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MedTech Product Development Framework for Post-Pandemic Era

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Abstract

A case study during pandemic revealed the major drawbacks of the traditional product development process for MedTech industry. Disruption of conventional manufacturing, urgent need for accelerated design and production, faster regulatory approval have challenged the industry. In this paper the conventional medical product development process is explored based on the intramuscular injector case study. The study revealed core areas for improvement of the medical devices development process. The paper proposes the Lean-Agile methodology with the incorporated elements of Concurrent Engineering.

Keywords: agile development, lean product development, organisation of product development

1. Introduction

1.1. MedTech product development challenges

The peculiarity of the MedTech industry is its reliance on regulatory directives. During the Pandemic, some governments introduced resolutions in order to reduce the approval time for some medical products to a week. The list of products included ventilators, oxygen generators, heart-lung systems, systems for extracorporeal gas exchange, respirators, thermometers. The FDA has several options for speeding medicines to market in urgent cases. For example, in the case of COVID-19, the FDA has granted special clearances known as emergency use authorization (EUAs) to products that have not yet been approved for U.S. sales (FDA, 2021a). In contrast to the evaluation of medicines, the supervisory framework for medical devices is fragmented and there is no single 'go-to' authority, which can be problematic for some products (Pharmaphorum, 2021). Most Class 2 medical devices in the US go through a 510(k)-clearance process (FDA 510(k)), which might take up to six months on average to receive the clearance (Eisenhart, 2017).

The critical factors impacting the FDA decision time for submissions are the type of submission and the change of efforts in FDA policy (Medina, 2013). Same study revealed that the impact of product related factors is relatively low. The COVID-19 crisis has revealed a need for the accelerated design, production, and regulatory approvals for healthcare products forcing regulatory authorities to bring changes to the approval process.

With the end of pandemic, partially remote work, broken supply chains, travel bans, components availability, semiconductors shortages will remain for some time. This creates a pressure on the product development teams, as the gain in time should not compromise the safety aspects of new products. Therefore, an improved MedTech product development process is needed to design products faster, more efficiently and within new conditions.

1.2. Paper objectives and structure

The general goal of the paper is to define the MedTech development process as it was organized for a specific device development, to find out the core areas for improvement, and to propose a framework for efficient MedTech product development in a post-pandemic era.

Therefore, the first objective of the paper is to perform the design study of the medical product development process. The second objective is to propose an approach for effective medical product development process based on Lean-Agile methodology with the incorporated elements of a Concurrent Engineering framework.

The paper is structured as follows. In Section 2 the literature review is provided covering the product development frameworks (sub-section 2.1) and best practises of rapid design and manufacturing in crisis (sub-section 2.2). Section 3 explains the research methodology. Section 4 describes a MedTech case study - an intramuscular injector development (sub-section 4.1), the design interviews methodology (sub-section 4.2), and the study of the product development process "AS-IS" (sub-section 4.3). The key findings are summarized in sub-section 4.4. A framework for Agile-Lean System Thinking approach in the medical devices development process is proposed in Section 5. The conclusion and discussion are present in Section 6.

2. Overview of MedTech product development

2.1. Traditional Product Development Frameworks

Medical device development is performed within strict regulatory requirements that put constraints on the development, manufacturing, marketing strategy and continuous improvement of medical devices (Medina, 2012). Regulatory authorities recommend using the waterfall development process for simpler medical products and Concurrent Engineering for complex medical systems (FDA, 1997). Waterfall approach divides development and testing into two different stages: design team builds a feature and then passes it to the quality assurance team (QA) for testing. The QA team creates and implements detailed test plans. They also file defects that might appear in existing features after integration of a new work. Major drawbacks of a waterfall model are the long development cycle, very low flexibility and adaptability of the processes, rigid structure of the decision making. Feedback and iteration primarily at validation stages result in a very cumbersome QA testing process. In the end, such an approach creates value delivery delay for the customer.

The Concurrent Engineering approach is more beneficial for complex medical products (FDA, 1997). This model implies simultaneous development and encourages continuous testing. When well implemented, concurrent design can significantly optimise overall development time. However, this approach requires great communication and involvement across all teams. It also becomes challenging to introduce requirements changes as it strongly influences the work of the dependent component.

