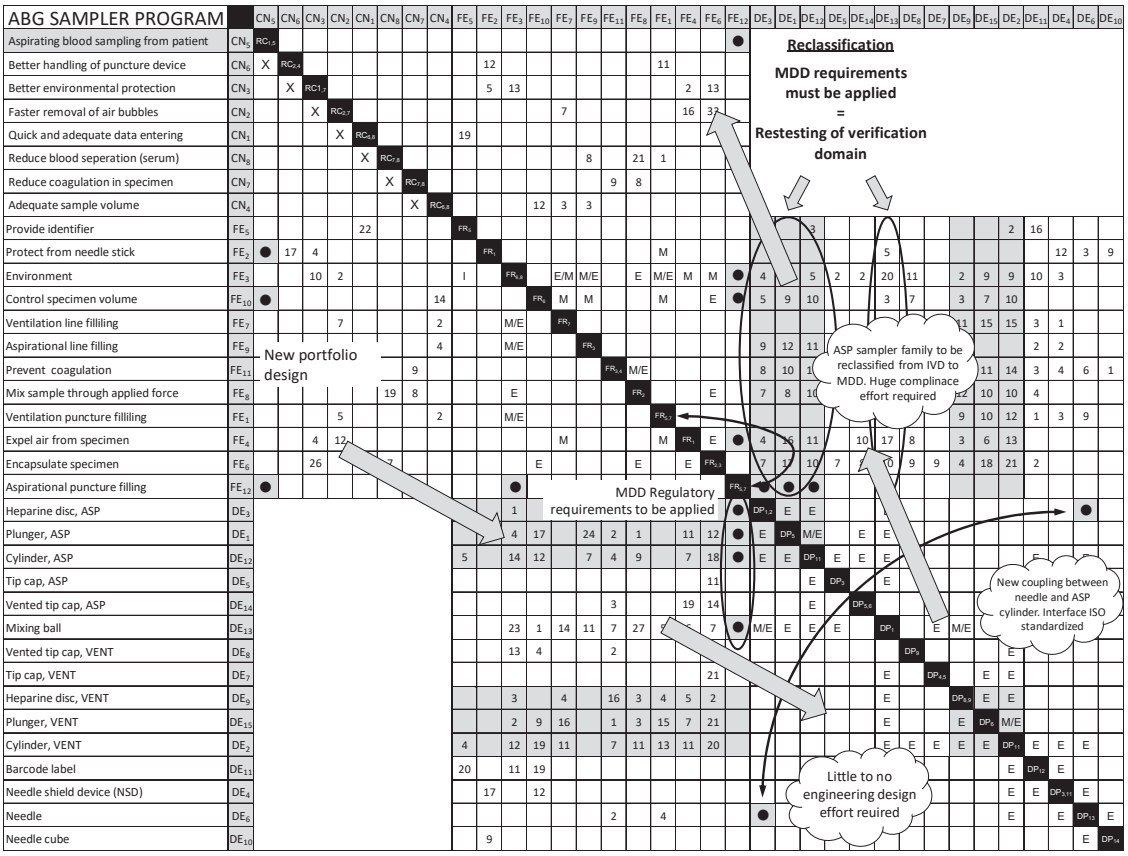


Fig. 7.36: Quantitative evaluation of conceptual design, based on As-Is situation developing the new "Product B"

When evaluating the program effects from a product point of view, the desired arterial blood sampling from patient (CN_5) was translated into the functional domain by means of analysing its possible impact while adding a new functional element to the domain, i.e. the aspirational puncture sample. This was then translated to the physical domain. The solution to design problem was to attach the already existing needle (DE_6) with the already existing ASP cylinder

(DE_{12}). Thus, only a new interface would appear. This conceptual design was evaluated based on the product and verification test view provided by the CACE modelling tool. As indicated, the design solution was quite simple from an engineering design point of view, but from a compliance viewpoint, this new variant would require the ASP families to be reclassified following the MDD requirements in order to be accepted for market introduction. The compliance-related burden was evaluated to be enormous and therefore, the conceptual design was rejected. Also, another conceptual design was evaluated using the CACE tool. Here, again the new customer need was translated, first to the functional domain and later the physical domain following the downstream product view of the CACE tool. The design solution, to create a new plunger based on the original design, the plunger, VENT (DE_{15}), was evaluated (Fig. 7.37).

