Investigating the Transformation of a Medical Enterprise: Can a Medical Device Company Truly Become Agile?

By

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ABSTRACT

With the competitive landscape of technology increasing at a rapid pace, medical device manufacturers are struggling to keep up with the demands of the market and provide hardware and software solutions to support connected health technologies. Over the last decade, in an attempt to match the pace of the market, an increasing number of enterprises have shifted their product development processes from traditional stage-gated models to iterative development models, including Agile.

Using the architecting innovative enterprise strategy (ARIES) framework, literature reviews, and gathered knowledge from subject matter experts and stakeholders relevant to the enterprise, this thesis explores the benefits, challenges, and impact of transforming a medical device enterprise's product development process from waterfall to Agile methodologies. The interfaces of the enterprise within both its internal and external ecosystems were assessed in this research; due to the complexity of the medical device industry, stakeholder analysis was used as a tool to identify and prioritize the key interfaces which are critical for a successful enterprise transformation.

Approaching the challenge of imposing organizational change in a systems manner ensures that the enterprise and the environment within which it operates are viewed in a holistic sense and that the proposed solution(s) satisfy key beneficiaries and stakeholders. The research demonstrates that the voice of the project team, cross-functional team alignment, and support and empowerment of senior management are crucial to the success of this transformation and ultimately will impact the ability of the enterprise to meet their objectives and sustain their envisioned future.

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BIOGRAPHICAL NOTE

Arlesa Hubbard has a background in medical device development with specific training in risk management, design controls, and quality systems management of medical devices. She is passionate about developing safety systems and currently works as a Risk Manager at Sanofi where she supports the development of various technologies to assist with the treatment and/or management of diabetes and select rare diseases. In her current role, she focuses on the design and development of both combination drug-device products and standalone software as medical devices and their connected ecosystems.

Prior to joining Sanofi, Arlesa held roles as both a process validation engineer, risk management engineer and quality systems manager for a medical device companies which developed and manufactured apheresis and dialysis systems, respectively.

Arlesa holds a Bachelor of Science in Biomedical Engineering from The University of Miami and, a Master of Science in Regulatory Affairs from Northeastern University.

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TERMS & DEFINITIONS

Table 1 - Terms & Definitions

Term	Definition
21 CFR 820	FDA 21 CFR Part 820 is the Quality System Regulation (QSR) which outlines good manufacturing practice regulations that govern methods used in and for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices. (MasterControl, 2019)
Architecting	The act of creating a blueprint for the enterprise to follow to achieve its desired transformation vision (Nightingale & Rhodes, 2015)
Design Controls	Process that ensures the design of medical devices and associated manufacturing practices are controlled, documented, and reviewed at predetermined phases prior to release of device for commercial distribution. (FDA, 1997)
Design Freeze	The milestone during development (typically prior to design verification) after which any changes to the design are subject to a formal change control process.
Design History File (DHF)	A collection of records that detail the design history of a medical device (includes objective evidence for test records). (FDA, 1997)
Design Input	The physical and performance requirements of a medical device that are used as a basis for device design. (FDA, 1997)
Design Output	The results of a design effort at each design phase. The total finished design output consists of the medical device and its packaging and labeling. (FDA, 1997)
Design Review	A comprehensive and systematic examination of a design to evaluate the adequacy of the device requirements, to evaluate the capability of the design to meet requirement and identify potential problems. (FDA, 1997)
Design Transfer	Activities necessary to ensure the device design specification are appropriately translated into production specifications. Activities include process validation and design validation. (FDA, 1997)
Design Validation	Establishing by objective evidence that device specifications conform to user needs and intended use(s) of the device. (FDA, 1997)
Design Verification	Establishing by objective evidence that confirms design outputs meet design input requirements. (FDA, 1997)
Ecosystem	The part of the world that is relevant to the enterprise, and is characterized by the external regulatory, political, economic, market, & societal environment in which the enterprise operates and competes/cooperates with other related enterprises (Nightingale & Rhodes, 2015)
Enterprise Strategy	Overarching strategy that is a determinant of success of an enterprise in delivering value to stakeholders while pulling from and contributing to its own ecosystem (Nightingale & Rhodes, 2015)
FDA	Food and Drug Administration

Term	Definition
Human Factors/ Usability Engineering	Application of knowledge about human behavior, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability.
HW	Hardware
IEC 62366	International Electrotechnical Commission 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices. Defines process of usability engineering. (International Organization for Standardization, 2019)
Innovative	Being forward looking so that the enterprise evolves to stay ahead of changes in its ecosystem that may impact its ability to survive and thrive (Nightingale & Rhodes, 2015)
ISO 13485	International Standards Organization 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes. The standards that outlines requirements for quality management systems for medical device manufacturers. (International Standards Organization, 2019)
ISO 14971	International Standards Organization 14971:2012 – Medical devices – Application of risk management to medical devices. Outlines a process to conduct risk management (in regard to safety) for medical devices. (International Standards Organization, 2019)
NPD	New Product Development
Quality	The totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
Risk Management	Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (to patient, user, property or environment).
Stakeholder	Individuals and groups who contribute to, benefit from, and/or are affected by the enterprise. Stakeholders may be either exogenous or endogenous to an enterprise, depending on the perspective taken. (Nightingale & Rhodes, 2015)
SW	Software
Usability	Characteristics of the user interface that establishes effectiveness, efficiency, ease of user learning, and user satisfaction.
VDI 2221	Guideline - Systematic Approach to the Development and Design of Technical Systems and Products

CHAPTER 1: INTRODUCTION

This chapter outlines the context, research motivation, scope and objectives, as well as the research approach followed for this thesis.

1.1 The Medical Device Landscape: Regulatory Environment and Standard Processes

A medical device is defined by the FDA as "any device, apparatus or instrument that is used to diagnose, prevent or treat a disease, that accomplishes its purpose by something other than a chemical action" (FDA, 2018). The primary goal of medical device regulators such as the FDA (US) or notified bodies (European Union) is to ensure that only safe and effective medical devices are able to be marketed and available for use by consumers. Since the Safe Medical Devices Act of 1990, Design Controls have been included as part of the FDA's requirements for Good Manufacturing Practices. The 1997 Guidance released by the FDA for Medical Device Manufacturers outlines 5 project stages (Design and Development Planning, Design Input, Design Output, Design Verification and Validation, and Design Transfer) and two project tasks (Design Review and Design History Files) that should be completed prior to commercialization of a product to assist with ensuring devices have been developed in a controlled manner.

During the Design and Development Planning stage, manufacturers are required to create and maintain plans that both outline the design and development activities in detail and also identify the resources whom are responsible for implementation of those activities. The Design Input phase of development requires manufactures to implement sustainable procedures that guarantee all requirements associated with the device meet its intended use which include the needs of both the patient and user. The third stage, Design Output, mandates that manufacturers "establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements" (FDA, 1997).

Design Verification and Validation, the phase where the bulk of regulatory requirements fall, mandates manufacturers to ensure not only that the design outputs meets the design input requirements but also, the design meets user needs and the identified intended use of the device. In this phase, all objective evidence of the tests and test methods used to verify and validate requirements are required to be documented within the Design History File (DHF). During the final stage of the Design Control process outlined in the FDA Guidance, Design Transfer, manufacturers are required to develop procedures that guarantee the device design can be translated into production specifications and guarantee the device can be manufactured reliably and consistently (FDA, 1997).

Waterfall (also known as stage-gate) product development methodologies have commonly been associated with Design Control stages, which aligns with the design guideline VDI 2221 that segments product development into 7 phases (Schuh, Dolle, Kantelberg, & Menges, 2018). Medical device manufacturers may have been biased to follow the same development process due to the fact that the 1997 FDA Guidance included a diagram (refer to Figure 1) that illustrated how to align design controls with the standard stage gate process.

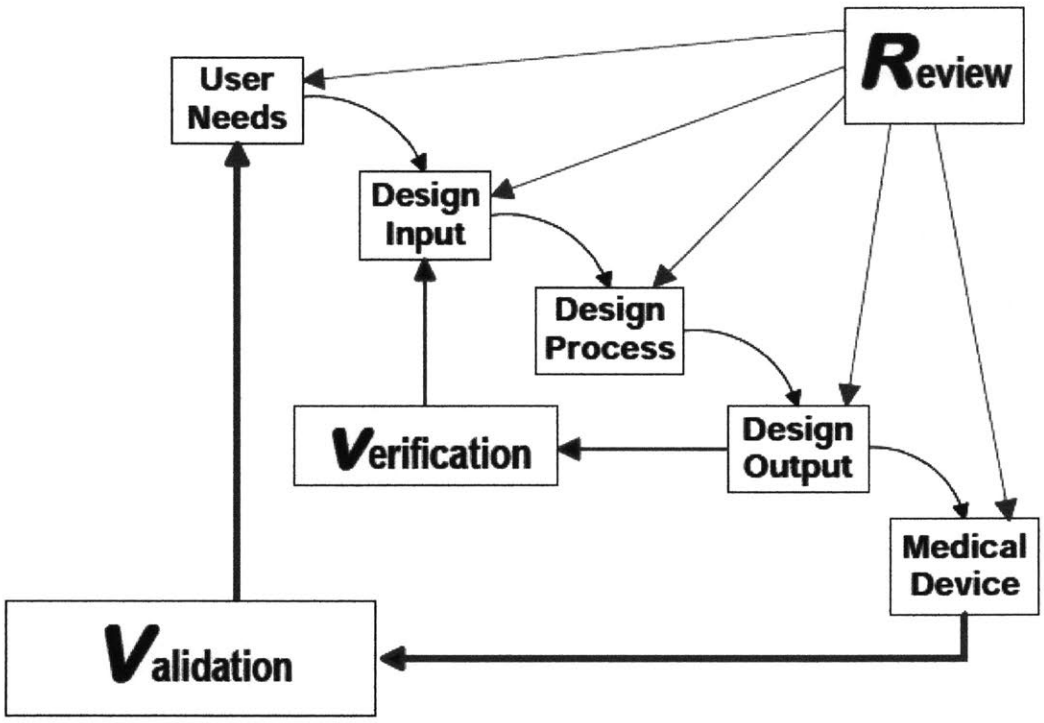

Figure 1 - Design Controls Applied to Waterfall Stage-Gate Process (FDA, 1997)

In addition to Design Controls, manufacturers are required to conduct Risk Management in accordance with ISO 14971: The application of Risk Management for Medical Devices. The international standard mandates that manufacturers assess, evaluate, control, and monitor risks that may impact patient or user safety both during the development process and after the commercialization of the device. Integration of the risk management standard with the design control and quality management processes often is a pain point for enterprises which stands to support the rationale for following traditional product development processes due to the fact that examples of integration of those key requirements exist and have demonstrated compliance to regulatory agencies.

1.2 Challenges of Current Development Practices

Traditional medical development processes are stage-gated and have been "regarded as too slow, bureaucratic, rigid" (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017). Due to the heavily regulated nature of the medical device field, it stands to reason that manufacturers would choose to employ processes that afford them maximum control of their product through every phase of development and production cycle. Adherence to consensus standards such as, ISO 14971: Risk Management for Medical Devices and IEC 62304: Medical Device Software – Software Life Cycle Processes, best aligns with stage-development processes due to the planning and management of changes that the standards require. Compliance with these standards in addition to the baseline regulatory requirements and testing standards that medical device companies must meet increases the development timeline significantly.

1.3 Research Motivation

With competition increasing and the technology landscape evolving, it would behoove medical device enterprises to implement practices that would enhance their ability to develop at a competitive pace. Development should not be limited to introducing new products; medical device companies should be prepared to introduce changes and improvements in a timely fashion to marketed products based on received market feedback. Companies, often in an effort to reduce timelines struggle with acquiring feedback early in the development process as well as incorporating received feedback into future designs or product iterations. Too frequently are products commercialized which either neglect needs or only address a subset of needs of its users.

A growing number of organizations are beginning to incorporate Agile practices in their development practices and have demonstrated success in both the customer satisfaction and employee satisfaction domains. Successful implementation of Agile development

methodologies may be part of the solution to not only developing medical devices that users desire but also commercializing those devices in a timelier fashion. This research intends to investigate the medical device environment and identify obstacles which impede the adoption of new product development practices and propose sustainable recommendations for facilitating adoption of new practices.

1.3.1 Author Perspective

After witnessing several business units attempt to work in an Agile fashion and ultimately regress towards the tried and true waterfall product development process, my curiosity peaked and I began to wonder what was meant by the term Agile and why were several independent business units unsuccessful in their efforts of implementing Agile practices. On the surface, it appears that the failed examples of implementation shared few commonalities (e.g. different organizations and business units, unique devices – standalone software versus dialysis machines versus insulin pens). It appeared however, that these organizations and business units failed in similar fashions by hastily implementing processes without holistically assessing the impact of those changes on the organization. Recognizing that these organizations would re-attempt to become Agile, I wanted to understand why previous attempts had been unsuccessful and if there were ways to ensure a successful conversion to Agile on the next try.

From personal experiences, I have noticed that the word Agile is used frequently but rarely is it defined or executed consistently within an organization. There is a general misunderstanding or lack of knowledge regarding what the Agile process is and both the advantages and disadvantages its implementation can have on the product being developed and the teams responsible for development.

This research is intended to investigate whether a full conversion to the Agile product development process is possible for a medical device enterprise, specifically Sanofi. Sanofi

was selected as the organization for analysis due to their relative newness to the medical device space and the potential value that could be offered by transforming the enterprise during its learning stages. While the company has been involved in device development since its inception, a large portion of development is accomplished through partnerships with established design partners who are required to abide by Sanofi's development processes which occasionally inflict points of frustration for both partners.

1.4 Scope and Objectives

The scope of this research is limited to one development unit within Sanofi's organization due to access of information, access to stakeholders and time constraints. Only the development phases, Design Input through Design Validation, were considered in this research; the manufacturing and life-cycle management phases of medical devices produced by the development unit are out of scope for this research.

This research seeks to answer the following questions -- how can a medical device development enterprise be transformed to adapt Agile product development methodologies? Secondly, what barriers prevent Agile methodologies from being successfully adopted? And lastly, what benefits could medical device enterprises gain from adopting Agile principles? By gaining insight into the limitations and challenges associated with the transformation and methods to best circumvent them, this thesis intends to consider those lessons learned in the proposed recommendations for the future enterprise.

The primary objective of this research is to systematically investigate the Agile product development methodology and gain an understanding of current challenges associated with medical device development processes and determine how those processes can be adjusted while using the ARIES framework to develop a strategy and recommendations to transform

an enterprise so that it may be capable of optimizing its new product development practices for a more timely delivery of value to end users.

1.5 Research Approach

This research is comprised of a literature review, stakeholder analysis, and insights communicated in discussions with stakeholders. Utilizing the framework of the Architecting Innovative Enterprise Strategy (ARIES) (Nightingale & Rhodes, 2015), this research systematically examines the current state of Sanofi's medical technology device development division (MEDTech). The ARIES framework provides ten lenses through which the current enterprise can be assessed, and the future enterprise can be architected.

The research explores the transformation of MEDTech's product development process by defining the current state of the enterprise, assessing its environment and capabilities, determining the needs of the enterprise and how several needs can be satisfied by the product development process, conducting stakeholder analysis and identifying priorities, generating concepts for transformation of MEDTech's development process, and lastly, evaluating the options using Pugh Matrix Analysis and selecting the solution that best satisfies stakeholders' needs.

1.6 Thesis Organization

This thesis is comprised of six chapters that evaluate the transformation of product development processes within a medical device environment. Each chapter explores the impact of integration of Agile development practices on existing enterprises through various lenses. A high-level summary of the content of each chapter is provided below.

Chapter 1 – Introduction:
This chapter outlines the context, research motivation, scope and objectives, as well as the research approach followed for this thesis.