2.2. Alternative Product Development Frameworks

With the vast implementation of Agile development approaches across different industries, the medical device industry also found its benefits from adopting Agile (Shuren and Maizel, 2021; Gottlieb, 2019; FDA, 2021b; Pathfinder, 2013). Agile intends to review and iterate at earlier stages in a design, thus providing a much higher flexibility, variability and speed (Glazkova, 2019). These characteristics were revealed to be crucial for the medical product design and development during the COVID-19 pandemic.

The other widely used methodology is Lean with the major purposes of waste elimination, value delivery and knowledge gain. Historically, Lean principles are well applicable to manufacturing process, supply chain and warehouse management. Although Lean approach helps to optimise the workflow and to lower costs, the pandemic has revealed the risks of such a strategy (Eckert et al., 2019). When supply chain and production disruptions occur, providers have little-to-no notice and can experience major difficulties to purchase products necessary to operate.

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2.3. Best practices of rapid design and manufacturing in crisis

The best practices of rapid design and manufacturing in crisis were collected through the market research. The focus was made on the analysis of approaches, tools, and methods used by product teams while developing new devices within a short period of time during the pandemic.

The first responders to COVID from the design industry were makers communities that started exploring additive manufacturing technologies to create end products for the market. For example, 3D printed connector that can keep together a non-invasive ventilation (NIV) mask, a filter and a PEEP valve to facilitate breathing (Materialise, 2020). The product called NIP has been designed as a response to ventilators shortage. According to (Meisenzahl, 2020) the process from initial designs to trials was fast. In only a few days, the design team went from an idea to a proof of concept with a pulmonologist to trials on healthy people. Other examples of products that were quickly produced by additive manufacturing include door and shopping cart handles, protective equipment, face masks and different spare parts for medical equipment (Molitch-Hou, 2020).

The other example is Canada's largest medical device service provider (StarFish Medical) whose Winnipeg Ventilator 2.0 to battle the COVID-19 was certified by Canada through an Interim Order.

Large corporations also tried to cope with the COVID-19 crisis and introduced their solutions in a prompt manner. In some cases, the companies have used their resources and platform abilities to support fast product development. For instance, Xiaomi Youpin platform released F95 mask for children, easy to breathe and better fit for Asians in early 2020 (Sean, 2020).

O2IN lungs training device, developed by RUKI LLC has been also delivered during the pandemic. Originally aimed for the sports industry to train athletes' lungs, it turned out to be useful to restore regular breathing for patients as a relief tool after a COVID-19 (O2IN). The development began in the summer of 2019; molds were ordered in the spring of 2020 and the first batch of products was ready in the summer of 2020. We found that direct and easy access to a production factory that developers knew before and had already well-established relationships with was crucial. The company implements Agile approach and uses the backlog of product functions, launches the first version early, waiting until customer feedback to launch the second version. Among the tools to facilitate the development process and track tasks, designers use Basecamp. For knowledge acquisition, the company uses the blog format, as well as a Telegram channel.

Among more complicated MedTech products there is Raytheon - C-FAST Rapid Covid-19 Diagnostic device, developed by a multidisciplinary team in a collaborative mode. The team at Raytheon BBN Technologies identified that a technology originally designed to detect respiratory disease in cattle could be adapted to detect COVID-19 in humans. Their lateral flow molecular assay-based LAMP test for POC COVID-19 detects the presence of the SARS-CoV-2 RNA in either saliva or nasal swab specimens, without needing to send samples to a lab (Cortex-Design).

3. Research methodology

Having this rich background of examples of the rapid design and manufacturing in crisis, at the first step the conventional design process for MedTech product development has been studied. For this purpose, a small and medium enterprise (SME) engineering design company was involved in the study. By the moment of design interviews setup, the company already completed a project aiming at the development of an intramuscular injector device (to be discussed in sub-section 4.1) following its own conventional design process. The design team members of this project were interviewed using the system concept representation framework (Menshenin and Crawley, 2020) (the framework is to be discussed in sub-section 4.2).