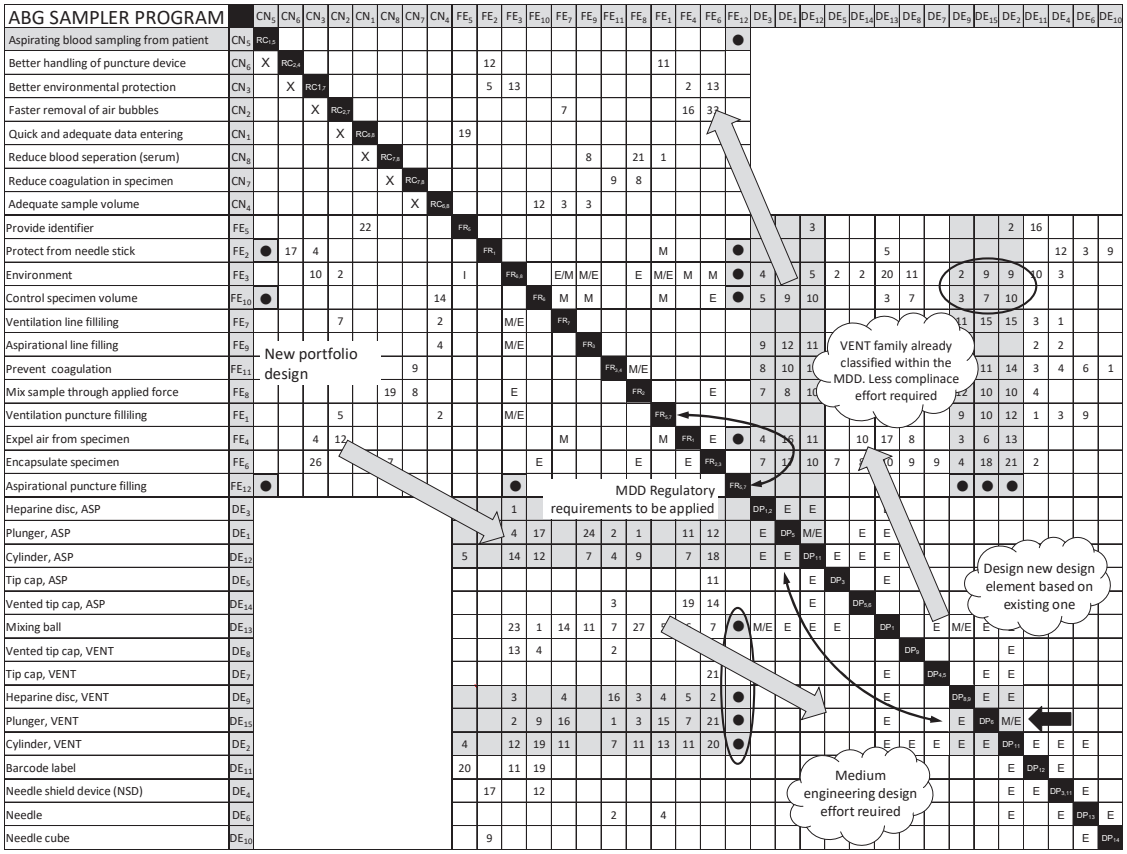


Fig. 7.37: Quantitative evaluation of conceptual design, based on To-Be situation using introduced the new modular platform architecture to develop "Product B"

The evaluation, reviewing the conceptual design from a product realization point of view, showed that much more design effort was need unfolding view of the product architecture. A redesign would require new engineering design of the elements constituting the vented plunger, but would be based on well-known elements and compositions, it would require supply chain

setup, manufacturing processes, etc. While, evaluating the design solution based on the verification test and documentation view, revealing the impact on the compliance work related to bringing this new solution to market. Here, it was found that because the design elements of the vented samplers are already MDD classified, which would lead to much fewer test being executed and the resources and time spend on compliance-related work would drastically be reduced compared to the outcome of evaluating the first conceptual design.

Thus, the CACE modelling tool provided the team with the possibility to evaluate conceptual designs based on the product and compliance viewpoints. By applying the CACE tool, the company found it to be insufficient to undertake the straight-forward solution, which was readably at hand and at that time, introducing the CACE tool, was the desired solution to the problem. Thereby, the tool added to the basis for making qualified decisions in the font-end.

7.3 CLOSURE: EFFECTS OF THE CACE METHOD

The company studied had set the strategical goal to launch five new product variants to the marketplace. Meanwhile, the company was facing difficulties maintaining its current product program covering the 27 product variants. Specifically, the company was challenged with the compliance burden maintaining the current medical device program while bringing new products to market. Meanwhile, the company had difficulties overseeing the consequences of initiating new product development project looking into the compliance burden.

To understand what it has meant to the company applying the Compliance Architecture Concept Exploration (CACE) modelling tool, the company was asked to evaluate outcome. Thus, to shed light on the capabilities of applying the proposed CACE tool in the industrial setting, the company was asked to evaluate their pipeline (new development projects) prior and post to applying the CACE tool.

The evaluation revealed how the entire project portfolio looked prior and post to introducing the modular platform architecture and taking the necessary actions based on the results revealed by the modelling tool (Fig. 7.38). The different new initiatives were quantitatively evaluated based on three parameters: (1) probability of success, (2) time-to-application, and (3) the resource consumption. Hence, this evaluation primarily considers the tool's capabilities within the front-end of new medical devices. The evaluation specifically evaluated how the application of the tool led to a more solid understanding of product program and thereby provided the company with a solid foundation by which it could make thorough decisions for actions to be taken. The diagrams have been established based on inputs from the department of quality assurance engineering (QAE), regulatory affairs (RA) and research and development

(R&D). Thus, the evaluation comprises the opinions by the three functional areas of main concern.

