NORDDESIGN CONFERENCE
REYKJAVIK, ICELAND, 12-14 AUGUST 2024
Article published in DS 130: Proceedings of NordDesign (Reykjavik, Iceland, Aug. 12-14, 2024) pp. 486-495. Design Society.
The final published version available at https://doi.org/10.35199/NORDDESIGN2024.52

Agile Systems Engineering for the Development of Smart Medical Technologies

Julia Guérineau

École de technologie supérieure, Systems engineering department
1100 Rue Notre-Dame Ouest, Montréal, QC, H3C 1K3, Canada

Abstract: Smart medical technologies arise from the collaboration of multiple engineering disciplines, resulting in increased technical and organizational complexity. Compounded by the intrinsic complexities of the medical sector, their development can prove challenging. In this sense, this article focuses on their development from a methodological standpoint. Leveraging the review of six distinct product development approaches and processes, the proposed research direction explores Agile Systems engineering and especially a V-model-Scrum process model for the development of smart medical technologies.

Keywords: Design Methods, Medtech, Medical Devices, Smart Products Engineering, Systems Engineering (SE)

1 Introduction: leveraging digital and connectivity technologies in healthcare

In response to current and future healthcare challenges, such as an ageing population, the increasing prevalence of chronic diseases and multimorbidity (Ryan et al., 2018), and a looming workforce shortage, decision-makers and innovation ecosystems are increasingly recognizing technology as part of the solution. Medical technologies for post-surgery monitoring or remote monitoring, and, in the future, for the preventive diagnosis of certain diseases, are expected to be progressively integrated into patient healthcare trajectories (Chen et al., 2023). This direction is in line with the adoption of preventive, predictive, personalized, and participative medicine (P4 medicine), which will require data collection and analysis capabilities (Flores et al., 2013; Hood and Friend, 2011). These capabilities can be materialized by connected sensors, wearable technologies, and artificial intelligence algorithms, embodying concepts such as “digital health”, “e-health”, “health 4.0” or the “Internet of Medical Things” (IoMT) to name a few (Chen et al., 2023; Dunn et al., 2018; Kashani et al., 2023). Overall, the common denominator remains the same as witnessed in the manufacturing industry with the widespread adoption of digital and connectivity technologies into healthcare systems.

In this context, there is an increasing demand for “smart” medical technologies fitted with data collection and wireless communication capabilities (Karen et al., 2018). Combining hardware and software components, smart medical technologies result from the contribution of multiple engineering disciplines, such as biomedical, mechanical, software, electrical and electronic, as well as information and communication technology. These medical technologies arise from a development that is, by definition, multidisciplinary. Accordingly, these products unlock new capabilities for patient monitoring and disease prevention, but come at a greater cost in terms of technical and organizational complexities (Menshenin et al., 2023a; Mishra and Behdinan, 2023). These complexities compound to the legal, regulatory, normative, commercial and clinical complexities intrinsic to the medical technology sector. The number of stakeholders gravitating around product development also contributes to the high level of complexity. The term “five-headed beast” has been heard more than once to depict this complex stakeholder landscape, composed of public hospitals and private clinical centres, healthcare practitioners (*e.g.*, medical doctors, nursing professionals), patients, payers, and policymakers. Still in terms of complexity, the range of medical technologies is vast, as is their level of risk and their average development time, which ranges from 1 to 5 years (Lucke et al., 2009) and up to 10 to 15 years between the idea and the market launch of a certified medical equipment (Davey et al., 2011; Mejtoft et al., 2022). The product development time could be further prolonged as the technical and organizational complexity increases (Zhang and Thomson, 2016). This is where the methodological aspects of product development come into play (Koivukangas et al., 2015; Santos et al., 2012), contributing to a better grasp of the increasing multifaceted complexity, which leads us to the point of this article.

This article explores medical technology development from a methodological standpoint. In other words, the research focuses on the scientific literature pertaining to its development, hereinafter, from a macro-level standpoint, *i.e.*, approaches and processes (Guérineau et al., 2018). Considering the specificities of smart medical technologies, the question of how to develop them remains partially answered and has motivated various research efforts over the last decade. Some of these efforts are presented in the next section, before introducing a research direction at the crossroads of Systems engineering and Agile for the development of smart medical technologies. The proposed research direction and its perspectives are discussed before concluding.