At the next step, the IDEF0 (Presley and Liles, 1995) diagram for Level 1 was built. The purpose was to define the product development process “AS-IS”, in other words, how it was organized during the intramuscular injector device development. This is further discussed in sub-section 4.3. The key findings from the case study summarised in sub-section 4.4. Based on them, the framework for Agile-Lean System Thinking approach in medical devices development process is proposed in Section 5.

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4. Case Study: intramuscular injector development

4.1. Case description: Intramuscular injector

The internal team working on the intramuscular injector device included a mechanical engineer, an electrical engineer, an industrial designer, a manufacturing coordinator, the CEO and the CTO. The purpose is to provide effortless automatic drug injection, enabling non-professionals to safely administer the drug without the involvement of third-party assistance, eliminating the psychological and other barriers. Using the device does not require any special training or experience. The idea goes in line with modern trends of independent and digital healthcare at home.

Due to the variety of drugs used for intramuscular injections and different syringes of different types and volumes, the injector is designed to be versatile. After pressing a start button, the needle is inserted quickly and at 90 degrees as recommended by injection techniques (Shepherd, 2018). Drug administration speed and needle penetration depth are adjustable. The injector is capable of performing a wide range of intramuscular injections (designed for 2-, 3- and 5-ml syringes of any manufacturer). The body of the injector is designed so that it is completely comfortable for the user to use one hand to make an injection. The position of the syringe and the needle in the injector ensures the correct process. Injection speed is present at the optimum rate. The body of the injector hides syringe and needle eliminating the psychological fear of an injection.

The device is particularly innovative for developing countries. Being not that popular in Europe and the US, injection therapy is still widespread in many countries. Studies show that of all injections given in developing countries, 5% or less were done for immunization purposes, while 95% were given for curative purposes (Simonsen et al., 1999). Symptoms that are commonly treated with injections in developing world include fever, upper respiratory infections, colds, ear infections, tonsillitis, pelvic inflammatory disease, pneumonia, skin infections, diarrhoea, malaise, fatigue, and others (Simonsen et al., 1999).

The need to visit a clinic, external assistance for the injection at home, potentially multiple injections during a treatment course - there are all the challenges associated with a course of intramuscular injections. At the same time, the self-injections or injections by non-professionals can pose the risk if poorly performed, leading to bleeding, abscess formation, cellulitis, muscle fibrosis, nerve injuries, direct needle traumas, toxic effects of injected agents on nerve fibers and surrounding tissues, nerve compressions (Sisson, 2015; Kim et al., 2017).

The design process took almost 4 years and many iterations, prototyping, electrical engineering and tests. Due to pandemic the team was not able to visit the manufacturing company to finalise the golden sample and launch the certification process.

4.2. Design interviews

Following the research methodology, explained in Section 3, at the first step, the design process for the intramuscular injector device development in the engineering design company was studied. For this purpose, the system concept representation framework (Menshenin and Crawley, 2020), transformed into the set of questions (see Figure 1) has been used. Each member of the design team developing the intramuscular injector was interviewed individually, following the proposed framework described in (Figure 1). Since the framework contains the set of specific terms, if needed, each of them was explained to the interviewee.

The process for design interviews was organised as follows. In all cases the interviews were organised as face-to-face meetings and were conducted with each team member individually. The respondents' answers to each of the 28 questions indicated in (Figure 1) were written down on paper by hand. The interviews had different duration - from 1 hour to 2 hours 30 minutes. The interviewees were not given any guidance on how long the answer on each question from (Figure 1) should be. Therefore, in some cases the discussion related to a specific question could last 20 minutes. The definitions of each entity from (Figure 1) are contained in the previously published work (Menshenin and Crawley, 2020).