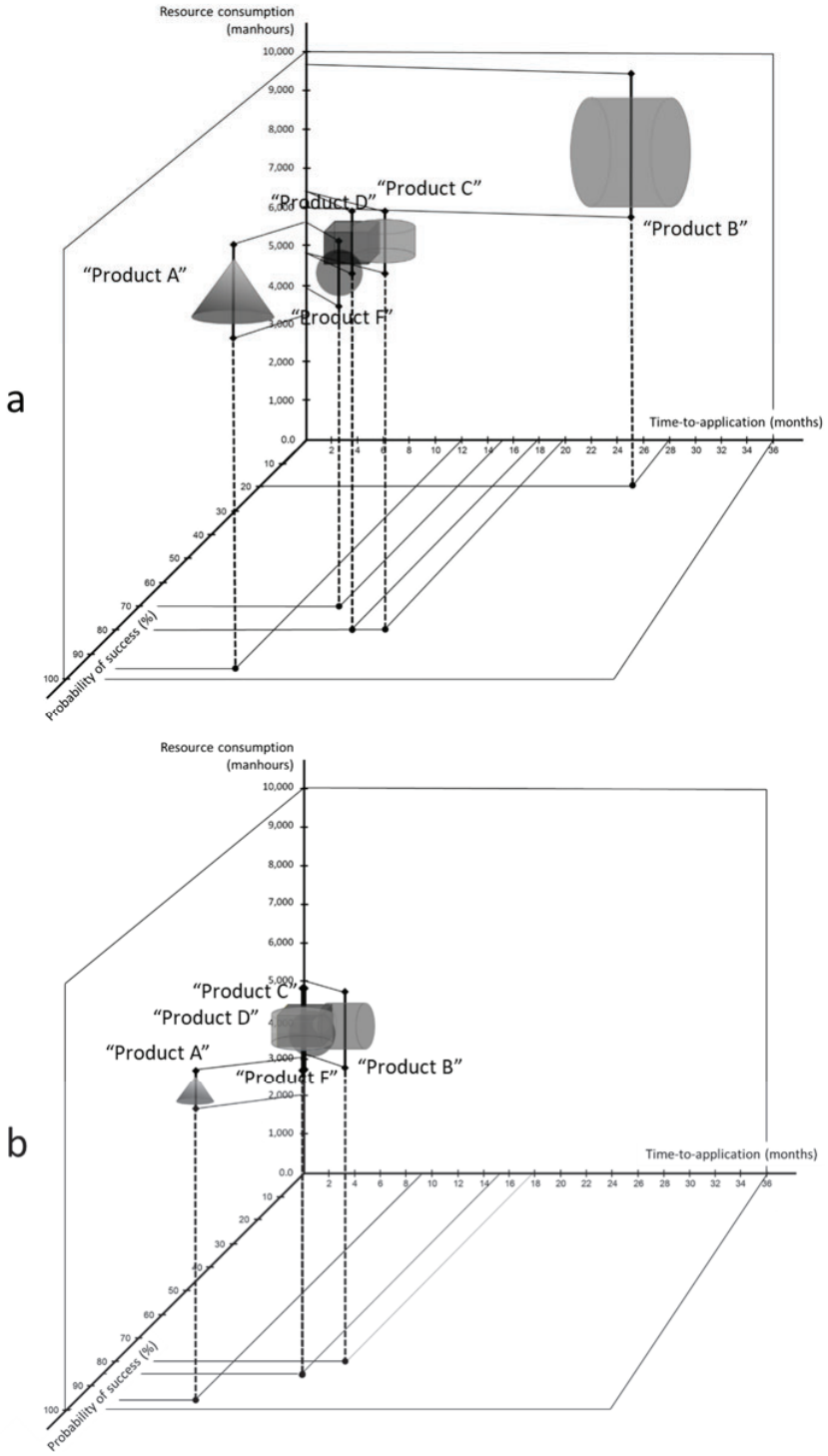


Fig. 7.38: Projection: Portfolio evaluation prior (a) and post (b) to introducing the new modular platform architecture by means of using the CACE modelling tool

The above illustration shows a projection of lead-time, resources and probability of success. As the obtained data shows, both the lead time and resources spent would be reduced, while the probability of reaching technical success will rise. The reason for this is, that by applying the CACE tool, the company has gained insight into how changes to the marketplace affected the company's current medical device program. By applying the tool, the company was able to evaluate current and possible future architectures and identify the dependencies that obstruct modularity from a compliance point of view. Thereby, the company was able to make appropriate decisions about the program leading to a more modular program architecture. Meanwhile, the CACE tool offered the possibility to evaluate new conceptual designs, not only by evaluating the product itself from an engineering design perspective, but also evaluating the design proposals from a compliance point of view, which totally shifted the perception of the goodness of the designs in terms of resources and time forecasted to be spend on the product development project. Therefore, it can be concluded that applying the CACE tool in this company had significant impact on future launches of medical devices while it led to significant changes to the situation.