Chapter 2 – Literature Review:
This chapter offers a literature review from the research applied to the transformation of the medical device enterprise. This review details the approach of enterprise architecting (ARIES framework) and identifies contributing success factors and challenges associated with both medical device development and the implementation of Agile practices.

Chapter 3 – Sanofi's Enterprise Landscape:
This chapter provides background information and context of the environment within which the transforming enterprise operates. This section identifies both the needs and desired capabilities of the enterprise. This chapter is intended to provide an understanding of the enterprise's ecosystem and the value a successful transformation could offer.

Chapter 4 – Stakeholder Analysis:
This chapter identifies the scope and boundary of the MEDTech division within MED. In addition to the boundaries of the division, this chapter recognizes and categorizes stakeholders based on their influence and needs. The analysis of the stakeholders provides important insights into the current state of the organization.

Chapter 5 – Analysis for Architecting the Future of MEDTech:
This section identifies the holistic vision of the future of MEDTech. Techniques used to generate architectural decisions and concepts were employed to provide supporting analysis for the presented future concepts of the enterprise.

Chapter 6 – Discussion:
This chapter identifies the research findings, provides recommendations for transformation and summarizes the research objectives. The findings illuminate the areas of improvement for converting from the stage-gated development process to an Agile development process. From the research results, recommendations are provided for transforming the enterprise at both the organizational and individual level. The chapter concludes with the identification of limitations of the research and areas for further exploration.

CHAPTER 2: LITERATURE REVIEW

This chapter includes a literature review from the research applied to the transformation of the medical device enterprise. This review details the approach of enterprise architecting (ARIES framework) and identifies contributing success factors and challenges associated with both medical device development and the implementation of Agile practices.

2.1 Enterprise Architecting – ARIES Framework

Understanding that one of the primary objectives of this research is to generate recommendations for medical device enterprise adoption of new product development practices, the ARIES framework was chosen as the means for creation of concepts to change the organization's development process. The Architecting Innovative Enterprise Strategy framework is a systems method used to re-architect or transform an organization. Through a series of seven steps (see Figure 2), it guides users to create multiple architectures for the future state of the enterprise, evaluate those concepts, and resultantly select the best concept prior to initiating formal organizational change.

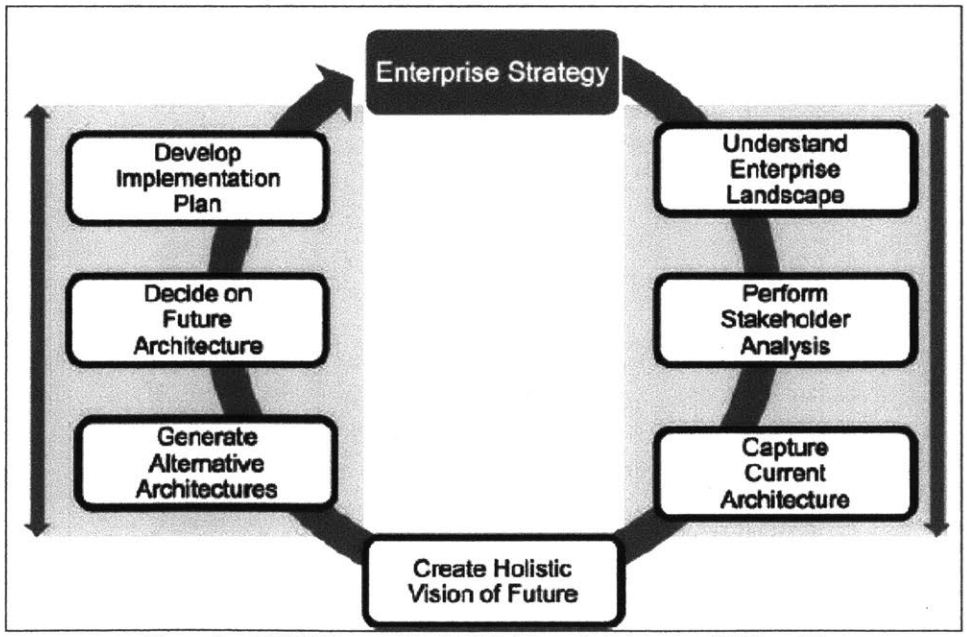

Figure 2 - ARIES Process Model (Nightingale & Rhodes, 2015, p. 23)

The research examines the medical device enterprise, Sanofi, by means of the first three architecting steps – understanding the enterprise landscape, performing stakeholder analysis, and identifying the current architecture. The remaining architecting steps will be considered as inputs to the supporting analysis for architecting the future of Sanofi (Chapter 5) which includes the generation of several solutions to integrate Agile product development techniques throughout the organization.

A large number of enterprises unsuccessfully complete transformation efforts due to siloed views of the enterprise. Nightingale and Rhodes, (2015, p. 2) state that neglecting to include multiple elements of an enterprise will result in an architecting failure. The ARIES element model guides enterprise transformers to view the organization undergoing change through ten unique lenses with the purpose of identifying interactions between the various elements, ensuring the context within which the enterprise operates is understood and comprehensively assessed. Those lenses are identified and defined in Table 2.

Table 2 - Elements of Enterprises (Nightingale & Rhodes, 2015, p. 19)

ELEMENT	DESCRIPTION
Ecosystem	The external regulatory, political, economic, market and societal environment in which the enterprise operates and competes/cooperates with other enterprises
Stakeholders	Individuals and groups who contribute to, benefit from, and/or are affected by the enterprise
Strategy	The strategic vision along with the associated business model and key strategic thrusts, goals, and performance management system
Information	Information the enterprise requires to perform its mission and operate effectively in accordance with its strategy
Infrastructure	Enterprise enabling systems and information technology, communication technology, and physical facilities that enable enterprise performance
Products	Products the enterprise acquires, markets, develops, and manufactures, and/or distributes to stakeholders
Services	Offerings derived from enterprise knowledge, expertise, and competencies that deliver value to stakeholders, including support of products
Process	Key leadership, lifecycle, and enabling processes by which the enterprise carries out its mission and creates values for its stakeholders
Organization	Culture, organizational structure, and underlying social network of the enterprise
Knowledge	Competencies, expertise, explicit, and tacit knowledge, and intellectual property resistant in and generated by the enterprise

2.2 Success Factors for Medical Device Development

To gain insight into factors that contribute to the successful development of medical devices independent of the development methodology utilized, literature was reviewed to identify commonalities that resulted in success across various industries which used a variety of product development practices. In 2008, Russell and Tippett defined critical success factors as "the limited number of areas in which results, if they are satisfactory may ensure successful competitive performance for the organization; these factors "directly contribute to the success of an organization" and are an "explicit representation of KPIs". To ensure consistency throughout this thesis, the lenses of the ARIES framework are used to view influencing and critical success factors relevant to the transforming enterprise. Using those lenses (as defined in Table 2), various critical success factors impacting medical device development have been sorted in the tables below for internal and external contributing factors, respectively.

Internal Success Factors:

Table 3 - Internal Success Factors (Identified from Literature Review)

ELEMENT	SUCCESS FACTOR
Strategy	• Communication of NPD priorities to teams (Medina, Kremer, & Wysk, 2011) • Communication of goals and metrics to teams (Chow & Cao, 2008)
Information	• Preliminary market analysis (Chen, Ravichandar, & Proctor, 2016) • Use of financial analysis (including costs of regulatory submissions, patents) (Chen, Ravichandar, & Proctor, 2016)
Infrastructure	N/A
Products & Services	• Technical innovativeness rated by the complexity or technical challenge (Medina, Kremer, & Wysk, 2011) • End user engagement and requirements must capture & "take account of the needs of these groups" (Brown, Dixon, Meenan, & Young, 2008)
Process	• Product development process • End user/customer involvement
Organization	• Role of Senior Management • Organizational Structure
Knowledge	• Experience

Table 3 identifies common success factors that were gleaned from literature. From the vantage point of strategy, it has been observed that teams succeed when objectives and goals are communicated (Chow & Cao, 2008). The communication assists with instilling not only a sense of purpose but educates teams on their role within the organization and provides insight into the greater reason (and occasionally motivation) for the work they are asked to perform. Viewing factors through the element of information, literature shows that feasibility and technology assessments as part of pre-development activities are crucial to the success of a product. Device developers need to understand the shortcomings that competitors have encountered and the realistic capabilities of the device under development. Per Brown et al. 2008, Health Technology Assessments are becoming increasingly important for companies to consider; prior to reimbursement of a new device, both the cost and clinical efficacy is expected to be compared to marketed alternatives. By conducting this assessment in the conceptual phases of development, the manufacturer minimizes downstream risk of developing a product that will not fare well in the market due to the refusal of insurance agencies to reimburse patients. From the process standpoint, it is important to remember that

an enterprise's product development process may govern the level of quality of planning for the development of the device; a more completed process is more likely to produce a successful product not only because quality will have been built into the design but the design will also address the primary needs of its users. Research shows that early integration with customers and users is correlated with success for new medical technologies. It is important that customer involvement occurs throughout the development process and not only during pre-development stages or solely during the design validation phase (MacCormack, Crandall, & Toft, 2012). The organization needs a management team that is capable of motivating their staff, removing roadblocks, and providing necessary resources and tools for development. The product development team also contributes to successful product when it is diversified with cross-functional members and leaders who are accountable and communicate effectively (Misa, Kumar, & Kumar, 2009).

In alignment with Table 3, Medina, Kremer, & Wysk (2011) identified 5 primary categories that impact success of product development – the organization, company culture, the influence of senior management, strategy, and finally the product development process.

Table 4 - Identification of Success Factors of NPD (Reproduced from (Medina, Kremer, & Wysk, 2011))

NPD Process	Quality of planning before entry into the development phase	Continuous commercial assessment of the NPD project during all phases of NPD process	Orientation of the NPD process to the needs of the market	Distinguish between market orientation and customer integration into NPD	Integration of customers into the early and later phases of NPD
Organization	Cross functional NPD team	Strong and responsible project leader	NPD team with responsibility for the entire project	Commitment of the project leader and team members to the NPD product	Intensive communication among team members
Culture	Having an influential product champion				
Role and commitment of senior management	Define goals for the NPD program	Regularly monitor the attainment of goals		The monetary incentive to these goals	
Strategy	Define objectives and communicate the meaning of their attainment in terms for the overall goals for the organization		The NPD program should have strategic focus to give overall direction to the individual projects		Strategic framework relating the sum of individual projects

In addition to the factors that internally contribute to the success of an organization and the products being developed, there are several factors external to the enterprise that influence the success of its products and influence development priorities.

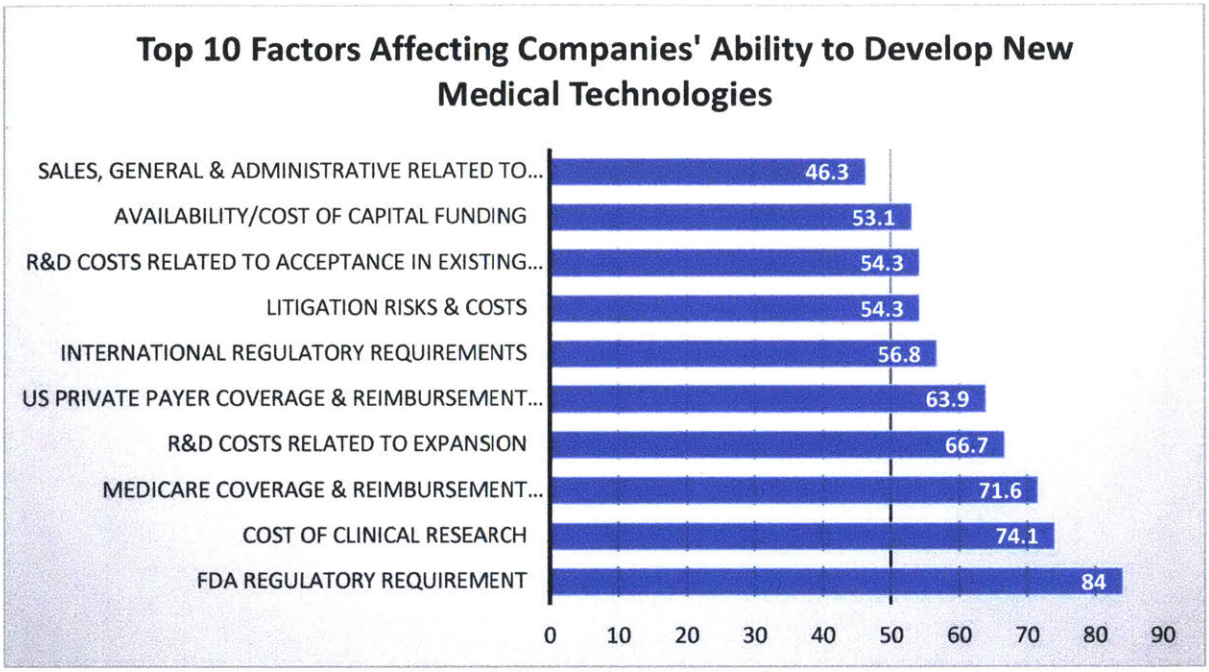

Figure 3 - Factors Affecting Device Development (Medina, Kremer, & Wysk, 2011)

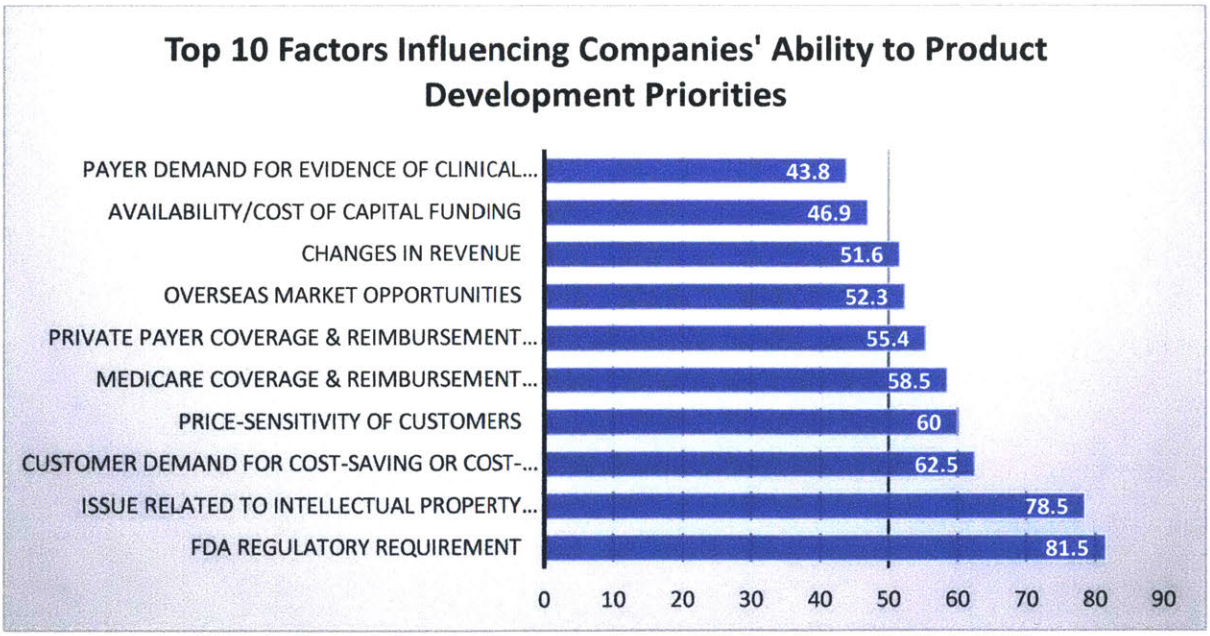

Figure 4 - Factors Influencing Device Development (Medina, Kremer, & Wysk, 2011)

Several of the identified external factors overlap with internal factors such as information, for example. External assessments of currently marketed competitor technology must also be considered internally as information and disseminated to the appropriate parties within the development team.