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The framework presented in (Figure 1) explores the level of awareness about the undergoing design process among the design team members: definition of the stakeholders and their needs (see Domain 1 in Figure 1); translation of needs into the requirements through the so-called solution-neutral environment (see Domain 2 in Figure 1); search for the potential concepts through the solution-specific environment (Domain 3); decomposition of the chosen concept, or alternative concepts (Domain 4); and the definition of the concept of operations (Domain 5). By asking those questions, we aimed at figuring out the level of consistency among the interviewees: whether they had the same understanding of stakeholders, product, how it is intended to operate, etc.

Domain 1 (D1) Stakeholders	
1	Who are the Stakeholders?
2	What are the Needs?

Domain 2 (D2) Solution-Neutral Environment	
3	What is Solution-neutral operand (SNO)?
4	What is the value attribute of SNO?
5	What is the other attribute of SNO?
6	What is Solution-neutral process (SNP)?
7	What is the attribute of SNP?

Domain 3 (D3) Solution-Specific Environment	
8	What is Solution-specific operand (SSO)?
9	What is the value attribute of SSO?
10	What is the other attribute of SSO?
11	What is Solution-specific process (SSP)?
12	What is the attribute of SSP?
13	What is the Generic Form?
14	What is the attribute of Generic Form?
15	What is the Specific Form?
16	What is the attribute of Specific Form?

Domain 4 (D4) Integrated Concept	
17	What are the Internal Operands (IO)?
18	What are the value attributes of IO?
19	What are the other attributes of IO?
20	What are the Internal Processes (IP)?
21	What are the attributes of IP?
22	What are Internal Elements of Form (IEoF)?
23	What are the attributes of IEoF?
24	What is the Structure?
25	What are the Interactions?

Domain 5 (D5) Concept of Operations	
26	What is the Concept of Operations?
27	What is Operator?
28	What is the Context?

Figure 1. System concept representation framework (Menshenin and Crawley, 2020) adopted for the design interviews

4.3. Product development process "AS-IS"

At the next step, the IDEF0 diagram (Presley and Liles, 1995) was developed with the purpose of documenting the design process as it was organised during the intramuscular injector development. The IDEF0 Level 1 diagram is shown in (Figure 2). The design process consists of 6 blocks representing the major activities the developing team performed. In IDEF0 syntax, each block is a manufacturing function with input entering the left side, controls entering the top, mechanisms and resources entering the bottom and outcome exiting the right side.

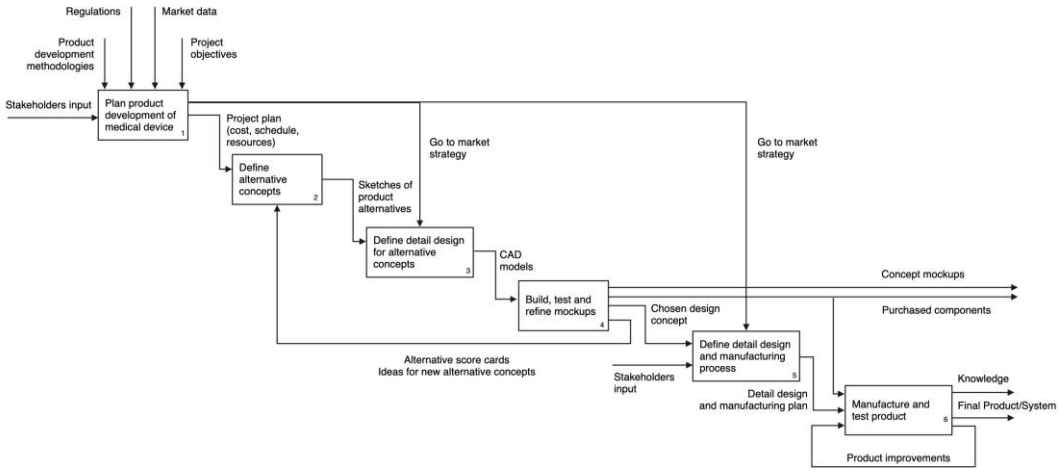

Figure 2. IDEF0 diagram "AS-IS" (Level 1)

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4.4. Findings from the case study

In a result of the design interviews and IDEF0 diagram, the key findings were defined which later form the basis for the Agile-Lean System Thinking approach in the medical devices development process (discussed in Section 5). (Figure 3) illustrates the critical points and major drawbacks of "AS-IS" design process.