2 Literature background: development for medical technologies

This section provides an overview of product development approaches and processes identified in the scientific literature for medical device and medical technology development. While both terms are used in the literature and sometimes interchangeably, the term "medical technology" (MedTech) is preferred hereinafter, as it captures a broader range of applications.

2.1 Systematic product development for medical technologies

The systematic approach, sometimes called the plan-driven approach, can be described as prescriptive and represents the "traditional" path of product development (Guérineau et al., 2022; Slattery et al., 2022). The systematic approach is embodied in process models such as Pahl & Beithz's model (Pahl et al., 2007), the VDI-2221, the "Stage-gate" model (Cooper, 2011) or the Waterfall model (Royce, 1970) to name a few. Some of these process models have been proposed to support the development of MedTech.

The U.S. Food and Drug Administration (FDA) published the "Design Control Guidance for Medical Device Manufacturers" in 1997. It introduced design controls through the Waterfall model, allowing "review", "verification" and "validation" to be graphically positioned during the development process starting with the "user needs" as input and ending with the "medical device" as output. Although the Waterfall model can be used in practice, Concurrent engineering (CE) is suggested for the development of "more complex devices" (FDA, 1997; Glazkova et al., 2022). One major aspect of using CE is the involvement throughout the development of other departments, including manufacturing, to avoid the "over-the-wall" phenomena. Besides reducing time-to-market and production costs, a desirable consequence is improved product quality. The involvement of other departments along the product development process can also be retrieved from the scientific literature, as detailed below.

Systematic process models have been adapted to the specificities of MedTech development. This specialization generally comes with process models offering a higher level of detail. For instance, Pietzsch et al. (2009) propose a five-phase stage-gate process model, from "early concept to post-market surveillance" for the development of "premarket approval and 510(k) devices". The five phases are detailed at a macro scale for most departments and include marketing, research and development, legal, regulatory, reimbursement, manufacturing and operations, quality, clinical, sales, as well as "cross-functional management" to lead the project. Similarly to Pietzsch et al. (2009), Ocampo and Kaminski (2019) present a stage-gate process model comprised of ten phases and eight gates, organized into three "macro-phases": pre-development, development and post-development. Each of these phases is also detailed for the different departments. These systematic process models, typically portrayed as linear processes, often lack formalized iteration loops. This lack of formalized iterations is one of the criticisms directed at them and can be misinterpreted. In fact, the iterative nature of the design process is by no means ignored; on the contrary, its importance is acknowledged and supported (Ocampo and Kaminski, 2019; Pietzsch et al., 2009; Shluzas et al., 2009).

Current MedTech developments tend be supported by systematic processes (Eatock et al., 2009; Koivukangas et al., 2015; McCaffery et al., 2016; Slattery et al., 2022). Although these models remain studied and implemented by companies, they are being challenged – not to say criticized –, especially when it comes to complex and multidisciplinary product development. Moreover, given the emphasis placed on project management reference documents (project charter, project planning, cost structure, etc.) and the need to ensure that they are adhered to throughout development, the Systematic approach tends to be perceived as rigid and unsuited to rapid changes in the environment and evolving requirements (Guérineau et al., 2016). These limitations have motivated researchers to explore other product development approaches, including Agile.

2.2 Agile development for medical technologies

Sometimes perceived as an antagonist to the systematic product development approach introduced above, the Agile approach can be outlined by the Agile Manifesto based on four values and twelve principles (Beck et al., 2001). The Agile approach is operationalized through different Agile processes that were initially proposed for software development, such as Scrum, Extreme programming (XP), Feature-driven development (FDD), Crystal, or more recently DevOps. Among its major benefits, the Agile approach aims to reduce development costs and time, improve code quality and accommodate changing requirements (Nyirenda et al., 2023). Given these advantages, researchers have explored its application to MedTech, as discussed in the next paragraphs.