External Success Factors

Table 5 - External Success Factors (Identified from Literature Review)

ELEMENT	SUCCESS FACTOR
Economic	• Medicare coverage & reimbursement requirements (Medina, Kremer, & Wysk, 2011) • Availability of capital funding (Medina, Kremer, & Wysk, 2011)
Regulatory	• FDA & European Union notified bodies (Medina, Kremer, & Wysk, 2011) • Regulatory class of the device
Competition	• Level of competition (also a predictor of success) (Ganfomani & Nafchi, 2016)
Market	• Size of market (also a predictor of success) (Dixon, Brown, & Meenan, 2006) • Unforeseen change in market (Dixon, Brown, & Meenan, 2006) • Market innovativeness of the device → Determined by relationship of the new product to market (new market to the world/company, extension to/in an existing market (Brown, Dixon, Meenan, & Young, 2008)

Note: Of the literature reviewed, no articles mentioned factors that could be categorized as geo-political or environmental

While the medical device industry has similarities with other regulated industries (e.g. automotive, aerospace), the industry does have a unique set of factors that impact new product development. According to a 2011 article authored by Medina et al., the Food and Drug Administration is the leading external (environmental) factor associated with product development and has the potential to impact a company's ability to develop new technologies. With extensive requirements (see Figure 5 for regulatory approval pathway) that increase based on the level of risk associated with the device, compliance to regulations significantly impact development timeliness. Failing to understand the expectations of the FDA (or other regulatory bodies outside of the United States) early during development can not only extend timelines but may lead to denial of approval to market the device.

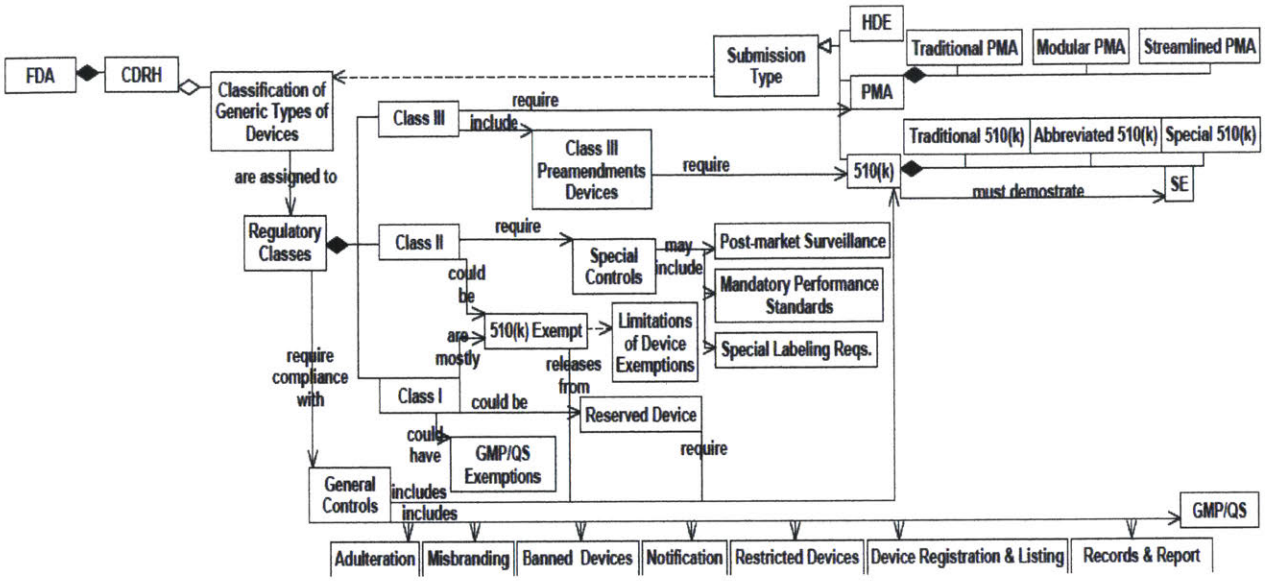

Figure 5 - Regulatory Framework & Pathway to Approval (Medina, Kremer, & Wysk, 2011)

While the main conclusion from the reviewed literature is that a product's success is correlated with understanding the user group, support from management, and a robust development process, it should be noted that amongst all of the studies conducted and literature reviewed, there were no standard or consistent measurements of success. It is, however, abundantly clear from the reviewed articles that "successful new to the world products generally have a more complete New Product Development process than less successful new to the world products. A similar pattern holds true for product modifications" (Medina, Kremer, & Wysk, 2011). It stands to reason that medical device enterprises should pivot towards the adoption of comprehensive development processes that are adaptable to change, incorporate user needs during pre-development, rely on the expertise of the team to drive the development to completion.

2.3 Agile Product Development Methodology and Its Benefits

Branded as a software development process centered around early and iterative integrated software modules, the Agile product development process encourages process implementors to take a learning-oriented approach to product development (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017). According to Schuh et al (2018) "Agile methods are characterized by diverse design specifications such as values, principles, practices, or process models". The Agile process emboldens developers to embrace opportunities for change prior to design freeze to maximize the value delivered to the product's end users. Because "Agile is all about recognizing and applying feedback", the process requires parallel execution of tasks which, in a traditional waterfall methodology, would have been sequential (Stare, 2014). Agile differs from traditional product development practices in four main categories – project scheduling, targeted user/client involvement, team structure, and the evolution of requirements and specifications.

Agile implementors pre-define project objectives in less detail than typical processes would anticipate. The project schedule is prepared at a high level which empowers the team to make changes but also is daunting to those whom are new to the process. This methodology enables project teams to frequently monitor, track, and redefine project plans; it is expected that detailed plans are only generated for small development cycles, called sprints, which last 2-4 weeks on average and allow teams to break down information into digestible chunks and more holistically review the "lessons learned, current results, and new ideas," discovered during the sprint cycle (Stare, 2014). The main takeaways and actions of the review sessions are then used as the primary input for detailed planning (as granular as estimated hours of work) for subsequent sprints. The team is responsible for governing how, when, and by whom tasks and challenges will be tackled at the beginning of each sprint.

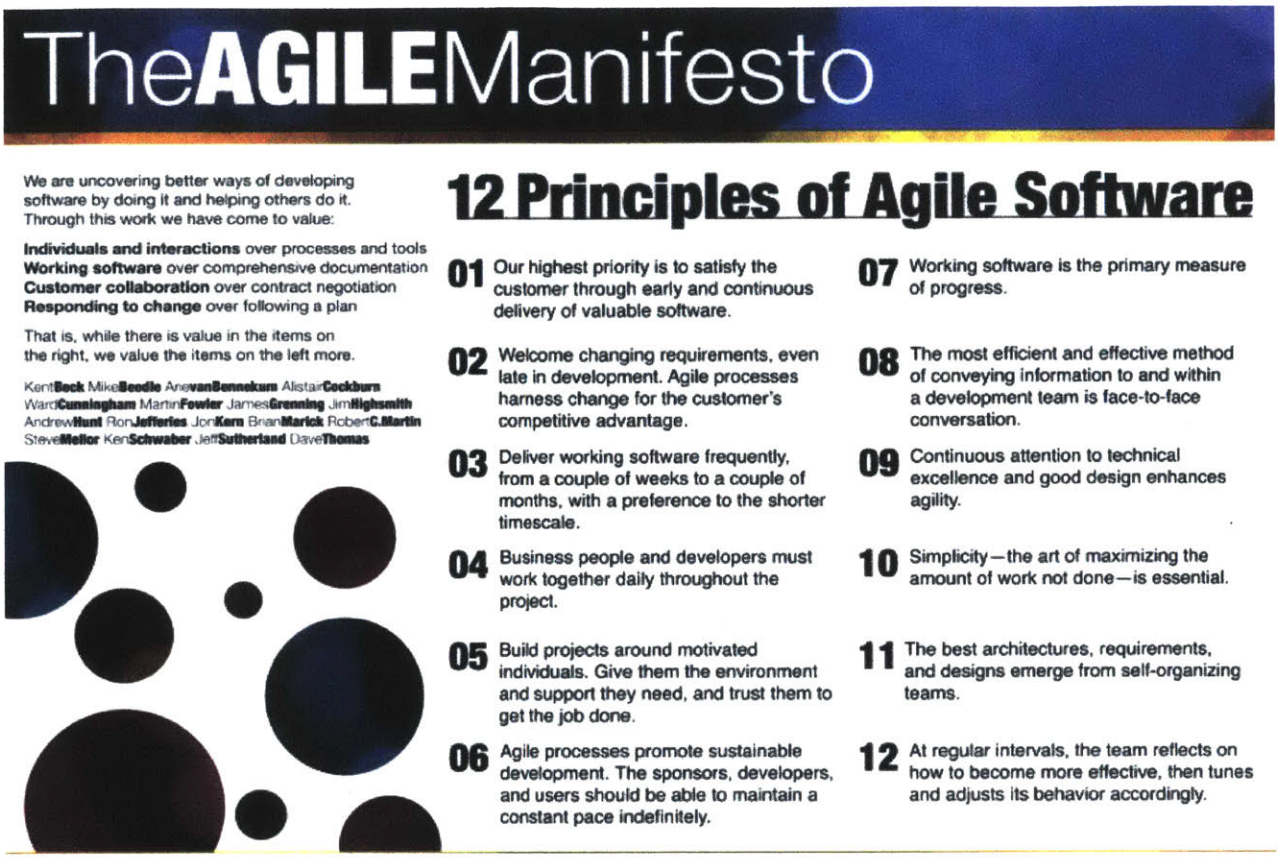

Figure 6 - 12 Principles of Agile (Strongbridge Team, 2017)

The number one principle of Agile highlights the importance of user-centered design. The Agile Manifesto (Figure 6 - 12 Principles of Agile states that the "highest priority is to satisfy the customer through early and continuous delivery of valuable [software] products" (Beck, 2001). Input and feedback from targeted user groups is imperative for the success of commercialized products, so much that "requirements are often documented in user or persona stories" (Schon & Escalona, 2015). Being that the end user(s) are key stakeholders in the product development process, typical Agile project teams either include representatives of the desired user group or the teams conduct formative human factors studies at regular intervals while key product functions and features are being developed and finalized.

The Agile principles not only stress the importance of delivering a product that satisfies the end user but also the importance of the cohesion of the team developing the product.

Principles 4 and 5 of the Agile Manifesto state that "business people and developers must work together daily throughout the project." Because the team is responsible for determining and maintaining their velocity, it is crucial to "...build projects around motivated individuals. Give them the environment and support they need and trust them to get the job done." To be successful, the team must be supported by their organization and empowered to execute tasks in a manner that is not dictated by those external to the project. Research conducted by Schon & Escalona (2015) demonstrates the importance of the relationships between those responsible for following the Agile process which supports the eleventh principle of the Manifesto which claims that "the best architectures, requirements, and designs emerge from self-organizing teams" (Principle #11 – Agile Manifesto). Because individuals typically desire autonomy and want to be able to demonstrate knowledge, self-organization of teams has not only shown valuable in strengthening relationships but also provides a sense of satisfaction to those involved – developers and customers alike (Dikert, Paasivaara, & Lassenius, 2016). Collaborative and cross-functional teams gain a deep understanding of how the product functions and how challenges impact the greater team and development of the product as a whole; "a good understanding of the product helps the developers to make better decisions during implementation" (Schon & Escalona, 2015). Being that the success of the product relies heavily on the team, effective communication is fundamental to achieve the team's goals. In a traditional Agile environment, teams are expected to meet briefly each day as a whole group to communicate daily deliverables or tasks, recently encountered challenges, new ideas and/or test results.

Unlike stage-gated product development methodologies, Agile methods were "designed to accept and efficiently manage change" (Dikert, Paasivaara, & Lassenius, 2016). Implementers expects change to occur and for the project to be capable of progressing with known unknowns. Typically, requirements and their implementation solutions are not fully derived; based on user feedback, new scope in the form of features or functionality may be added as well. In a 2015 study conducted by Schon & Escalona with the purpose of assessing product

development and teams implementing Agile, eighty-six percent of ninety-three survey respondents believed that the "product manager should have the ability to create a rudimentary concept of the product which is then elaborated in more detail" (see Figure 7). While requirements are often created cross-functionally by the team, external stakeholders, and the targeted user group at the initiation of the project, they are expected to evolve with the project and are prioritized based on the stakeholder mandated importance of functions or features.

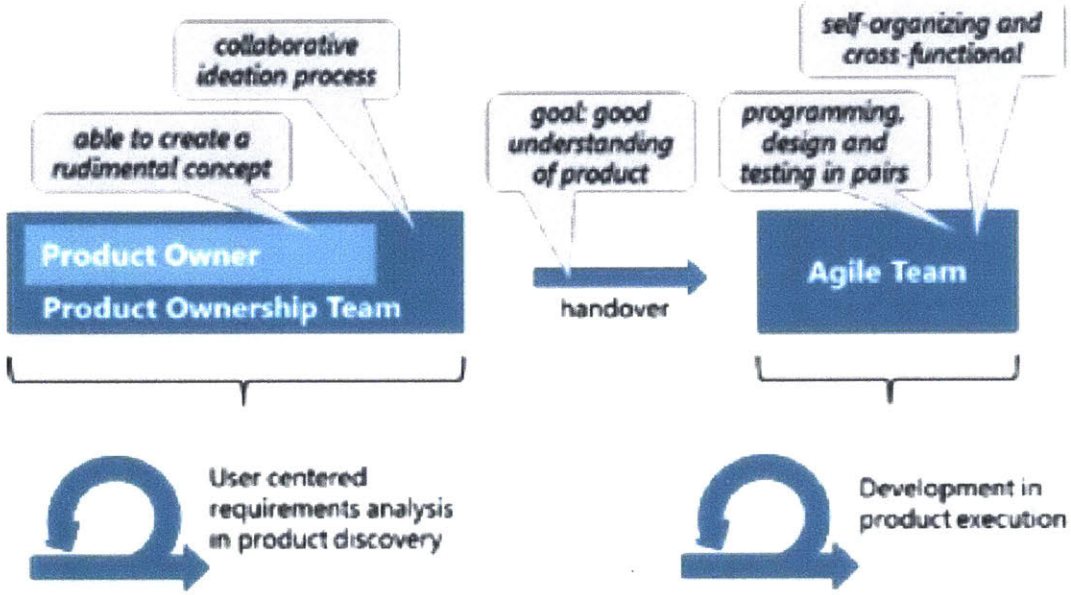

Figure 7 - Transfer of Knowledge from Product Owner to Development Team (Schon & Escalona, 2015)

2.3.1 Various Approaches to Agile:

There are several variations and approaches to the implementation of Agile methodologies; two of the most practiced approaches are Scrum and Extreme Programming (XP). Scrum is defined as a "method focusing on project management viewpoint of Agile development, prescribing timeboxing, continuous tracking of project progress and customer centricity" (Dikert, Paasivaara, & Lassenius, 2016). Progress of projects is measured by the efficiency of the team and their implementation of the development process. Extreme Programming is described as an assortment of development practices (including scrum) that when used in

accordance with each other facilitates incremental development. Typically, this approach is utilized for research and development projects where objectives and requirements are the most ambiguous (Dikert, Paasivaara, & Lassenius, 2016).

For the purposes of this thesis, the focus is on the integration of Agile scrum practices into medical device development as scrum is the most prevalently used method.

For manufactures who may be unable or unwilling to adopt gateless development methodologies, hybrid product development processes were created, combining both scrum and stage-gate product development approaches. In these processes, design increments are segmented by high level phases while the execution of the project follows the scrum process. "Connection between both [processes] is defined by project portfolio coordination which coordinates the development teams and the operating organization by using physical boards for visualization [also known as Kanban]" (Schuh, Dolle, Kantelberg, & Menges, 2018). Due to the complexity of change management for marketed products, this approach is oftentimes adopted by enterprises that must concurrently design and manufacture hardware products.