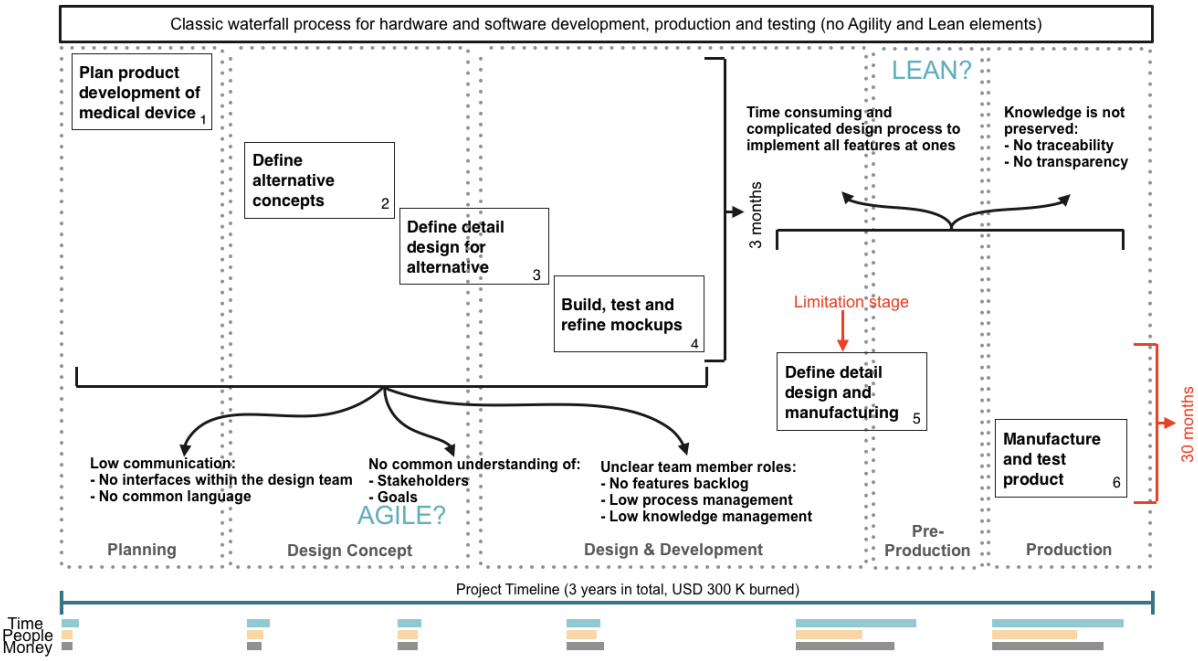

Figure 3. Drawbacks of the design process based on "AS-IS" IDEF0 diagram (Level 1)

The first finding from design interviews is that a limited communication within the product design team led to lack of common understanding of key elements of the intramuscular injector design process. For example, team members did not have a common view of who the product was developed for. Answering the first question from (Figure 1) "Who are the Stakeholders?", mechanical engineer said "no idea"; the CTO - "patients"; the manufacturing coordinator named many potential stakeholders - from contractors to doctors and investors; and the CEO referenced the above-mentioned team members. A potential solution to overcome this challenge is to establish a common understanding of the core definitions of the specific product development as early as possible, and to be able to return to those definitions iteratively.

Another issue identified is that there was misunderstanding among team members of the final product's functionality. This contributed to the 30-months long detailed design, manufacturing and testing phases.

A potential solution is to establish interface management for design team members. The domain specialist should clearly know the details of his/her part of the work, but it is also important for the domain specialist to know what, when, and how is planned to be exchanged with other team members. Such interface management would ensure knowledge management and integration throughout the design process. This also includes a critical need to early start knowledge gathering and documentation for regulatory approval.