"Wisdom is not a product of schooling but of the lifelong attempt to acquire it."
– Albert Einstein

Chapter 8

Conclusion: Achievements, Critical Analysis and Recommendations

The objective of this chapter is to close the thesis. This is done by (1) answering the research questions stated in the beginning of the thesis and have been a guiding tool for navigating the research study, (2) conduct a critical analysis of the research study and its results by means of verification and validation, and (3) make recommendations for future research based on the findings of this study and the limitations to it.

8.1 Answering the Research Questions

The overall research question by which the research of this thesis has been guided was: *"How can a program of products be efficiently and effectively modeled and synthesized to support medical manufacturing companies?"*. In context of this overall question, the research has been guided by four subsequent questions raised following the design research methodology for the staging of this research study. The established research questions have been grouped together according to varies purposes, which has been stated in sequential order, to frame and build the research study.

RQ1.1: What are the challenges of the medical industry, and what are the specific needs of the medical manufacturers?

To answer this question, initial surveys followed by detailed discussions and finally explorative case studies have been executed in order to get a broad and detailed understanding of the challenges that medical manufacturing companies face in today's world. Further, a short literary study has been conducted to get insight into the phenomenon of manufacturing medical devices.

Contributions of this research

In this research, study of literature and interactions with the industry have founded the basis for revealing the current challenges to the medical industry from an engineering design and product development perspective. The findings are described in chapter 1 and 4. It was found that companies continuously are challenged with the ability to bring new products to market while they face difficulties maintaining products already launched to market. Further, it was found that tightening regulatory requirements demands medical device companies to have increasingly extensive compliance processes in place – processes which are often unreasonably costly compared with the engineering design effort spent when developing or maintaining the product program. Furthermore, it was found that regulatory frameworks contribute significantly to resource consumption and time-to-market for even very simple medical devices – within the medical industry, not much seems simple, but in this research study, more predominant aspects of the entire medical complexities, have been revealed. Namely, market complexities, product complexities, process complexities, and organizational complexity by which the first two have been the focus of this research.

Limitations to this research

An initial broad survey was carried out in the beginning of the research study so as to clarify the challenges and opportunities that could be pursued along the study – it has had both synthesis and rationalization aspects applied to it in order to shed light on critical aspects and their impact within the frame of the project. The survey was broadly and loosely framed and so was the more detailed discussion with company representatives. Therefore, no comparative data exist. Findings of both the survey and the more detailed discussions with industry practitioners showed that the industry face quite huge challenges when it comes to both maintaining its products at market while lunching products to the global marketplace. Although a variety of companies participated in this broader survey and detailed discussions, not all types of companies have participated, and the participating companies do not reflect the entire industry as such. Therefore, it cannot be certain that the outcome fully reflects the industrial needs in its totality. But it can confidently be argued that the subject treated in this research study targets several companies within the medical domain. The challenges are somewhat the same across industry: The regulatory frameworks, and the related compliance burden to maintain medical device programs while bringing new medical devices to market seems to be a predominant challenge of the industry.

Following the exploration of challenges and problems in industry, the second research question focuses on exploring possible solutions within academia. Here, it has been the aim to explore the current solution space identifying possible answers and then evaluate these against their probability of meeting the identified challenges. Thus, research question RQ1.2 is prescriptive by nature.

RQ1.2: What options does the industry have addressing its challenges and what possibilities do medical manufacturers have meeting its needs?

This research question was answered by conducting a review-based literature study. The literature study primarily focused on the predominant tools and methods described in literature, though it also touched upon concepts relevant to the research topic. The research question emphasized the exploration of product and compliance views from a structural complexity management perspective, clarifying the regulation-driven compliance domain.

Contributions of this Research

This research study clarified the current availability, i.e. the options the industry has addressing its challenges, based on a state-of-the-art literature review (chapter 5). Answering this research question, the research of this thesis identified a couple of case examples pointing towards the opportunity for advancing the chosen research area. Namely, the potential to overcome regulatory challenges facing medical companies by developing modular platform architectures. Guided by this finding, the literature of this research has contributed to three areas: (1) what main perceptions of family, platform, architecture and module currently is found in literature, (2) what main methodological contributions within the chosen field of study current exist, and (3) to what extent these contributions address the identified challenges.

In the literature study, several tools and methods were identified with the potential to take on the compliance driven modularization. The findings of contributions in published in literature was evaluated through well-defined parameters: (a) Scope, which emphasizes the level of abstraction. This has been important evaluating the contributions as in this research study the scope was on manipulated programs of products, not single products. This out ruled quite a few methods published in literature. (b) Aspect, which depict the life phase systems included or viewed by the tool. The aspect is important as this research focuses on compliance and thereby verification and validation test and documentation of the life phase of the product. Hence, compliance driven modularization, which further deducted findings. Last, (c) the purpose, which depicts whether a given tool is for analysis or synthesis purposes. This was important given the objective, as in this research, a holistic approach to product program design was sought developed to meet the identified challenge.