2.3.2 Benefits of Agile:

One of the most noted advantages of Agile is the increased knowledge of the product that the team gains. Teams "learn from testing and from customer feedback and incorporate knowledge obtained into the next iteration cycles" (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017). Because team members are more involved in all aspects of development than they would be in other stage-gate models, the team as a whole is capable of identifying challenges, product conflicts, and technical uncertainties at earlier stages in in development. By identifying key issues and removing uncertainties early, teams are able to reduce their time to market and reduce their number of resources needed to implement solutions to discovered challenges. Team health has also been demonstrated to be more positive in Agile environments and "team autonomy and diversity has a positive effect on response efficiency"

(Stare, 2014). Teams also need to be supported by their processes, so the employment of standardized methods and tools is invaluable when managing changes.

2.4 Known Transformation Challenges

Table 6 - Literature Review Identified Transformation Challenges

Element	Challenge(s)
Strategy	• Customized and communicated poorly (Dixon, Brown, & Meenan, 2006)
Information	• Communication barriers between problem identifiers and problem solvers • Data structure (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017) • Disconnected teams complicate data exchange (Chen, Ravichandar, & Proctor, 2016)
Infrastructure	• Rearranging physical spaces (Dikert, Paasivaara, & Lassenius, 2016)
Products & Services	• Global distribution challenges (Fogelstrom, Gorschek, Svahnberg, & Olsson, 2009) • Too high workload (Dikert, Paasivaara, & Lassenius, 2016)
Process	• Missing or too rigid and inefficient processes (including data management) (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017) • Insufficient data management leads to long delays and cost increases (Misa, Kumar, & Kumar, 2009)
Organization	• Organizational workflows are rarely adjusted to the requirements of the specific phase (Schuh, Gartzen, Soucy-Bouchard, & Basse, 2017) • Change resistance (Brown, Dixon, Meenan, & Young, 2008) • Interfacing between teams is difficult (Misa, Kumar, & Kumar, 2009) • Autonomous team model challenging to adapt to (Serrador & Pinto, 2015) • Requires higher level organizational culture change (Dikert, Paasivaara, & Lassenius, 2016)
Knowledge	• Lack of training & coaching (Chen, Ravichandar, & Proctor, 2016) • Misunderstanding Agile concepts (Dikert, Paasivaara, & Lassenius, 2016)

There is no shortage of institutions that have struggled with transitioning to Agile methodologies. As shown in Table 6, there are a multitude of challenges that have been observed, which have been organized by the elements of the ARIES framework. Viewing challenges through the lens of strategy, literature shows that poor customization [of practices] may lead teams to adopt only practices that reflect their current needs" and ultimately lead to their failure to manifest changes within their processes or company culture (Chen, Ravichandar, & Proctor, 2016).

In regard to the element of information, ineffective communication is a barrier to success, especially when transformation extends the boundaries of one particular business unit or project team. It is imperative that all affected units are recognized as stakeholders who "need to be informed and consulted" to develop a process that addresses their needs (Dikert, Paasivaara, & Lassenius, 2016). Because the "Agile way of working does not allow strict slicing of projects", difficulties arise when Agile practices are scaled and distributed across a number of sites in varying geographic locations (Chen, Ravichandar, & Proctor, 2016).

Several of the greatest points of contention can be discovered in the organizational element. Schuh, et al. [2017] noted that hierarchic organizational structures not only impede teams' abilities to make decisions efficiently but also increases the difficulty of identifying roles and responsibilities. As expected with any set of changes, individuals within the organization are reluctant to change without understanding the rationale for and benefits of adopting a new process, which could result in loss of productivity. A unique point of concern related specifically to Agile implementation is the impression that individuals "felt that they were being monitored more because of the increased level of interaction within the team and between stakeholders" (Sheffield & Lemetayer, 2013). There are also misconceptions surrounding the Agile process that challenge its implementation and place within an organization; common misconceptions include Agile being unable to be adapted for development of complex devices and a requirement that Agile implementation must be rigid and prescriptive and daily stand-up meetings will adversely impact the efficiency of the team.

When adopting new practices, organizations often look to literature or self-identified subject matter experts for implementation advice; poor guidance received from external sources can lengthen the conversion process or may result in the adoption of processes that are not suited for the enterprise (Dikert, Paasivaara, & Lassenius, 2016).

All of the success factors, contributing factors, benefits, and challenges identified within this section will be considered and used to help inform the strategy for Agile adoption as it relates to Sanofi, the medical device enterprise undergoing transformation.

CHAPTER 3: SANOFI ENTERPRISE LANDSCAPE

This chapter provides background information and context of the environment within which the transforming enterprise operates. This section identifies both the needs and desired capabilities of the enterprise. This chapter in intended to provide an understanding of the enterprise's ecosystem and the value a successful transformation could offer.

3.1 Current Enterprise

Headquartered in Paris, France, Sanofi was established as a pharmaceutical company in 2004 after the merger of Aventis and Sanofi-Synthelabo. The enterprise which now offers healthcare solutions in over 150 countries worldwide is comprised of 5 primary business units and has 4 research and development centers in Europe, North America, and Asia. Sanofi's portfolio includes therapies for oncology, immunology and inflammation, rare blood disorders, rare and neurologic diseases, and diabetes and cardiovascular diseases.

Sanofi is now committed to leading the industry in medical device enhanced therapies. Drug-device integrated capabilities have significant potential to add value to the patient, the healthcare community and to the commercialization of drug products. The growth of the biologics market is driving increased interest in drug-device combinations which are typically administered via an injection. By combining the drug formulation with an injection system or even an implantable device which may also have the capability to provide data feedback, patient therapy and outcomes can be improved. To this end, Sanofi has made a significant commitment to Medical Device Development such that they are able to build upon their realized successes, expand and enhance their internal capabilities, and align with strategic partners to form a best-in-class medical device development organization.

3.2 Enterprise Needs Analysis

Historically a pharmaceutical company with little to no experience in medical device development, Sanofi is now moving into the medical technology space – for connected medical devices and software applications (also referred to as connected or digital health). The organization needs to adjust their current practices to remain competitive and prevent innovation impediments while simultaneously adhering to regulatory requirements and creating an end product that is compliant, safe and effective, and something that users would desire.

To understand Sanofi's cultural environment prior to any transformation, it was imperative to assess their organizational structure, mission and vision to ensure any proposed solution would remain true to their objectives. Subsequently, comparing the global mission to the perceived current state of the Cambridge MEDTech division would then help inform what needs to be transformed or improved in an attempt to help the company remain consistent in following their mission and vision.

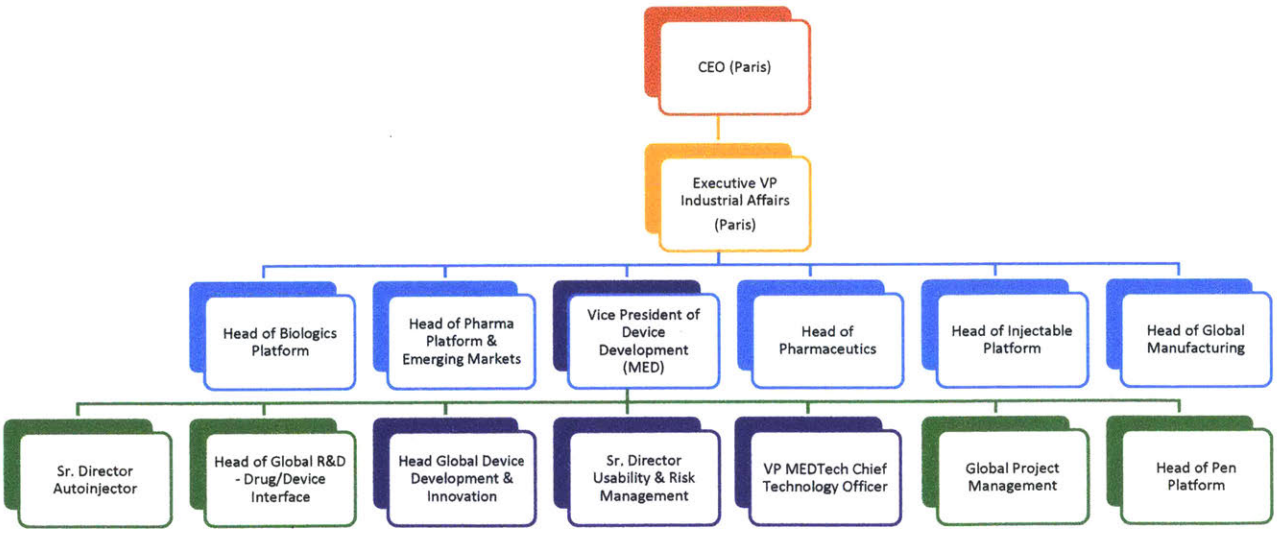

Figure 8 - Organizational Chart for Medical Device Unit

Note: Those cells colored in purple are directly involved in MED and MEDTech operations.

Sanofi's mission which is expressed internally as "empowering life" is defined as "support[ing] people as a health journey partner. Wherever people live and whenever we can make a difference, Sanofi seeks to protect, enable and support those who face health challenges so they can live life to its full potential" (Sanofi, 2019).

PURPOSE	PRIORITIES
• "A **close partnership with the business,** on how they see these devices adding value to their portfolio". • "A focus on **patient's needs** in such a way that we can bring the right value to the patient based upon the specific challenge that they have". • "An **end-to-end approach to make sure we design the entire system and not just the device.** We really need to design the formulation, the container and the device, to maximize the patient experience that we've defined in close partnership with R&D and other parts of the Industrial Affairs organization" • "A **focus on a few core platforms that will require for differentiation** and success in this market place"	• **"Diabetes**, the focus area of our drug delivery devices over the last 10 years. And we have to continue to serve the diabetes patients first and foremost with the innovative products that we are bringing forward". • **"Support the alliance projects,** such as Regeneron and other alliances that we are now partnered with in order to use the expertise we developed over the last 10 years to make that portfolio of products successful". • **"Focus on the emerging Sanofi biotech portfolio** that is coming and to ensure that we have the devices that are needed in order to successfully deliver those products"

Table 7 - MED Purpose & Priorities (Sanofi, 2019)

After analyzing the purpose and priorities of MED collectively, those items were translated into categories of ways the Cambridge MEDTech office can adjust their current practices to support global Sanofi in their efforts to maintain their mission.

1. Doing Different Things:

- Focus on shaping the future of connected health, in collaboration with customers and industry
- Focus on embracing innovation and harnessing great technology
- Design systems, not just the device

2. Doing Things Differently:

- Product evolution and portfolio expansion
- Leverage more data from connected solutions to improve products (more quickly)
- Drive cultural change through fostering curiosity
- Early identification of potential challenges and proactively mitigating project risks

3. Doing Things Better:

- User-centered design
- Thorough evaluation of market landscape
- Efficient responses to market feedback of commercialized products
- Instill sense of pride in employees regarding the work being performed
- Reduction in time to market (including more efficient development process and minimization of rework)

It is expected that transformations along these dimensions of the MEDTech division of Sanofi are targeted towards achieving the overarching vision and will additionally deliver greater value to the global Sanofi environment.

3.3 Force Field Analysis

To apply a systems-thinking approach to both the Internal Landscape and External Ecosystem factors, the factors were analyzed holistically in consideration of each element in the force field discussion that follows. Figure 9 shows the internal landscape factors and the details that were considered. Not all factors are weighted equally, as seen on the Force-Field analysis.

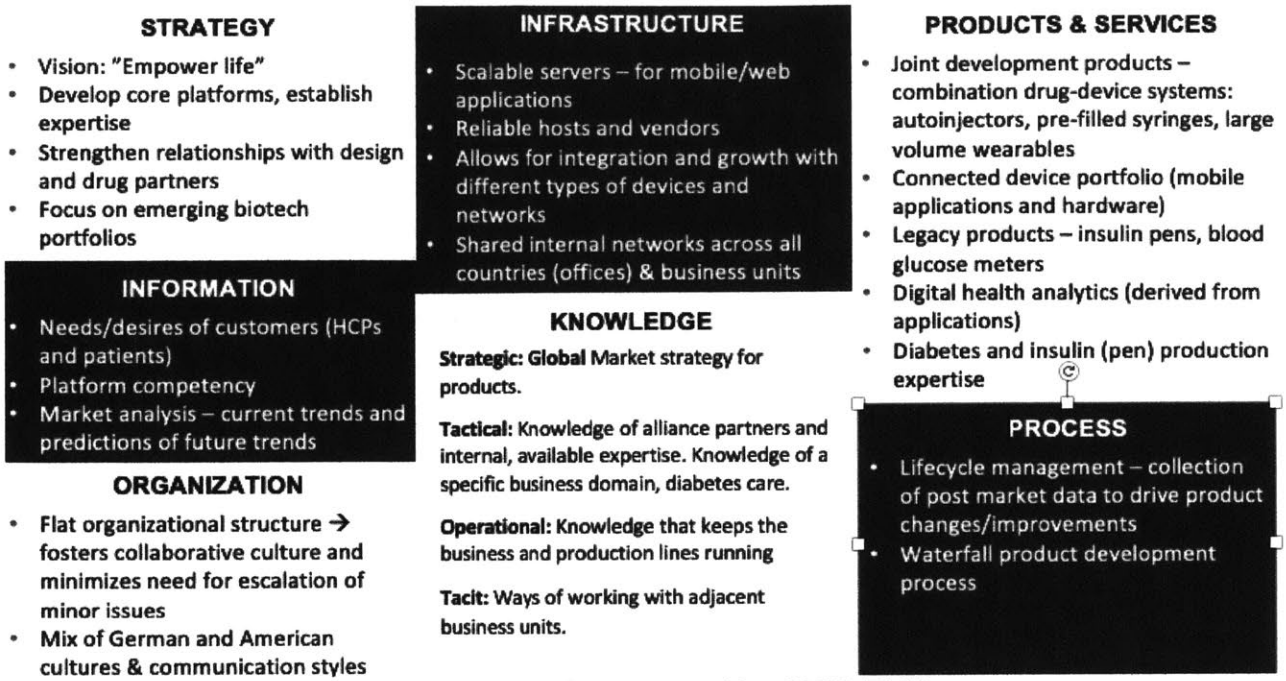

Figure 9 - Internal Landscape Factors of Sanofi MED Division

Figure 10 - External Ecosystem Factors of Sanofi (MED Division) displays the external ecosystem factors and the details that were considered. Not all factors are weighted equally, as seen on the Force-Field analysis.