Although the IDEF0 diagrams were created on a functional base, the sequential nature of design process is still present on them. This provides the opportunity to include the concurrency and agility into the proposed Agile-Lean framework. The case study illustrates that there is a need to include a faster iterative design process in the proposed framework. It is possible to use the software that partially covers the mentioned drawbacks of the studied design process. For example, WiKi pages, Confluence are designed for knowledge management; Jira, Trello - task management; Valispace - provides solution neutral environment and interfaces for the design process. However, each of these

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software tools solves a specific problem, and there is a need to integrate those tools across the design issues appearing throughout the entire lifecycle and within a proposed Agile-Lean framework.

5. A framework for Agile-Lean System Thinking approach in medical devices development process

The framework that integrates the key findings (described in sub-sections 4.3 and 4.4) from the case study is required to facilitate a reliable and efficient development process.
(Figure 4) illustrates the proposed MedTech development framework for the post-pandemic era that incorporates principles of Agile, Lean, and concurrent design approaches.

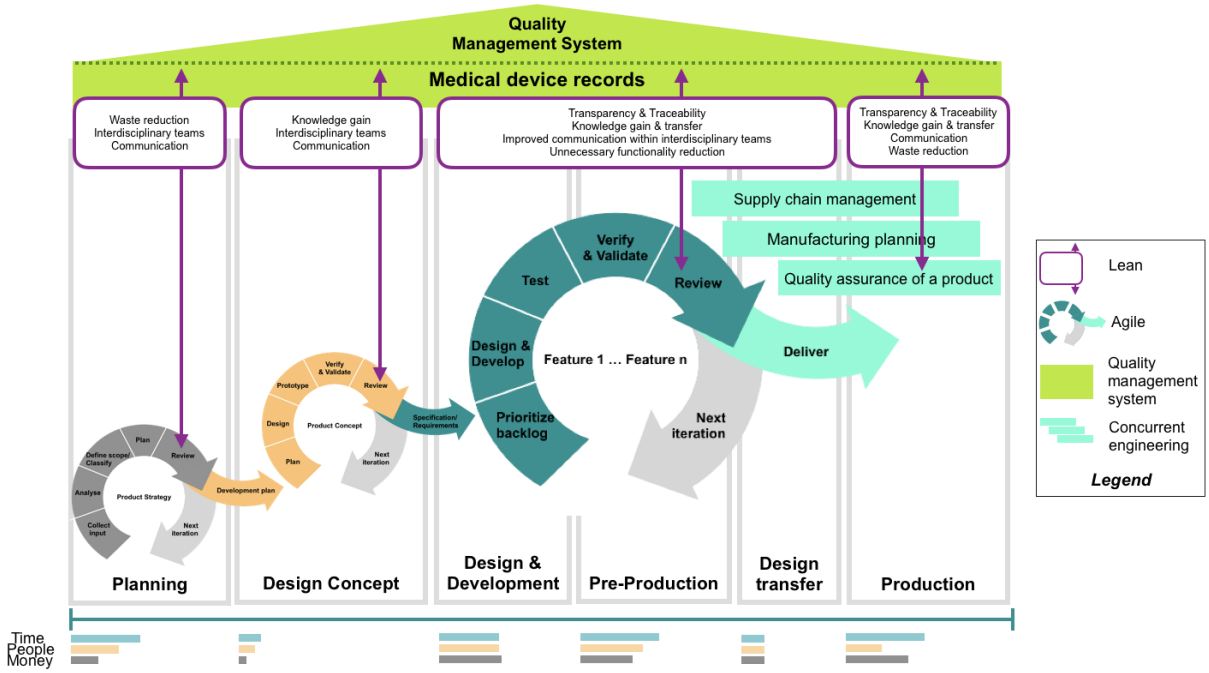

Figure 4. Proposed medical product design and development framework for post-pandemic era