The literature study concluded, that although much research has been done within the field of modularization, little to no research contributions are currently offering solution pointing directly at the identified challenges. Although, modularization as a phenomenon is well explored from multiple angles, generally the contributions were found to explore the topic from the compliance aspect. Conclusively, the research of this thesis unfolds a novel topic to the research community – the topic of compliance driven modularization.

Limitations of this research

Although the literature study has been quite comprehensive, the literature has not been explored and compiled from multiple perspectives. The literature study has primarily had an engineering design and product development perspective and therefore solutions have been sought from that point of view. One could argue that additional literature searches should have been carried out, as the research subject spans across multiple disciplines, and therefore, the literature study should have been carried out by this scope. Meanwhile, it was found during the investigation of current challenges and needs, that primarily the R&D departments suffers from not having a structural modelling tool at hand, and during the frame of reference, it was found that modular platform architecture designs could have a positive impact on these conditions. Therefore, it was chosen to explore the solution space from an engineering design and product development perspective.

Following the initial exploration loop, the second purpose of this research study was about establishing the support for manufacturers within the medical domain building on the theoretical foundation of design science. This purpose was supported by the remaining research questions.

RQ2.1: How can a medical device program be modelled with regards to compliance test and documentation considering the market conditions of the medical domain?

The third research question is prescriptive and is about creating a holistic modelling tool for modular platform architecture development and exploration. The research question emphasizes the need for explicitly visualizing and describing dependencies bridging across product and compliance aspects of a medical device program design that give the design team a better overview of the entities and relations.

Contributions of this Research

The research study has shown how medical device programs can be modeled with regards to compliance test and documentation while considering the market conditions of the medical domain. Hence, this research contributes with a clarification of the new concept, i.e. compliance driven modularization – a new catalyst for modularization emphasizing a new additional compliance view on the product program design. In this research, it is argued that products can be viewed from many angles, as described in literature, but the concept of compliance driven modularization reveals a novel view on product programs. Not only should modularization be about the design object itself, it should also be about the tests and documentation that follows it. Further, this research contributes with a support tool that meets the challenges identified and follows the introduced concept – the Compliance Architecture Concept Exploration (CACE)

modelling tool. The tool emphasizes the modelling of a medical device program from a product and compliance point of view. It builds on well-founded theories and yet provides new capabilities.

The CACE tool emphasizes market analysis from multiple angles in order to maintain and upgrade the program. It reveals how the customer domain should be established based on both customer preferences and regulatory requirements while analyzing the segmentation grid based on risk classes and intended use, for the purpose of getting a solid foundation for evaluating the product program. The CACE tool builds on the multiple-domain matrix (MDM) methodology to capture and manage diverse domains, while it extends the current methodology by providing a new delta-domain mapping matrix (ΔDMM), which is used as support for carrying out cross-domain analysis of dependencies between the product and compliance view on the medical device programs. This research has introduced a new catalyst for modularization, i.e. for compliance test and documentation reuse, which can enable better control and upgrade of documentation packages during new medical device development.

In this research, it was found that the CACE tool can enable: (1) traceability and prioritization using risk measures in multiple-domain matrix, (2) Cross-domain integration evaluation of product-to-compliance discrepancies, (3) architecture modularization for compliance testing and/or documentation reuse, and (4) evaluation of new variants based on compliance architecture concept exploration. The research showed how the CACE enables evaluation of external changes (customer and regulation) while it founds the basis for deciding on realization of new product variants. Thus, it enables modeling of inter- and intra-relations, their alignment and potential for complexity management and reduction. Meanwhile, it provides the ability to detect discrepancies for rationalization purposes, while establishing a sound foundation for new product development. Finally, it supports the modeling of conceptual architecture designs for the exploration of optimal new product introduction considering the regulatory environment and its effects on the product and compliance view of the product program design. By the CACE tool, the design team would create a solid foundation upon which they can make decision about rationalization and synthesis of the program design.

By contributing with the CACE modelling tool considering compliance matters, this research predominantly contributes to the theory of dispositions. By use of this tool, the design team can account for regulatory frameworks and the compliance phase during the early stages of new product development. The results are elaborated in chapter 6.

Limitations of this research

The scope of the modelling tool provided is quite broad giving the objective to contribute with a holistic modelling tool to support medical manufacturing companies. Hence, the CACE modelling

tool encompasses seven different inter-related domains to model and visualize the downstream product view and upstream compliance view while considering the market complexities, and the functional and physical domain of the product program layout. The contribution has focused on enabling the entire program with regards to both the product and compliance view. This broad scope has resulted in less details on all the entities of the program element. Thus, this research is limited when it comes to its description of property modelling and test architecture mapping understanding how e.g. a documentation architecture could be established. Further, this research does not sufficiently focus on the upper part of the down and upstream part of the CACE tool. Namely, this research does not sufficiently describe how the product portfolio design and validation test and verification view inter-relate based on its elements. Therefore, much research is still to be done on the theme of compliance driven modularization.