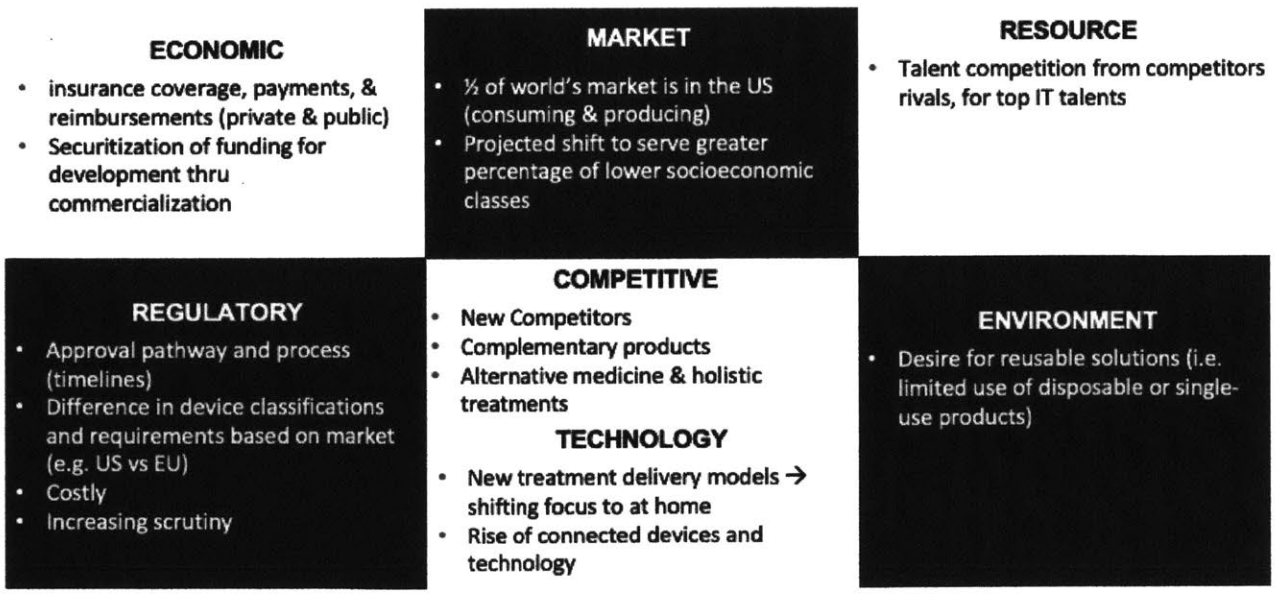

Figure 10 - External Ecosystem Factors of Sanofi (MED Division)

With strategic imperatives setting the general tone and possible directions of transformation, a force field analysis was generated to view the driving forces for and against the MED transformation. To begin, a SWOT (Strength, Weakness, Opportunity, and Threats) analysis of the current MED division was performed (shown in Figure 11 - SWOT analysis of current MED division).

Strengths	**Weaknesses**
• Abundance of internal expertise • Strong alliances with external business partners (e.g. Regeneron, DCA) • Awareness of competitors products (success and pitfalls)	• Lack of clarity in direction • Siloed business unit • Resistant to change • Slow development process for both hardware and stand-alone software products • Historically delayed reactions to predicted trends • Inefficient communication
Opportunities	**Threats**
• Growing and emerging connected health and digital health market • Access to data from current applications • Customers' loyalty to company • Employee engagement and motivation to deliver impactful products • Demand for seamless integratable solutions (for in home & clinic use)	• Faster competition • Decreasing budget (asked to do more with less) • Regulatory changes and inconsistencies between markets • Talent competition

Figure 11 - SWOT analysis of current MED division

The division's primary strengths stem from the relationships forged with external business partners which have provided access to an abundance of knowledge that is now capable of being internally distributed. This affords the enterprise the ability to build their tribal knowledge and reduces the dependency on business partners and the need for them to fulfil the role of technical experts. The majority of the weaknesses could be attributed to a three root causes – poor communication, competing visions, and cultural differences. Being a German based division, not only do communication styles differ between German and US-based colleagues but communication methods differ as well; often times messages that are

delivered face-to-face are received and interpreted differently via email or teleconference. There is also a general cultural attitude that is resistant to change. Copious amounts of time and effort have been invested to reach the level of efficiency the current processes exhibit which breeds a resistance to change for fear of starting from scratch. The overall development process is slow because of the large number of stakeholders evolved and ineffective communication within project teams. Being one of the global leaders in drug and biologic development, Sanofi is in a great position to be able to leverage their access to emerging technologies, alliances with external business partners, and internal knowledge to achieve their vision of globally supporting users' health journeys. To achieve their goals however, Sanofi must ward off threats in the competitive arena by reducing their time to market and by staying abreast of current and proposed regulatory changes.

The above SWOT attributes, in conjunction with previously identified strategic imperatives, could systematically be classified as either drivers for, or against change in the Sanofi MED division:

Drivers for change→	**←Drivers against change**
• Growing market • Customer needs – new & improved products that minimally interfere with users' everyday life or workflow • Competition • Ability to leverage data • Emerging technology • Collaborations • Focused trajectory – targeted areas of product portfolio development & expansion • Desire to be a main contributor to digital health market • Expanding drug portfolio	• Limited resources • Talent competition • Limited budget • Regulations (e.g. medical device specific, data privacy) • Change resistance • Communication challenges • Learning curve for new technologies and/or processes

Figure 12 - Force Field Analysis on MED Division

Notably, the company's vision to "empower life" translates into a desire to be customer centric, forming a key change driver for the MED approach to device development. The division's need for effective communication and improvement of the development pace to remain a relevant leader amongst the increasing competition is driving the necessity for transformation. Besides aforementioned attributes and factors, additional potential drivers against change may surface in the form of internal backlashes like change-resistance and employee complacency.

3.4 Enterprise Capabilities

Enterprise capabilities are defined as "system properties that provide the ability to perform and to respond to challenges and opportunities in a certain way" (Nightingale & Rhodes, 2015, p. 37). These capabilities which are unique to the enterprise tend to vary from stakeholder perspectives and help identify the pathway for architecting the future of the enterprise being transformed.

Table 8- Enterprise Capabilities Definitions (Nightingale & Rhodes, 2015)

Capabilities	Definition
Adaptability	Ability of an enterprise to sustain value delivery by transforming itself to respond to changes in its ecosystem
Agility	Ability of an enterprise to shift rapidly from one strategy to another to sustain enterprise value delivery
Competitiveness	Ability of an enterprise to deliver products and/or services providing value to stakeholders perceived as equal to or greater than competing enterprises
Evolvability	Capacity of an enterprise to transform by leveraging successful features of the current architecture
Replicability	Ability to reproduce enterprise entities (e.g. processes, products/services, business units) effectively to create or sustain value deliver
Resilience	Ability of an enterprise to cope effectively with changing circumstances and recover from disruptive events
Responsiveness	Ability to respond in a timely and effective way to emergent stakeholder needs, threats, and opportunities
Robustness	Ability to sustain consistent value delivery in spite of changes and perturbations in the enterprise ecosystem

Capabilities	Definition
Scalability	Ability to expand or contract the enterprise to meet changing circumstances in order to sustain value delivery
Sustainability	Capacity of enterprise to endure over time as related to environmental, economic, and/or social dimensions

In addition to the literature reviews, discussions with stakeholders (see Table 12 - Summary of Gathered Information from Internal Stakeholders) assisted with the identification of capabilities that would be required by both MED and MEDTech. The device units should encompass ***adaptability, competitiveness, evolvability, replicability, responsiveness and sustainability.***

- ***Adaptability*** is defined as the "ability of an enterprise to sustain value delivery by transforming itself to respond to changes in its ecosystem" (Nightingale & Rhodes, 2015). This capability is essential in the fast-paced medical device technology landscape. Being adaptive to its ecosystem affords organizations flexibility and encourages a proactive approach to tackling potential uncertainties or complexities.

- ***Competitiveness,*** which is defined as the "ability of an enterprise to deliver products and/or services providing value to stakeholders perceived as equal to or greater than competing enterprises" (Nightingale & Rhodes, 2015). Sanofi as an organization desires to be a leader in drug-device combination products and connected health solutions. To achieve that goal, the products delivered to the market must offer at least as much value to stakeholders, if not more, than existing commercialized solution.

- ***Evolvability*** is the "capacity of an enterprise to transform by leveraging successful features of the current architecture" (Nightingale & Rhodes, 2015). To increase their current pace, the organization should not completely refresh all elements of their process but develop an architecture that is able to be re-used and improved overtime.

- ***Replicability*** is the "ability to reproduce enterprise entities (e.g. processes, products/services, business units) effectively to create or sustain value deliver" (Nightingale & Rhodes, 2015). The enterprise should be able to develop and implement solutions that are not prescriptive to one product or business unit but can be employed across several product families or units.

- ***Responsiveness,*** defined as the "ability to respond in a timely and effective way to emergent stakeholder needs, threats, and opportunities" (Nightingale & Rhodes, 2015) is a critical element of product success. The organization needs a mechanism to capture and address emergent needs in a timely fashion.

- ***Sustainability*** is defined as the "capacity of enterprise to endure over time as related to environmental, economic, and/or social dimensions" (Nightingale & Rhodes, 2015). This capability is important for the organization to prevent regression to old inefficient methods and processes.

CHAPTER 4: STAKEHOLDER ANALYSIS

This chapter identifies the scope and boundary of the MEDTech division within MED. In addition to the boundaries of the division, this chapter recognizes and categorizes stakeholders based on their influence and needs. The analysis of the stakeholders provides important insights into the current state of the organization.

4.1 Scope and Boundary of MEDTech

The Medical Technology (MEDTech) unit is situated within a larger unit (MED) which is responsible for all medical device development for therapies targeting diabetes, cardiovascular, immunology, and inflammatory ailments and diseases.

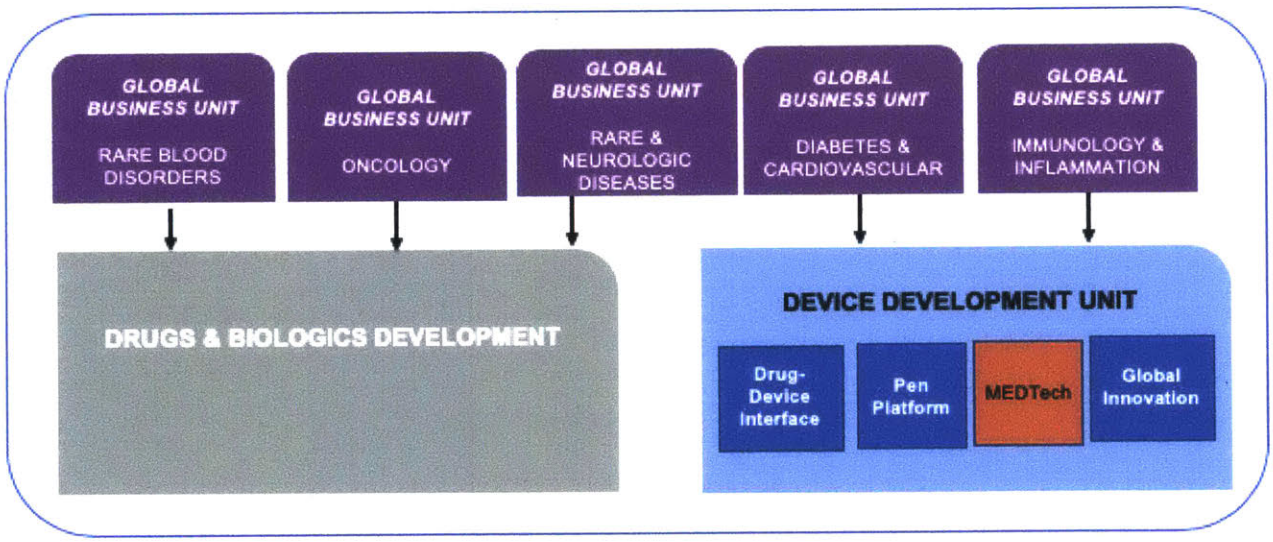

Figure 13 - Boundaries of MEDTech and Device Development Unit

Each Global Business Unit provides the respective development units with the business strategy, funding, and business requirements.

The Device Development Unit provides smaller units with platform requirements, functional requirements and relevant specifications.

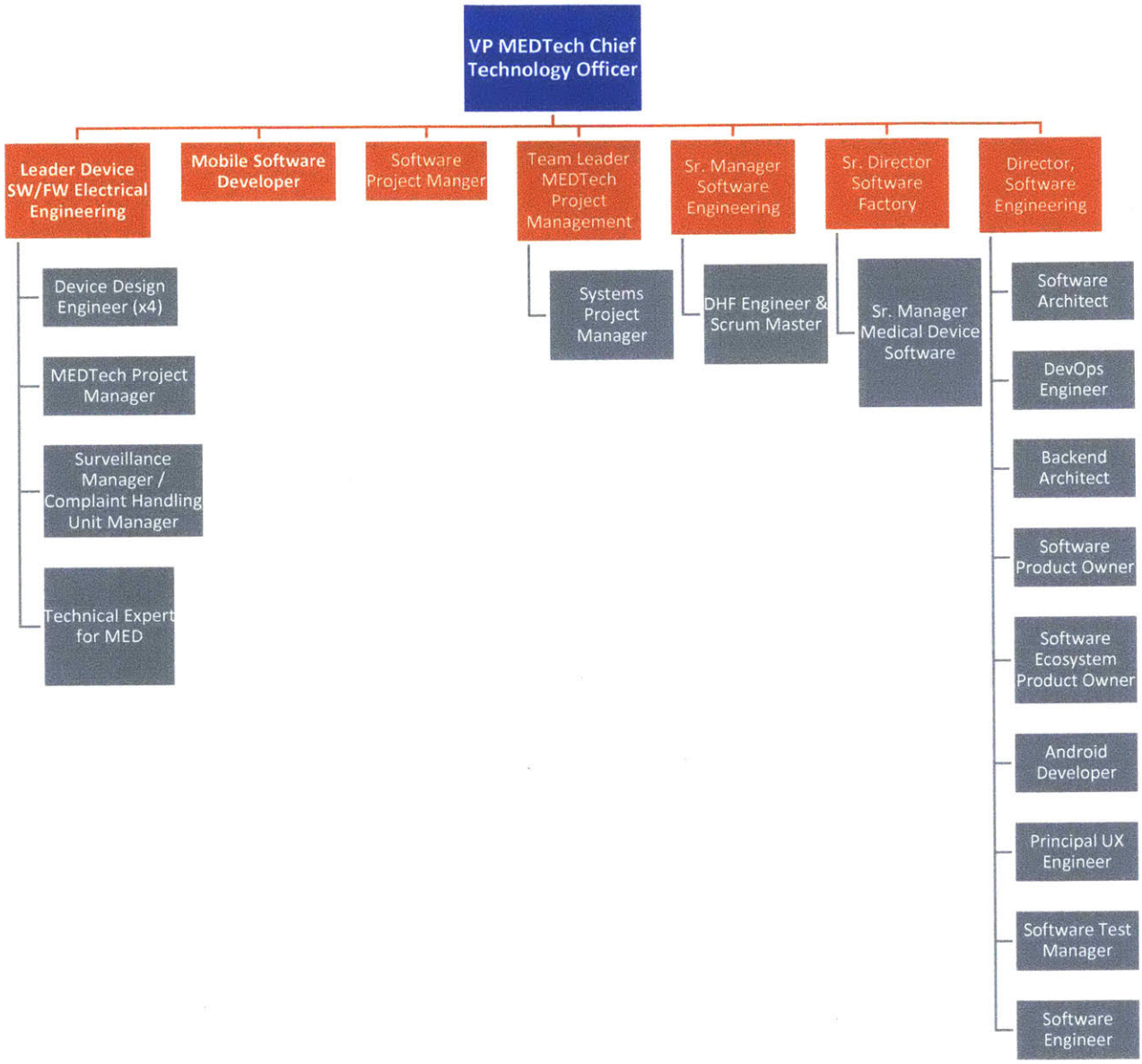

Figure 14 - Organizational Structure of MEDTech

4.2 MED Beneficiaries and Stakeholders

Table 9 - MEDTech Stakeholders & Beneficiaries

STAKEHOLDER	DESCRIPTION	PRIORITY	VALUE DELIVERED to MED	VALUE RECEIVED (OR DESIRED) from MED
Customers (Patients, HCPs)	Primary user group of the medical devices	HIGH	Information via patient/user data & trends Revenue Product/Service Promotion Understanding of primary customers' needs and dislikes	Safe & Effective, reliable product Easy to use (intuitive) device Affordable device (or covered by insurance) Data Privacy & Security Data integration (for connected technologies – MEDTech)
Global Business Unit (Diabetes & Cardiovascular)	Group representing Sanofi's business units worldwide. Monetarily sponsors MEDTech and communicates business requirements to MEDTech.	HIGH	Funding Visibility across the organization Understanding of strategic mission of business units and the role of MED device(s) in greater product portfolio	Revenue Product satisfying their needs Assists with building reputation of MED to other business units
Partnering Business Units (associated with combination drug-device development)	Group representing Sanofi's alliance partners for joint development products/projects. Responsible for communicating shared	MED	Visibility outside of the organization Exposure to and transfer of knowledge of skills related to	Visibility outside of their organization Exposure to and transfer of knowledge of skills related to the expertise of Sanofi