The green sector on the top of the diagram represents Quality Management System (QMS) with relevant medical device records. The next sector with purple rectangles represents the Lean principles that are applied at the review stage of each Agile loop to ensure knowledge gain, overall transparency, and traceability. The Agile cycles are evolving from planning to pre-production meeting the needs of each phase. The concurrency of the design process at the later stages is represented by the turquoise set of rectangles. At the bottom there is the resources bars (time-people-money) corresponding to each phase of the development process. These resources are evaluated from past experience and foreseen for the new process, represented in relative scale.
For successful delivery of MedTech products it is essential to assure regulatory compliance. Therefore, the proposed framework (see Figure 4) relies on building a concise Quality Management System (QMS) with the reference to the medical device records, including, but not limited to design history file, device master record, device history record, technical documentation file. The documentation that comes along with the QMS builds up a strong knowledge, transparency and traceability base for the company developing the product. The proposed MedTech development framework addresses the major challenges identified in subsection 4.4:

- One of the drawbacks was the lack of well-thought-out product strategy. To reflect this challenge, the proposed framework integrates product and regulatory strategies earlier in the product development cycle and suggests putting more effort and resources into the planning phase. The activities of this phase shall include deep analysis of stakeholders input, investigation of regulatory landscape, definition of scope and classification of medical

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product. By performing these activities in an Agile fashion (with iterative nature, constant feedback loops and time constraints for each iteration) the team can formulate requirements with stakeholders and end users and establish a common understanding of what product the user is expecting. Engaging interdisciplinary team members helps to satisfy the interests of different modalities and eases further communication within the company. A mature strategic development plan that includes product roadmap and regulatory strategy becomes an entry point for the quality management system and acts as an initial reference for the further development.

- To address the lack of process management during the concept and design and development phases, the framework proposes an Agile approach with the results during short sprint cycles. By implementing highly iterative process with prompt feedback from the end-users, it becomes possible to reduce waste and provoke intense cooperation in a team.
- The analysis of a case study showed that the detailed design and pre-production activities lasted for about 30 months partially due to the desire to implement large portion of product functionality at once. The new framework suggests avoiding over-complexity of the new medical product by moving to the feature-based Agile development. Prioritization of the functionality according to the stakeholders needs and risk assessment analysis allows to deliver minimal valuable product as early as possible according to Agile manifesto. Each cycle includes the review step to check an alignment with product strategy, requirements and other artifacts. This also enables quick response to the outcomes of the testing and prompt delivery of design corrections if applicable.
- The maintenance of quality management system across entire product development lifecycle resolves the transparency and traceability issues of "AS-IS" process. The framework suggests using Lean principles to accumulate knowledge and development efforts. Keeping medical design records as part of QMS eases the knowledge transfer across multidisciplinary teams, regulatory authorities and manufacturers.
- Production of a medical product with hardware and software components can hardly be delivered in Agile sprint cycles. Therefore, the framework suggests adapting Concurrent Engineering principles to mitigate long lead items. Keeping component purchase as an integral part of the design process is also a proposed solution. It is important to consider supply chain constraints early in the design process and to look for alternatives, such as raw material substitutions and alternative manufacturers or suppliers.

6. Conclusion and discussion

One of the results of the study is that the product development and regulatory approval data should be collected from stakeholders, including end-users, early in the design process. The proposed framework (Figure 4) outlines the regulatory compliance strategy as early as at the planning stage. In most cases this means involvement of a third-party consultancy to the design process.

Also, the framework proposes the integration and maintenance of the Quality Management System across all phases. Keeping the record of each major step and decision along the development process would provide the company with comprehensive documentation that could be retrieved by regulatory authorities upon necessity. Such records would also act as knowledge management and preservation mechanisms supporting the Lean approach.

Another result facilitated by the framework and related set of questions (see Figure 1) is the improvement of communication within a multidisciplinary product development team by implementing Agile instruments, such as scrum ceremonies; Concurrent Engineering, including the systems engineering methods for interface management and integration (Eppinger and Browning, 2012); and conducting the joint design sessions aiming at shaping the same answers on each question presented in (Figure 1).

Flexibility in decisions should be practiced through the design iterations, leaving the room for improvement. At the same time, the product design team should be aware of the critical decisions and when they are defined. This can be achieved through the implementation of an Agile iterative

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design process with a constant feedback loop at each stage: from planning to design transfer (see Figure 4).

The limitation of current work is its focus on studying the specific medical device development in a concrete SME. To overcome this limitation, a bigger set of case studies should be studied in future work.

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