The last research question has been stated with the objective to provide insights into the applications of the proposed tool, namely how the tool can be applied for the support of a medical manufacturing company.

RQ3.1: How can modularization of a product architecture be applied to address a medical device company's dependence of regulatory compliance?

This research question addresses the third and final research objective; namely, to provide insights into the applications of the research contributions hereunder show the utilization of the proposed CACE modelling tool.

Contributions of this Research

The study of a medical manufacturing company showed how the application of the CACE tool enabled traceability of the ABG sampler program, from market conditions to physical elements of the embodiment of the program (chapter 7)During the market analysis establishing the customer domain, more changes were identified that would soon have an impact on the current medical device program. Based on these finding, the traceability and prioritization exercise was carried out to reveal exactly how the market changes would affect the program. Further, the tool was applied to provide insight into the discrepancies between the product and compliance view on the program. Here, multiple discrepancies were identified, which lead to actions in the company. The tool was also used for exploring a new modular platform architecture. The tool revealed a few obstructions that should be eliminated to make the new modularized program work properly from both a product and compliance point of view. Last, the tool was used to evaluate different conceptual designs of new desired product. Here, it was found that one over the other would have much shorter lead time and require much less research in terms of compliance work.

Finally, this research showed by quantification, what benefits the company would receive from introducing the new modular platform architecture using the CACE modelling tool. Here, the portfolio of product development project was evaluated based on an As-IS and To-Be situation using the tool. This revealed that the company would, in terms of reaching its strategical target of launching five new product variants, gain competitive advantages by introducing the proposed modular platform architecture, which was based on evaluating the current product program from the different views provided by the CACE modelling tool. The tool, in evaluating the current program architecture against the new proposed modular platform architecture, revealed how such initiatives should be carried out. Namely, which actions that should be taken in order to reach the desired goal, to lower time-to-approval for new medical device variants.

Thus, this the case study conducted in this research did verify the tool's eligibility. Not only did the tool provide structural insight into the different domains and their inter-relations, or couplings, it also fostered very fruitful discussions among employees across borders of the functional units of the company. The tool enabled the company to better understand change and effects reading down, up, and across the model and by that the company was able to make well-founded decisions both for the current program based on analyzing using the tool, but also for the synthesis of the program launching new product variants to different markets. The case study comprehensively showed how the CACE model tool can be utilized in industry enabling competitive advantages of a medical company.

Limitations of this research

The research of this thesis showed how modularization of a medical device program can be applied to address a medical company's dependence of regulatory compliance by means of the using the proposed CACE modelling tool. Meanwhile, not all aspects have been tested and described by the conducted case study. The case study does not describe how the product portfolio and validation test domain inter-relates, as these were scoped out of the case study. Further, one could argue that the description of the case study is insufficient for replica. The case cannot necessarily be re-tested in other companies based on what has been revealed in this thesis. Moreover, only one case study has been described by this research, which limits its test and verification capabilities of the proposed tool. Finally, only selected examples of the findings have been described in this thesis, which limits the proven utilization in industry

Conclusively, it can be stated that the research conducted and described in this thesis answers the research questions asked, although quite a few limitations have been identified when evaluating the contributions of this research.

8.2 CRITICAL ANALYSIS: V&V OF THE RESEARCH

One of the challenges of conducting research within design science is to obtain an unbiased verification and validation. As it has already been pointed out, not only is design science and engineering design research often characterized by posing few quantitative indicators, and working within the front-end of the design process, which is the case for this research, has made it hard to ensure a strict validation of the research results based on observations. Therefore, as it was revealed when answering the case studies, the criteria have been qualitative, and the nature of the case studies has been characterized by many factors involving the overall performance of the cases studied.

Meanwhile, the research conducted and described in this this thesis heavily builds on case studies. In this research multiple case studies have been conducted with the objective of clarifying the research questions stated, spanning from identification of current challenges in medical industry, over clarification of the phenomena including "state-of-the-art" tools and methods available, to identification of possible new solutions to the challenges identified, and last but not least to solve, at least partly, the identified challenges. Thus, this research applied a mixed research methods approach, where both qualitative data from interviews and qualitative raw data has been collected from projects investigated during the case studies at the different stages of the research.

As described in chapter 2, in order to create a solid foundation upon which the research could build and reliable generalizable results achieved, the case companies were carefully selected within the medical domain. The cases conducted in this research were generally identified as representative. Case studies have been carried out from the first descriptive study over the following prescriptive study to the final descriptive study. Thus, case studies have played a serious role in shaping the research clarification and so, the final contributions. Meanwhile, it is still the opinion of the author, that more research studies should be done taking a few more loops using the design research methodology to ensure rigor of the research results.