STAKEHOLDER	DESCRIPTION	PRIORITY	VALUE DELIVERED to MED	VALUE RECEIVED (OR DESIRED) from MED
	business needs and removing roadblocks.		the expertise of the alliance partner	
Marketing & Sales	Communicates high level customer needs and forecasted trends and market analysis to Design Team.	MED	Information on market and emerging trends Understanding of customers' needs	Product satisfying customers' needs Revenue
Regulatory Affairs	Internal group responsible for communicating regulatory bodies' expectations and needs to project team. Responsible for facilitating communication with regulatory agencies.	HIGH	Understanding of regulatory needs (and differences across markets) Approval/Clearance to market device	Safe and effective, high quality product (demonstrated by compliance to regulations and standards Facilitating access to a helpful product
Cross Functional Project Team Members	Project team members who influence the design of device and ensure its product quality, safety, and effectiveness. Functions: Quality[1], Risk Management[2], Human Factors[3]	HIGH	Internal subject matter expertise Assistance with compliance to relevant standards (e.g.21 CFR 820, ISO 13485, ISO 14971, IEC 62366)	Safe and effective, high quality product (demonstrated by compliance to regulations and standards Opportunity to apply expertise to variety of devices
Design Team	Engineers responsible for design of device and implementation of	HIGH	Technical expertise	Rewarding work Recognition and compensation

[1] The Quality function is responsible for ensuring designed products are reliable and meets well defined specifications, defect less, and safe. (FDA, 2017)
[2] The Risk Management function is responsible for ensuring the medical device is both safe and effective. (FDA, 2017)
[3] The Human Factors function is responsible for ensuring the device is designed so that it is able to be used without use errors that could impact patient or user safety. (FDA, 2017)

STAKEHOLDER	DESCRIPTION	PRIORITY	VALUE DELIVERED to MED	VALUE RECEIVED (OR DESIRED) from MED
	requirements (e.g. SW, HW, Systems engineers & architects)		Innovation - creative solutions, new products Product meeting stakeholder needs Projects that are delivered on time and not extremely over budget	Opportunities for professional development and growth Project funding Resources
Senior Management	Leadership team within MED that is responsible for communicating business, enforcing Sanofi culture and mission,	MED	Strategic vision Removal of roadblocks and challenges that impede design team's progress Allocation of resources	On-time project delivery Increase in profits Employee satisfaction
Competitors and Biotechnology Ecosystem	MEDTech's primary competition is within diabetes space (e.g. Eli Lily, NovoNordisk) and biologics (e.g. Genentech) Biotechnology ecosystem consists of any technology that provides a connected health experience including data giants like Apple and Google.	LOW	Market trends Lessons learned from marketed products Motivation Collaboration opportunities and knowledge transfer	Lessons learned from marketed products Motivation Collaboration opportunities and knowledge transfer

4.2.1 Stakeholder Salience & Typology

Stakeholder theory was developed by Mitchell, Agle, and Wood (1997) in response to Freeman's *Strategic Management: A Stakeholder Approach* (1984) as a means to expand upon the work completed and "propose that classes of stakeholders can be identified by their possession of any or all of the following attributes: (1) the stakeholder's power to influence the [organization], (2) the legitimacy of the stakeholder's relationship with the [organization], and (3) the urgency of the stakeholder's claim on the [organization]" (Mitchell, Agle, & Wood, 1997).

Mitchell et al. [1997] categorize stakeholders by three high level attributes:

- ***Power*** – is the ability to impose will on an organization
- ***Legitimacy*** – is the "perception that actions of a stakeholder are desirable, proper, or appropriate within norms, values, beliefs of the enterprise" (Mitchell, Agle, & Wood, 1997)
- ***Urgency*** – is exhibited "when the stakeholder's relationship with the enterprise is important to strategy, operations, or is time-sensitive in nature" (Mitchell, Agle, & Wood, 1997)

After determining the attributes a particular stakeholder possesses, the theory divides stakeholders in separate classes based on their relationship with the organization. Because managing stakeholders and prioritizing their needs is an important in step in architecting any solution, this theory is used to assist with the identification of entities within the organization that shall be listened to.

	TYPE	**DEFINITION**
I	*Dormant*	Stakeholders who only possess power but lack legitimacy or urgency
II	*Discretionary*	Stakeholders who have legitimate relationship with the organization but lack urgent claims or the power of influence
III	*Demanding*	Stakeholders who have urgent needs that need to be addressed and require attention but lack power and legitimacy
IV	*Dominant*	Stakeholders who possess power and legitimacy within the organization and "matter to managers"
V	*Dangerous*	Stakeholders who possess urgency and power without legitimacy
VI	*Dependent*	Possess urgent and legitimate claims but lack power (they are dependent on others with power in the organization to champion for them)
VII	*Definitive*	Possess all three attributes

Table 10 - Definitions of Stakeholder Typologies (Mitchell, Agle, & Wood, 1997)

In total, 10 primary stakeholders were identified – Customers (patients and healthcare providers), Sanofi's Global Business Unit for Diabetes and Cardiovascular Care, Partnering Business Units associated with combination devices, Marketing and Sales, Regulatory Affairs, Cross Functional Project Team (including Human Factors and Risk Management), Design Team, Senior Management, and Competitors and the biotechnology ecosystem. The information gathered from senior management, a group of internal stakeholders, both reinforced the initial set of stakeholders previously identified and brought awareness to stakeholders that were initially overlooked (i.e. the biotechnology ecosystem). The conversations with members of MED and MEDTech's senior management were insightful and facilitated the definition of both senior management's stakeholder typology as well as the design and cross functional teams' typologies.

The inclusion of competitors and the biotechnology ecosystem as stakeholders was critical in aligning the perceptions of the MEDTech division with the communicated goals of the stakeholders; as illustrated in the table and figure below, it was discovered that this entity was a demanding stakeholder. Changes within the ecosystem will ultimately affect the direction in which MED and MEDTech pivot should the organization continue to strive for being a leader in the connected health domain.

Table 11 - Stakeholder Salience

STAKEHOLDER	*POWER (Y/N)*	*LEGITIMACY (Y/N)*	*URGENCY (Y/N)*	*TYPE*
Customers (Patients, HCPs)	**Y**	**Y**	**Y**	**Definitive**
Global Business Unit (DCV)	**Y**	**Y**	**Y**	**Definitive**
Partnering Business Units	**N**	**Y**	**Y**	**Dependent**
Marketing & Sales	**N**	**Y**	**Y**	**Dependent**
Regulatory Affairs	**N**	**N**	**Y**	**Demanding**
Cross Functional Team	**Y**	**Y**	**Y**	**Definitive**
Design Team	**N**	**Y**	**Y**	**Dependent**
Senior Management	**Y**	**Y**	**Y**	**Definitive**
Competitors & Biotechnology Ecosystem	**N**	**N**	**Y**	**Demanding**

I	*Dormant*	N/A
II	*Discretionary*	N/A
III	*Demanding*	Regulatory Affairs Competitors & Biotech Ecosystem
IV	*Dominant*	N/A
V	*Dangerous*	N/A
VI	*Dependent*	Partnering Business Units Marketing & Sales Design Team
VII	*Definitive*	Customers Global Business Unit (DCV) Cross Functional Team Senior Management

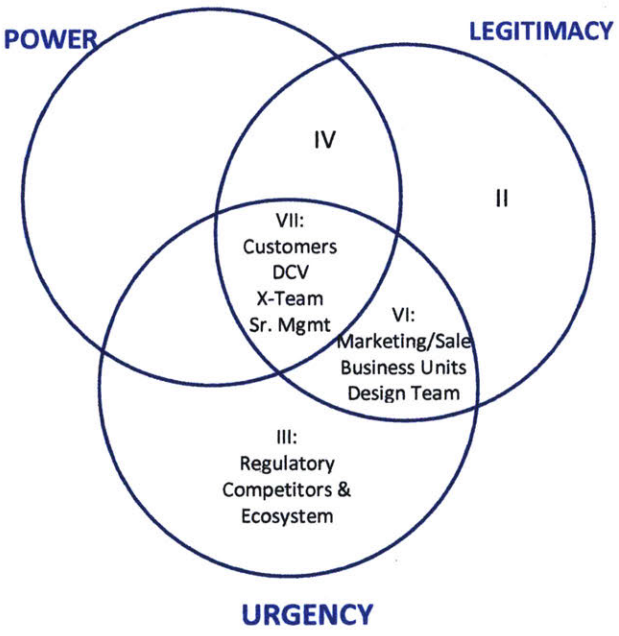

Figure 15 - Stakeholder Typology

The stakeholder salience and typology identified a gap in relation to the influence of the design team. In the current state of the enterprise, the design team has little autonomy and is expected to operate and create solutions that satisfy their primary customers, business units, and cross functional team members yet the design team is given little power to innovate outside of those bounds. This is a key observation that should be considered for transformation efforts because the lack of autonomy could be correlated to job satisfaction which ultimately negatively impacts job performance.

To assist with the understanding of the roles that are included in the design and cross functional team, Figure 16 is an example of a standard MEDTech project team structure. It should be noted for stand-alone software products, the project team is smaller, removing manufacturing, reliability engineering, and procurement functions.

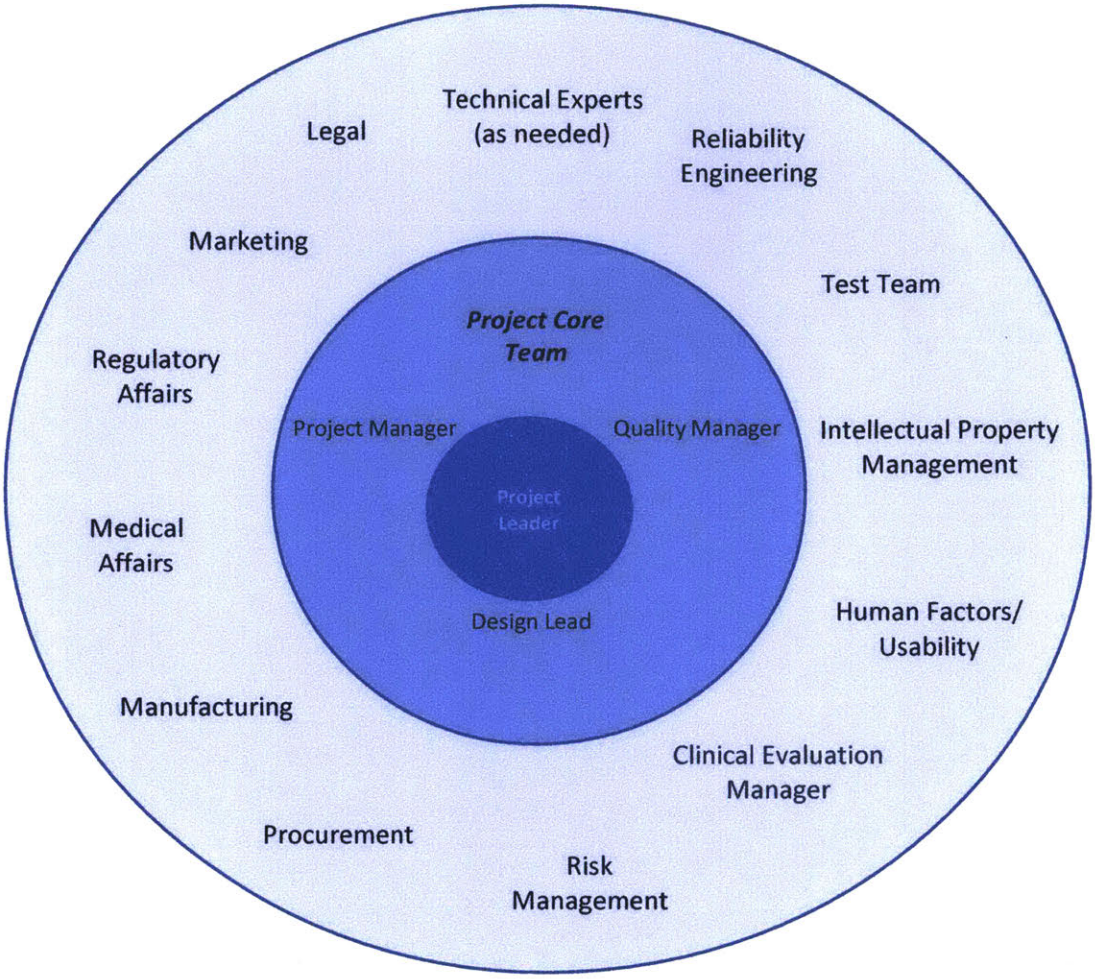

Figure 16 - Project Team Structure

4.3 Internal Stakeholders Analysis

As a means to inform the analysis and ensure delivery of a solution meeting stakeholder objectives, knowledge gathering sessions were conducted with several senior individuals and contributing design and cross functional team members across the organization in order to develop a better appreciation of the mental models of the key decision-makers and understand their needs in relation to a product development process. It was discovered that even though there were subtle differences in the understanding of the strategic purpose and current performance of the MEDTech division amongst the various

stakeholders, there were a few points that were unanimously agreed upon by all. They are as follows:

1) ***Understand what users want***: There was a consensus regarding the lack of user knowledge that informs product decisions. Frequently device decisions are determined by historical assumptions that are often not validated. Several stakeholders desire a more formal formative human factors process to be integrated with existing product development processes so that prototypes can be presented to user groups frequently to shape the design of device during the earliest stages of development.

2) ***Work Smarter***: Strategic goals are seldomly communicated clearly to all stakeholders, in particular the design team. Historically, designers have been asked to develop a device to later be informed of new needs regarding interfaces or customizability. Identification of all potential use cases, use environments, and uncertainties earlier in development would minimize time and efforts expended on rework.

3) ***Faster time to market and expansion into more markets:*** It is well noted that Sanofi as an organization desires to be a market leader therefore it is not surprising that this desire is widespread throughout the MEDTech division as well. One of the hurdles to minimizing time to market and maximizing expansion into more markets is the limited number of competing resources within the division. Several products are actively being developed in parallel with nearly identical project teams who lack guidance on priorities and market strategy.

Table 12 - Summary of Gathered Information from Internal Stakeholders

	Design Team	Chief Technology Officer (MEDTech)	Global Head of Quality (MED)	Sr. Director of Usability & Risk Management (MED)	Cross Functional Team
Mission of MEDTech & Level of Satisfaction with how the mission is being met	Design products that support and help patients on their diabetes journey Dissatisfied with how mission is being met – product usability could be improved	Provide a greater reach of technology – go broad into more countries, go deep and offer maximum functionality in products, go connected	Provide the infrastructure for regulated connected devices and software as a medical device within a cutting-edge quality system Dissatisfied with how mission is being met	Development of safe, effective, and usable products Satisfied with how mission is being met	As a whole, feel as though products could be designed better and want to build products that are more than good enough
Products	Stand-alone software product and connected device *feel as though connected devices are developed separately from the software	Satisfied with accomplishments to date but inability to generate to products in desired timeframes is frustrating	Hardware products: well controlled and quality products Software: lacking control, inefficient documentation and test strategies	Supports all device, drug, and combination products	Supports all device, drug, and combination products By being involved in other projects able to contribute lessons learned from similar projects
Product Development Process	Waterfall with elements of Agile	Agile champion	Following SOPs – Waterfall but is adaptable as long as all requirements are being met and procedures are followed	New to Agile but open to meeting team's needs with its implementation as long as HF and Risk Management processes are adequately followed	Waterfall

	Design Team	Chief Technology Officer (MEDTech)	Global Head of Quality (MED)	Sr. Director of Usability & Risk Management (MED)	Cross Functional Team
Strategy	Not always clearly communicated from management, lack of consensus of priorities	Aligned with Global Business Units - vague	N/A	N/A	Not always clearly communicated from management, lack of consensus of priorities
Knowledge	High technical skills and broad knowledge	Knowledge of what customer desire	Failed attempts at Agile demonstrate lack of knowledge around the process	Subject matter expertise	Subject matter expertise
Constraints	Lack of autonomy, time spent on escalating issues, resources. Coordinating with Europe	Budget and resources	Budget and resources	N/A	Lack of autonomy, time spent on escalating issues, resources. Coordinating with Europe

4.4 "As-Is" Enterprise Summary

4.4.1 Strategy

While the general purpose of the overall MED division is clear and the top priority identified is focusing drug delivery services on diabetes therapies, the division lacks a clear strategy as to how those purposes and priorities will be addressed. Upon discussions with senior level stakeholders and design teams, it became apparent that all entities are uncertain as to how MEDTech is expected to contribute to ensuring MEDs purpose is fulfilled. The lack of strategy is not necessarily a negative attribute for MEDTech; it could be a greater indication of the culture within the division and affords those within the division to experiment and determine how they choose to meet the high-level goals of MED without having pressure and priorities forced upon them.