The research results of this case study-based research are verified using the six aspects applied to the validation square of the design research methodology framework by Pedersen et al. (2000):

(1) *Individual elements* – The research has been based on widely accepted engineering design theory and theory of product development have ensured that the constitutive elements of the tested proposed modelling tool are accepted in the field. The proposed tool builds upon well-known modelling formalisms and thereby is accepted as such.

(2) *Internal consistency* – The research has been based on a widely accepted theoretical basis and the completion of 9 case studies for development, initial testing and refinement of

the proposed modelling tool, has ensured that the internal elements have been tested for consistency. More rigor consistency should be reached through the conduction of more case studies taking a few more loops in design research methodology. That said, the theoretical basis is rooting in widely accepted theories.

(3) *Appropriateness of example problems* – The conducted 9 case studies represent a wide spectrum of industrial settings across 7 medical device manufacturing companies. However, a common denominator for all the case companies is their growing compliance test and documentation complexity – a driving force for increasing time-to-approval and time-to-compliance, which is limiting their profitability and slowing down market introduction of new innovations. All case companies are developing and producing medical devices entailing mainly engineering disciplines (mechanics, electronics, software, and chemistry) ensuring that the example problems of the depicted case studies have served as a suitable basis for the aim and objective of the research study.

(4) *Useful outcome* – The case studies presented in this thesis all have been conducted in order to achieve the desired purpose of this research study and thereby successful meeting with the desired goal. The technique for achieving this result has been done by conducting multiple interviews with key stakeholders at different levels and across various life-phase systems while keeping a rigid focus on the overall aim of the research. The case study described in this thesis showed how the outcome, the proposed CACE tool, can impact the status quo situation bringing compliance to the front-end of new medical device development.

(5) *Link between method application and achieved usefulness* – As the case studies are staged in practical settings with great number of other impacting factors, this theorem is difficult to fulfill. Moreover, in case studies partially following an action research-based method, it is not possible to subtract the role of the researcher and thereby evaluate the case studies objectively. Therefore, to support the argument of a link between the application and resulting usefulness, the author can report that no 'competing' change agendas were present during any of the case studies, indicating that the achieved results ought not to be accredited to other resources. Thus, even though many factors are clearly influential, no other factors seem to be attributable to the achieved effects.

(6) *Usefulness beyond example problems* – It has been the research verification strategy to make the repeatability of the research results probable, by proving their usefulness through the conduction of a case study in a representative medical device company. Fundamentally, repeatability is context dependent and therefore it has been of crucial importance to depict case studies in companies that in some respects are alike while they differ across other dimensions, but still being in control of such deviations across cases.

That said, full repeatability has not been achieved. For the research results to be repeatable, they should be fully disclosed and thereby all influencing factor should be revealed, which has not been done in this thesis.

In this research, the measurable criteria have been of a very qualitative nature, and the nature of the case studies has been characterized by many factors involving the overall performance of the cases studied. Though, by applying the framework by Pedersen et al. (2000), the research is overall valid.

8.2.1 Verification and Validation of Theoretical Aspects

As mentioned in chapter 2, Buur (1990) suggests two approaches on how to verify a design theory, which is in line with the internal/external validity in the validation square of the research methodology framework. This research partially rests on both suggested approaches:

Logical verification – It has been difficult to ensure that all individual elements of the theory are complete. Meanwhile, it is argued that the observed phenomenon is relevant and can be explained, as it has been done in this research. The theoretical contributions of this research rests on well-established theories and do not conflict with those. The CACE modelling tool builds on the widely accepted multiple domain modelling (MDM) methodology, which has been accepted since its inception. The delta-domain modelling matrix is a contribution of this research that builds on a solid theoretical foundation while it expands the well-known theory. It is not new to research to apply deltas using multiple domain modelling techniques, the novelty of this contribution lies in the fact that it is new to apply it cross domain, namely the delta-domain mapping matrices. The concept of compliance driven modularization builds up on commonly known modularization theories and clustering algorithms, while the research of this thesis expands the scope of modularization to include compliance as an important factor to consider when developing modular platform architectures. Thus, it is argued that the contributions support both widely accepted methods and specific design problems. The reason why logical verification is not fully reached, is that completeness of the theories contributed by this research has still not fully been reached.

Verification by acceptance – It is argued that the contributions of this research is of high relevance to the research community. This research unfolds, still a very novel topic, but indeed a relevant one. Although the challenges identified lies within regulation and documentation, and therefore may seem to be on the borderline of the scientific community's interest, i.e. the design science, the problem is pointing towards practitioners within engineering design and product development, and great potential for solution to the challenges identified is highly relevant to the community of design science. The contributions of this research should therefore be of relevance and thereby be accepted by the scientific community. Whether or to what extent the

contributions of this research is accepted by the industrial practitioners is still difficult to conclude. Case studies have shown that practitioners and domain experts seem open towards the contributions, but it can still not be concluded that the theories have reached acceptance among practitioners and domain expert. Therefore, it can be concluded that the research seems verifiable by acceptance.