4.4.2. Areas of Improvement

Inferred from stakeholder discussions and stakeholder typology, it appears that the design team does not have much autonomy and would desire more. The team is asked to consider the needs and inputs from all stakeholders with the exception of themselves, which is an interesting observation considering the lack of information disseminated in reference to product strategies and priorities.

All stakeholders were in agreement that understanding and anticipating users' needs is essential for development of products that are both desired by users and competitive on the market. Also, the timeframe for addressing identified areas of improvements for software products should be minimized. The teams have the data but confusion around resources and priorities often results in no action being taken to implement minor changes that would improve the user experience.

4.4.3 Capabilities

One positive of MEDTech's organizational structure is its relatively flat hierarchy. Having a minimalist hierarchic structure clearly defines process owners and enables faster decision making, both of which are essential characteristics for successful transformations. The team also has several resident Agile champions in-house; they are leaders who are familiar with the practices and benefits of the Agile development methodologies and desire to create a development environment that is responsive and adaptive.

CHAPTER 5: ANALYSIS FOR ARCHITECTING THE FUTURE OF MEDTech

This section identifies the holistic vision of the future of MEDTech. Techniques used to generate architectural decisions and concepts were employed to provide supporting analysis for the presented future concepts of the enterprise.

5.1 Envisioned Future of MEDTech

The vision of the future for the MED division is comprised of three elements: user centricity, improved responsiveness, and evolvability. The knowledge gathered from stakeholders was the primary input for the envisioned future of the MEDTech division. All stakeholders were aligned on the importance of the users (e.g. patients and healthcare providers) and aspire to deliver solutions that are designed for their ease of use and adoption and enhance users' everyday life.

Supporting the element of user centricity, is the element of responsiveness. There is an abundance of data available both for competitor and Sanofi's products, yet that data is not being mined and analyzed. By improving responsiveness, the organization will be able to capture and address emergent needs in a timely fashion which will ultimately enhance the organization's competitiveness.

Understanding that MEDTech specifically aims to become a leader of connected health technologies, the future vision of the division should be developed with the intention of allowing processes to grow as the needs of the markets change and evolve. It would be beneficial to architect a solution that can both be re-used and improved overtime as needs emerge or transform.

5.2 Supporting Analysis for the Future of MEDTech

Prior to generating the concepts, a set of evaluation criteria was defined, and needs were derived from the knowledge gathered from the stakeholders and aligned to the capabilities identified in *Section*

3.4 Enterprise *Capabilities*. The importance of those needs to the respective stakeholders was evaluated (Table 13) and then the values were plotted in relation to the importance of the value and the anticipated effect the value would have on the enterprise's performance (Figure 17).

The following nine capabilities were chosen as the evaluation criteria:

- ***Adaptability***: Ability of an enterprise to sustain value delivery by transforming itself to respond to changes in its ecosystem

- ***Competitiveness***: Ability of an enterprise to deliver products and/or services providing value to stakeholders perceived as equal to or greater than competing enterprises

- ***Creativity***: Capacity to solve problems using innovative solutions, as well as the capacity to innovate

- ***Evolvability***: Capacity of an enterprise to transform by leveraging successful features of the current architecture

- ***Quality:*** Capacity to deliver excellent quality and support for the existing products and services

- ***Replicability***: Ability to reproduce enterprise entities (e.g. processes, products/services, business units) effectively to create or sustain value deliver

- ***Responsiveness***: Ability to respond in a timely and effective way to emergent stakeholder needs, threats, and opportunities

- ***Sustainability***: Capacity of enterprise to endure over time as related to environmental, economic, and/or social dimensions

- ***Industry Leadership***: Capacity to "shape the future of biotechnology"

STAKEHOLDERS	NEEDS	IMPORTANCE TO STAKEHOLDERS [*must have, should have, nice to have*]	GENERAL IMPORTANCE	RELATED VALUES
Customers (Patients, HCPs)	▪ Safe & Effective, reliable product ▪ Easy to use (intuitive) device ▪ Affordable device (or covered by insurance) ▪ Data Privacy & Security ▪ Data integration (connected technologies)	Must have Should have	High Medium	Quality Creativity Responsiveness
Global Business Unit (DCV)	▪ Product satisfying their dynamic needs ▪ Positive reputation ▪ Revenue ▪ Reliability in delivery	Should have	Medium	Quality Creativity Responsiveness Adaptability
Partnering Business Units	▪ Recognition ▪ Transfer of knowledge of skills	Should have Nice to have	Medium Low	Evolvability Replicability
Marketing & Sales	▪ Product satisfying customers' needs ▪ Brand recognition ▪ Customer satisfaction	Should have	Medium	Quality Responsiveness
Regulatory Affairs	▪ Compliance to regulations and standards	Must have	High	Quality
Cross Functional Team	▪ Safe and effective, high quality product ▪ Opportunity to apply expertise to variety of devices	Must have Should have	High Medium	Quality Replicability
Design Team	▪ Rewarding work ▪ Recognition and compensation ▪ Opportunities for professional development and growth ▪ Project funding ▪ Resources	Should have	High	Creativity Thought Leadership Competitiveness
Senior Management	▪ On-time project delivery ▪ Increase in profits ▪ Employee satisfaction ▪ Ability to scale	Nice to have	Low	Sustainability Replicability Evolvability
Competitors & Biotechnology Ecosystem	▪ Lessons learned from marketed products ▪ Motivation ▪ Collaboration opportunities	Should have	Medium	Competitiveness Responsiveness Adaptability Creativity

Table 13 - Stakeholders' Needs and Related Values

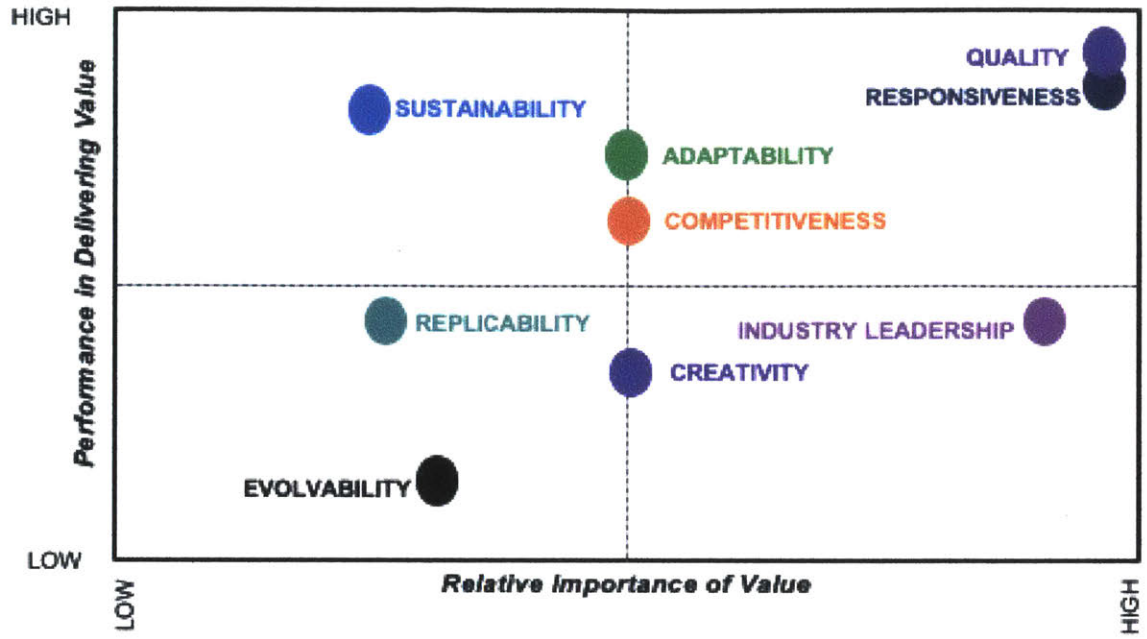

Figure 17 - Evaluation Criteria: Value Importance vs Delivery Performance

Quality, responsiveness, adaptability, and competitiveness are the values derived from stakeholder needs that are most influential in MEDTech's ability to deliver value to their stakeholders. The future transformation must be architected with the intention of maximizing the delivery of these values to the stakeholders.

5.3 Architectural Decisions & Concept Evaluation

To facilitate the systematic alternative concepts generation for the future of the MEDTech division, an outline was constructed to assist in the exploration of enterprise architecture possibilities. The outline was based on differentiable attributes of enterprises' internal landscape elements. Table 14 identifies how the internal landscape elements of the ARIES framework are used as architectural decisions for comparing and contrasting differentiating aspects of the various generated enterprise concepts.

Element	Consideration guidelines for differentiable aspects
Strategy	Primary goal, key thrusts, roles and functions
Information	Key information needed, collection, storage and management means
Infrastructure	Offices (size, quantity, mobility, location, "presence", "feel")
Product/ Services	Range, types, make/buy, customer engagement
Process	Core processes, rigidity, ownership, responsibilities
Organization	Structure, departmentalization style, command nature, culture
Knowledge	Ownership, sources, temporal aspects, competency texture, knowledge retention

Table 14 - Internal landscape elements as architectural decisions used for enterprise concept generation

With this framework, enterprise architecture alternatives were derived and eventually narrowed down to the following three distinct and representative concepts.

It is important to note that for all of these concepts the Design Controls process flow would change from Figure 1 to the figure below. The primary differences between the two process models are that the planning stage is continuous and verification and validation activities are executed concurrently while new features are being designed.

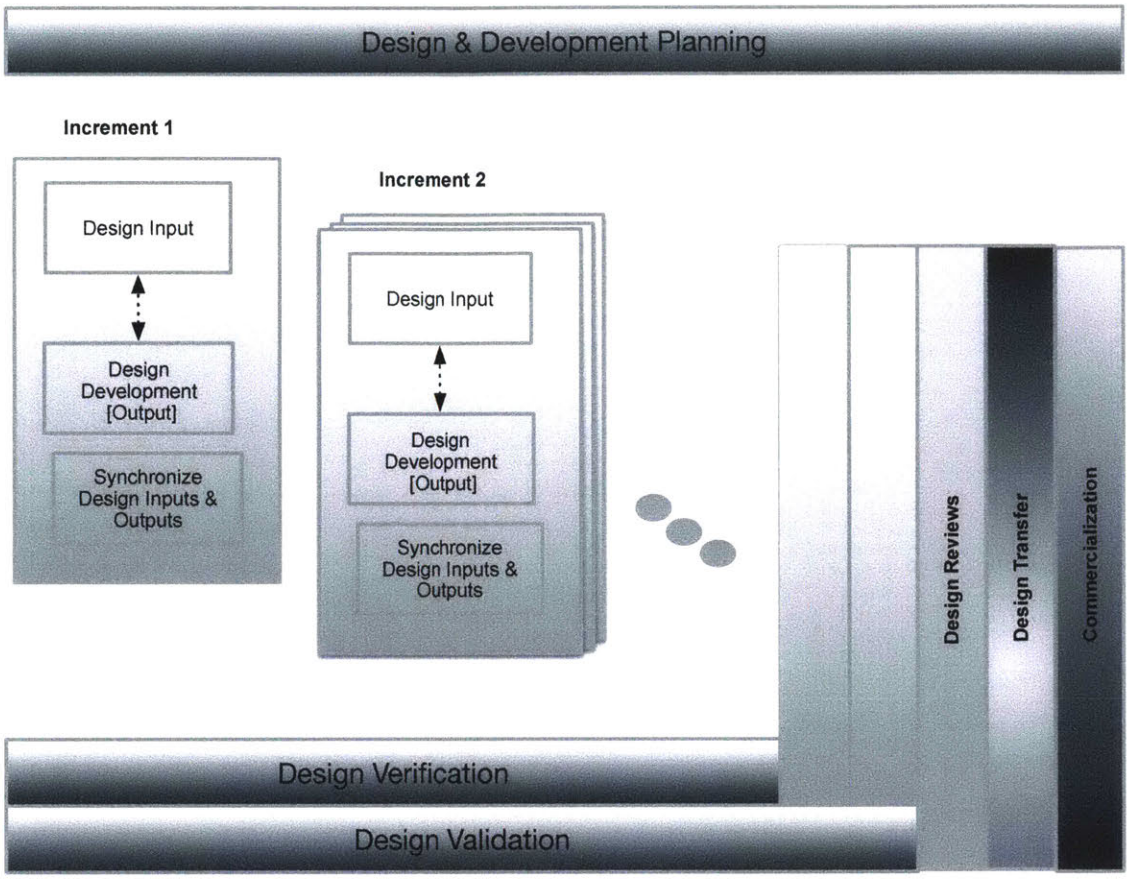

Figure 18 - Agile Design Control Development Model

5.3.1. Concept #1 – Full Agile Transformation

The underlying consideration driving the transformation towards this concept is the encouragement of commitment. Historically, the business has supported Agile implementation but only with the expectation that adoption of the process does not impact or affect the productivity of any business units. Implementation of Agile can be disruptive to multiple units and stakeholders, which is why it is essential that all parties involved are committed and fully understand the impact this transition will have on day-to-day operations and overall productivity. Literature shows that lack of organizational support is one of the contributing factors of unsuccessful Agile adoption. In an attempt to circumvent that lack of support and stakeholder buy-in, it was thought that all design and development teams would be converted to Agile processes. With a full Agile transformation across all

product families (i.e. hardware and stand-alone software) products will be able to be evaluated against similar criteria to determine progress and estimation of timelines. By eliminating existing development methodologies, all stakeholders would be expected to speak in one development process language thus facilitating interactions between product teams and reducing the risk of confusion and poor communication. As part of this concept, it is important to note that the Agile method implementation will not be customized to MEDTech's needs. Customization efforts are generally exhaustive, time consuming and are not conducive to attaining sustainable mindset and processes changes. Following the traditional Agile approach, design teams would have the highest degree of autonomy in directing and executing operations and escalating challenges only when necessary to senior management and other business units. Additionally, allowing the design team to own the process creates less resistance and affords the team to implement a solution that they defined as opposed to a solution that was mandated by leaders who are not responsible for execution. The characteristics of the concept identified in the table below attempt to address challenges associated with the respective enterprise elements (identified in *2.4 Known Transformation Challenges*), specifically in regards to the strategy, organization, process, and information elements.