The thesis has been based on the interpretation that verified results ensure that the process of obtaining them has been correct, and validated results refers to the assessment of the results or outcome being correct. Thus, the intention of the formulated research questions of this thesis has been to contribute with explanatory elements within the phenomenon of concern and a justification of the relevance of the proposed modelling tool. In order to further verify the research, five main characteristics that a research result may carry in order to be valid, is used as suggested by Olesen (1992):

Internal logic – In this research, consistency is found between the motivation / the identified problem, the research questions stated, and the research results achieved. The research complies to well-known and accepted theories. The research of this thesis has followed accepted design research methodologies while applying mixed methods to obtain the results, which is found to be a highly accepted scientific approach within the research community.

Truth – In this research, the problem-based and theory-based approach has been applied to ensure rigor of the research results. Meanwhile, it is argued that the problem and the derivative results of this research have been explored from both a theoretical and practical point of view, and the research results can explain a phenomenon that is in fact real.

Acceptance – The results are still to be fully accepted by the research community and so among practitioners and domain experts in industry. Though, it can be disclaimed that the research results of this thesis are of high relevance to both academia and industry, as it seeks to solve a relevant identifiable problem based on well-known theory to both the research community and industry.

Applicability – The case study of a medical manufacturing company showed how the research contributions can be applied in an industrial setting. Meanwhile, repeatability is still to be reached, meaning that this research has not shown that the results can be achieved in any given medical device company. Although, there is confidence that repeatability will be achieved applying the CACE modelling tool in companies relevant to the topic. By the case example, applicability has been showed.

Novelty value – First, the topic treated in this research is argued to be novel. Little to no effort has been made contributing to this field of research while, as found in this study, a need for such contributions is present. Further, the CACE modelling tool with its capabilities, and the

contribution of the delta-domain mapping matrix, is novel as they are approaches to the existing world.

Thus, the research results of this thesis seem to pose the five characteristics that a research result may carry in order to be valid. Thus, it can be concluded that according to Olesen (1992), the research revealed in this thesis is valid.

8.3 RECOMMENDATIONS FOR FUTURE RESEARCH

This research introduces the concept of Compliance Driven Modularization and propose a tool that support this concept. Although, many topics have been discussed in this research, much research is still to be executed. Generally, it is recommended to conduct research studies to explore the compliance driven modularization, its nature and capabilities, by exploring tools and methods that can contribute to this field of research. This research seeks to meet some of the predominant challenges by introducing a holistic modelling tool. Meanwhile, much research is recommended to be carried out clarifying different elements of the modelling. The below lists some of the most pesante recommendations for future research:

Requirements management is an enormous both scientific and practical area. It is specifically recommended that research studies are conducted investigating the process of translating requirements (relations) from external influencers to internal requirements, which has been scoped out of this research.

It is recommended that research is conducted exploring the capabilities of the **customer domain**. The market for medical devices is two-folded and in this research a recipe is provided to model the domain. Although, research is still to be carried out clarifying the relations especially when it comes to the intended use, which has been found to be a key driver for relating customer preferences and regulatory requirements.

Impart **requirements reuse** in the catalyst for modularization and investigate the outcoming using this as a strategic vehicle for achieving competitive advantages. Hence, regulation isn't an obstacle to thriving free markets – it's a vital part of them. Conducting this research, it was found that requirements drive compliance test and documentation, and therefore its suggested to look into the possibilities of including this in the catalyst.

In this research, two **quantitative measures** have been introduced, i.e. the systems impact index (SSI) and the test impact index (TTI). It is recommended that further research is conducted to clarify these quantitative measures and their usefulness based on its current representation.

This thesis builds on the module-based platform architecture theories. It is recommended to undertake scientific studies on **scale-based platform** architectures, to see if this approach will benefit the scientific and industrial community. Scale-based platforming seems to have the potential to meet the challenges.

In this research not much has been done investigating the **product portfolio** design and the **validation test and documentation** domains. Hence, research should be done on these domains to clarify inter-relations and eventually reveal how these domains can be mapped and compared using the CACE modelling tool.

Decoupling is a prerequisite for modularization. In this thesis, research results point towards which elements that should be decoupled. Research is still to be done on **decoupling principles**. It is recommended to undertake scientific studies on robust design principles for clarifying structural characteristics and thereby establish the desired decoupling principles.

It is still to be disclosed how such tools and methods as the CACE modelling tool is to be implemented in **organizational settings**. Within the medical industry, quality management systems are the fundamental to the companies' existence. Therefore, it is recommended to carry out research on how to implement and drive such tools given the characteristics of the medical companies.

It is recommended that research is carried out **evaluating trade-offs** between the compliance driven modularization and other well-known drivers for enabling product modularity. In this research it is suggested to introduce a new catalyst for modularization, namely the driver for test and documentation reuse, but trade-offs are still to be disclosed ensuring the rigor of results showing that such a new catalyst will benefit both academia and the industry.

Thus, it is recommended that quite a few studies are to be carried out exploring the phenomenon, the contributions of this research and to extend the contributions to this field of interest.

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