Element	Characterizing Description
Strategy	• Limited customization of Agile methods • US based & focused product development group - specialized in product creation for specific new technologies. • Fully commit to implementation of Agile throughout MEDTech
Information	• Increased use of communication tools (e.g. Slack, Skype, Zoom) to encourage frequent communication • Develop a means to acquire market/user feedback more efficiently (i.e. regular cadences of formative studies or focus groups) • High level customer needs would be collected and brought in from business unit (marketing/sales) • Information also collected on competitors, have an internal resource dedicated to market research • Data stored and managed locally
Infrastructure	• Adaptable office space that encourages cross-functional and team interactions (i.e. open seating, huddle rooms)
Product/ Services	• Legacy and currently marketed products and any products in final validation stage are out of scope • New products currently undergoing development are in scope
Process	• Design team (with input from stakeholders) defines process & appropriate length of sprint cycles • Design Controls Processes would be adapted to become more flexible for Agile means • Cross functional team procedures (e.g. Quality, Human Factors, Regulatory, Risk Management) will remain unchanged but will be integrated within the new processes • Implementation of consistent change management processes • Standardization of development and project planning tools and methods
Organization	• Restructure entire team to align with scrum model • Component based teams (separate scrum teams for mobile, web, hardware, and system team) • Clearly defined roles and responsibilities
Knowledge	• Educate all teams and stakeholders on Agile (including common misconceptions and misunderstandings) • Leverage internal expertise to create new procedures and restructure teams • Ensure component teams have working knowledge of overall system (including a system architect or representative as part of the team)

Table 15 - Concept #1 Characteristics

5.3.2. Concept #2 – Hybrid of Stage Gate & Agile

This concept was generated to address concerns of global development. In comparison to the first concept, this architecture is thought to be better suited for intercontinental development, where design teams are not all co-located, which is how Sanofi operates currently. With the implementation of Agile, cohesiveness within teams is crucial for success. Although communication tools are helpful, challenges still arise when teams are separated by time zones. In an attempt to address communication and team organization challenges, this concept proposes the adoption of a hybrid development process that follows Agile methods for software products (the majority of which are US-based) and stage-gated methods for hardware products (all of which are Germany based). Shared project resources, such as cross functional team members would maintain their standard roles in both processes, however for software products following Agile methodologies, members should be aware that the scope of their work may not be as well defined or cadenced in comparison to the work outlined for hardware products. This concept requires less of a process change overhaul as the software teams will be the only stakeholders obliged to define new process for Agile implementation; other stakeholders, however, should be included in establishing the ways of working amongst interfacing teams. The following table outlines the characteristics of this concept in relation to the elements from the ARIES framework.

Element	Characterizing Description	
Strategy	• Groups work in parallel to develop/design aspect of connected health ecosystem • Hardware and software products are developed under different processes (Hardware – Stage-gate and software- Agile)	
Information	• Increased use of communication tools (e.g. Slack, Skype, Zoom) to encourage frequent communication • Customer needs would be collected and brought in from business units • Information also collected on competitors, have an internal resource dedicated to market research • Data stored and managed via a means that all sites can access	
Infrastructure	**Stage Gated** • Teams distributed across US & Germany	**Agile** • Adaptable office space that encourages cross-functional and team interactions (i.e. open seating, huddle rooms)
Product/ Services	Products to address specific customer needs, designed in-house (with fully resourced team) or with collaborative partners (if limited resources)	
Process	• Formal, top down driven processes • Seamless transfer of responsibilities to Product operation & sustaining processes when product is ready for commercialization	• Strategic planning processes (needed) • Ideation, development & deployment processes
Organization	• Rigid & formal • Results oriented • Clearly defined roles and accountability • Use of design partners as needed to shorten timelines	• Ad-hoc teaming • Results driven • Shared responsibilities
Knowledge	• Gained from experience & through design partnerships with • Leverage subject matter expertise and tribal knowledge	• Centralized knowledge • Communicate lessons learned frequently amongst team

Table 16 - Concept #2 Characteristics

5.3.3. Concept #3 – Segmented Shift to Agile

Research highlighted that "stress caused by combination of schedule pressures and an abundance of changes all at once can pull people back to old ways" (Stare, 2014). With the intention of developing a concept that will encourage adoption, this third concept proposes to gradually scale up Agile implementation across MED's product portfolio. The implementation would commence in MEDTech, the smallest subdivision of MED. On a product basis, Agile methodologies would be steadily adopted until all new products are being developed in similar fashions. This approach is designed to minimize disruptions within and amongst projects while simultaneously allowing project teams to learn from each other and establish ways of working prior to project initiation. Similar to the first concept, this concept attempts to place full autonomy in the hands of the design team, however unlike Concept #1, this would not be a universal culture shift at once; this shift would occur on a project basis which allows project teams to define their level of desired autonomy based on takeaways from previous projects.

Element	Characterizing Description
Strategy	• Implement Agile practices on a project basis – products currently in development would not be impacted • Establish full set of procedures prior to implementation and pilot them with newest development project • Focus on product creation for new technologies
Information	• Increased use of communication tools (e.g. Slack, Skype, Zoom) to encourage frequent communication • Develop a means to acquire market/user feedback more efficiently (i.e. regular cadences of formative studies or focus groups) • Customer needs would be collected and brought in from business units • Information also collected on competitors, have an internal resource dedicated to market research • Data stored and managed in accessible means (for both sites)
Infrastructure	• Adaptable office space that encourages cross-functional and team interactions (e.g. open seating, huddle rooms etc.)
Product/ Services	• Innovative products that address customer needs and incorporate feedback efficiently
Process	• Gradual change and shift in processes on a project basis • Design team (with input from stakeholders) defines process • Shift towards processes that allow flexibility
Organization	• Structure-flat and fully autonomous on a project basis • Culture-open, fast-paced on a project basis
Knowledge	• Communication of lessons learned from other products/projects • Strategic partnership with design houses and prototypers for new products

Table 17 - Concept #3 Characteristics

CHAPTER 6: DISCUSSION

This chapter identifies the research findings, provides recommendations for the transformation of MEDTech, and summarizes the research objectives. The findings shine light on the critical elements of transformation that must be considered when converting from a stage-gated development process to an Agile development process. Also provided in this chapter are recommendations for transforming the enterprise. The chapter concludes with the identification of limitations of the research and areas for further exploration.

6.1 Research Findings

The two primary mechanisms used to conduct research were a literature review and the ARIES process model. The following sub-sections discuss the main takeaways from those research explorations.

6.1.1 Literature Review

The literature review that was conducted focused on uncovering the challenges and success factors that influence new product development practices specifically for medical device manufacturers. The search also included articles which addressed the implementation of Agile practices across several industries (including hardware driven non-medical industries) and identified best practices and common challenges encountered with the transition to Agile.

For medical devices, regardless of the development process employed to design them, early engagement with regulatory agencies and customers were identified to be of the utmost importance in determining the potential success of a new product.

Because improved customer engagement, a desire for team autonomy, and the need for a reduction in the time to market were elements that Sanofi was looking to improve upon, the

implementation of Agile product development strategies was determined to be a method to assist in achieving those goals. For Agile implementation, literature revealed that the support of senior management, team buy-in, and effective and consistent communication, and flat organizational structures with clear roles defined were a few of the primary criteria of success for Agile adoption.

6.1.2 ARIES Process

Following the ARIES Process model, the current landscape of Sanofi's organization was assessed, and stakeholder relationships, needs and values were analyzed to better understand the enterprise and propose a solution for transformation of Sanofi's development process.

By following the framework, deficits in the team's understanding (and communication) of strategies as well as the team's ability to collect and leverage customer inputs to inform design decisions were identified. Based on the identified deficiencies, concepts were generated to address the knowledge gaps. The created concepts also were created with the intention of addressing essential values (quality, responsiveness, adaptability, and competitiveness) related to performance that were derived from the stakeholder needs

6.2 Recommendations

This section identifies the optimal concept for MEDTech's adoption of Agile practices and as provides considerations for implementation.

6.2.1 Selected Concept

To assist with objective selection of a concept for MEDTech's development process transformation, a Pugh Matrix was utilized to evaluate each concept against the current state of the enterprise's process. The nine enterprise capabilities defined and described in Section

5.2 *Supporting Analysis for the Future of MEDTech* were selected as the evaluation criteria for each concept. In addition to the nine capabilities, two other criteria were added – ease of implementation and cost. Ease of implementation accounted for the estimated level of disruption (related to productivity) each concept would incite. This criterion also took into consideration existing parts of the current development process that could be leveraged for the transformation. The second additional criterion, cost, was selected because it is a factor that often drives business decisions. When determining where each concept ranked on the cost spectrum, the acquisition of new resources (e.g. developers, engineers, scrum masters), acquisition of new tools (e.g. communication, project management, etc.), and training resources (e.g. consultants, in-house workshops) were considered.

EVALUATION CRITERIA	**CONCEPT #1** *Full Agile Transformation*	**CONCEPT #2** *Hybrid of Stage Gate & Agile*	**CONCEPT #3** *Segmented Shift to Agile*
Adaptability	+	=	+
Competitiveness	=	=	=
Creativity	+	=	+
Evolvability	+	+	+
Quality	=	=	+
Replicability	-	=	=
Responsiveness	+	=	=
Sustainability	+	+	+
Industry Leadership	=	=	=
No. of '+' (improvement)	5	2	5
No. of '=' (equivalent)	3	7	4
No. of '– '(declination)	1	0	0
Ease of Implementation	Low	High	Medium
Cost	High	Low	Low

Table 18 - Pugh Matrix Analysis

As shown in

Table 18, Concept #2 was evaluated as being the most similar to the current state of the enterprise and resultantly was the first option that was excluded. Concepts #1 and #3 faired best in terms of improvements from MEDTech's current development process. The first concept, however, performs negatively in terms of replicability due to the fact that a complete Agile transformation would hinder MEDTech's ability to reproduce processes or products effectively until the majority of hurdles associated with implementation have been crossed and the teams are achieving their goals without much tension. A full-scale Agile transformation for all of MEDTech would be rather disruptive; team members would need to define their Agile process and develop procedures which would impact the progress of projects currently in development. A high cost is associated with this option as well because of the influx of resources (e.g. training staff, product and project management tools) that would need to be acquired to assist with the transition. Concept #3 was selected as the most attractive choice because it did not perform worse than the current state of the enterprise in regard to potential capabilities. While this option is not the easiest solution to implement, it is one of the most cost effective. By limiting the scope of the Agile transformation to new projects which have not yet completed the design and development planning stage (per the design controls stage-gated model), MEDTech would be able to pilot the transformed practices on a limited scale (for either hardware or stand-alone software products). Also, by narrowing the scope to be project specific, less training of Agile principles is required for the overall organization at one time; training could be delivered internally from the pilot project team to the next project team – this also would foster communication of lessons learned that are specific to MEDTech.

6.2.2 Implementation Considerations

Applying Agile principles to the development of stand-alone software may be less challenging then applying those same principles to hardware, solely based on the

discrepancy of available literature and established resources for the two types of products. For hardware, it is important to consider that sprint cycles will vary greatly in comparison to the traditional two-week sprint cycles utilized for software development. For both software and hardware, it will require several sprints of data before team members will be able to provide accurate estimations of completion timeframes to the team. For new products leveraging existing process capabilities, it is important to consider analyzing historic data to support sprint estimations. Also, between hardware and software teams, expect the number of resources to vary; for a physical device procurement, manufacturing, and reliability engineering functions, and a breadth of technical experts become part of the project team model (see Figure 16).

From an organizational standpoint, prior to implementation, all affected business units and project teams need to be informed so they are able to provide feedback on the process to ensure it accounts for their needs. Often times, enterprises undergoing transformation become high stress environments due to the pace of change and existing pressure of performance; this concept was chosen to minimize stress and the likelihood of regressing to former processes by encouraging a steadier, isolated rollout of the new methods. As the implementation scales up, however, the teams should be prepared to transfer lessons learned as well as share documentation and tools that facilitated the success of the transformation.

6.3 Review of Research Objectives & Analysis Summary

This research was conducted to seek answers to the following questions:

- How can a medical device development enterprise be transformed to adapt Agile product development methodologies?
- What barriers prevent Agile methodologies from being successfully adopted?
- What benefits would medical device enterprises gain from adopting Agile principles?

Supported by the findings uncovered from the literature review, this research determined that for large medical device enterprises, like Sanofi, the transformation process should be gradual. To minimize disruptions and the risk of failed adoption and resistance, it would be best if enterprises piloted revised processes and procedures with a new project that has not officially entered the design input stage of design controls. A gradual adoption also allows the enterprise to learn lessons in a more controlled manner and apply those learnings to future projects or business units undergoing transformations.

The majority of barriers preventing successful adoption of Agile methods are linked to the culture and organizational elements of the enterprise. Insights gained from stakeholders and literature shed light on the fact that when leaders fail to educate and inform stakeholders of the value of transformation, the transformation efforts are met with resistance and often times are unsuccessful. Organizations also hastily make changes prior to assessing and collecting input from all interfacing business units, a critical mistake when developing or adopting a new development process.

Medical enterprises often struggle with developing products in a timely manner and very few organizations take risks to truly innovate and deliver maximum value to their customers. The enterprises instead, will acquire small companies that have taken those risks and developed device solutions independently. Traditionally, larger medical device institutions follow a linear stage-gated model which forces developers to freeze a large percentage of the device design during the initial stages and making changes to those early decisions proves increasingly difficult as development progresses. By adopting Agile practices, more flexibility will be incorporated in the device development process which should encourage designers to continually assess the product under development and determine if the needs of its customers and stakeholders are being addressed with each iteration of the product. Early customer integration is an element that is often overlooked; in the medical device atmosphere seeking customer engagement also helps reinforce the motivation for the therapies being developed. The adoption of Agile can shorten development timelines and

affords enterprises the opportunity to commercialize those therapies as quickly as possible to positively impact customers' lives.

6.4 Limitations and Future Work

6.4.1. Limitations

This research was limited due to the availability of stakeholders and time constraints. If more time had been available, it could have been used to expand the sample size of stakeholders to include other units within MED. There is a unit responsible for testing (including test method development, test execution for all product families) based in Frankfurt which has implemented Agile practices. Although they are not a development unit, in the future they should be consulted to acquire enterprise specific insights into the experienced challenges and accomplishments associated with Agile adoption.

6.4.2. Areas for Future Exploration and Work

One shortcoming of the Agile development process is that is does not encompass the entire product lifecycle (from feasibility to commercialization to post-market monitoring). For medical device technologies, quick responses to post-market feedback are invaluable and it would be interesting to explore potential benefits of extending Agile principles to life-cycle management approaches.

Due to the complex nature of large medical device enterprises, it would be valuable to more comprehensively analyze and determine which business units would benefit the most from transformation. This could be done by extensive stakeholder value mapping and a comprehensive needs analysis for additional business units since it may be possible that adoption of Agile development practices is not needed or may not positively impact all development units.

Upon successful implementation of Agile development process to both hardware and stand-alone software products, a guidance document could be developed to assist other units with the transformation. This would also be a means to ensure that internal knowledge associated with the transformation is not lost. It would also be worthwhile to explore team dynamics across projects to more accurately determine if Agile processes improve team health and individual satisfaction.

6.5 Closing Remarks

With the current landscape of medical technology rapidly evolving, device developers need to discover a way to keep up with the pace of the industry and the evolving needs of their customers. To remain competitive in this environment it is imperative device manufactures develop a strategy to produce safe, effective, and useful devices efficiently (i.e. with reduced timelines). A growing number of patients now desire personalized medical solutions that enhance their quality of life and impose as little of an inconvenience as possible which drives the need for developers to determine the needs of their customers early in the development process. To more effectively determine and meet customers' needs, device companies should involve customers early and often when creating requirements for the medical device under development. By utilizing a product development process that enables designers to adapt to changes and continually improve the product in iterations, design teams can leverage the flexibility of the process to determine when iterations of the device should be presented to potential customers for feedback generation. While it stands to reason that medical device enterprises should pivot towards the adoption of comprehensive development processes that are adaptable to change, incorporate user needs during pre-development, rely on the expertise of the team to drive the development to completion, further research can be conducted to comprehensively explore the differences within an organization between business units following Agile versus waterfall development processes. This research could be used to gain support for future

transformation efforts because, as demonstrated by this research, resistance to change occurs when transformation champions fail to communicate the value and benefit of change to stakeholders.

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