As observed by Slattery et al. (2022), "most of the literature concerning Agile product development in the medical device field relates to medical device software, with no major work concerning physical medical devices". Among the few works identified for "physical medical devices", Goevert et al. (2019) propose an adapted Scrum process exemplified on microtiter plate, a low-risk lab equipment. The proposed Scrum process is organized within a four-phase framework and includes risk and requirements management. The addition of risk and requirements management is also included in the Scrum process for medical device software proposed by Zamith and Gonçalves (2018). Taking the adaptation one step

further, the Scrum process of Zamith and Gonçalves (2018) formalizes safety classification and incorporates traceability elements, including software architecture, development plan, requirements, configuration items list, and formalized "non-conformance" reporting by an independent quality assurance team. These additional elements are expressly added to comply with regulations and audits in the context of certifiable medical device software. Finally, also relying on Scrum elements, Schidek and Timinger (2022) introduce a five-phase process model with a stronger emphasis on verification, validation and change control than the previous two Scrum adaptations. Their proposed process model aims at being used in both software and hardware developments. In addition to Scrum-based process models, research focused on FDD, XP and DevOps for medical device software, mainly through extensions or adaptations, also deserves mention (Alsaadi et al., 2019; Lie et al., 2020; Mehrfard et al., 2010).

As with the systematic development processes, most work introduced in the previous paragraph conducted adaptations which aim at a better fit with the specificities of the MedTech industry. One common observation among the different research on Agile for MedTech is that Agile might not be suitable "as-is", but require some tailoring and adaptation, mostly to comply with the strong regulations and certification process (Cawley et al., 2010; Nyirenda et al., 2023). This is emphasized by Schidek and Timinger (2022), who state that "it could be demonstrated that regulatory requirements and agility do not automatically have to exclude each other, but that a compatibility is definitely possible through certain adaptations". The adapted Scrum processes described in the previous paragraph tend to address these gaps but would require a further application in the industry.

To some extent, adaptations can be regarded as being closer to hybridization with other approaches and process models, an aspect that will be examined in more detail in section 2.7. Some hybridizations are conducted in pairs with Lean product development, an approach introduced in the next section.

2.3 Lean product development for medical technologies

The Lean approach is best known by companies through "Lean manufacturing", which focuses on streamlining operations on the shop floor. However, it has also made inroads in product development, with a focus on decreasing costs and shortening the time to market (Anderson et al., 2011; Davis, 2012). Lean product and process development, as defined by Liker and Morgan (2006), is a set of thirteen principles organized among people, process, tools and technology. In a nutshell, Lean focuses on customers and delivering value to them, while eliminating potential sources of waste.

Unlike the literature on Lean manufacturing, there seems to be a limited body of scientific literature on the application of Lean to the development of MedTech (Davis, 2012; Slattery et al., 2022). The application of Lean product development has been used to re-engineer the implemented process model with an emphasis on cost and time-to-market reduction. In the literature, this application of Lean in MedTech development is mostly presented through the usage of "tools and techniques" to improve product development. Examples of such "tools and techniques" implemented by researchers are Kaizen, Oobeya rooms, Value Stream mapping, "Artwork", and "Hansei" (Anderson et al., 2011; Davis, 2012; Slattery et al., 2022). For instance, in Slattery et al. (2022), Lean "tools and techniques" are applied to improve CE and stage-gate processes which are still commonly used, as mentioned previously.

In the context of this article, the development of smart MedTech is of particular interest, and is acknowledged for its complexity. By contrasting Salgado and Deckers' study with McManus' book, Slattery et al. (2022) raise the question of whether the application of Lean to complex product development is truly relevant. By the same token, the question of exploiting the full potential of Lean product development in the MedTech field must be asked in light of the multiple activities required to comply with regulations, including, for example, FDA and European Union constraints, and clinical trials (Anderson et al., 2011).

After reviewing the distinct applications of Lean and Agile to MedTech, the next section explores the "Lean Startup" approach at the convergence of Lean and Agile approaches (Ries, 2011).

2.4 Lean Startup for medical technologies

Lean Startup emphasizes a three-step process - build, measure, learn - coupled with the concept of a "minimum viable product" (MVP) and the ability to "pivot". In essence, an MVP is a version of a product that focuses on core features in order to quickly test assumptions with the "minimum amount of effort and the least amount of development time" (Ries, 2011). Lean Startup combines the iterative and incremental aspects of Agile, with a focus on cost minimization and bringing value to the customer from Lean. This approach seemed to have resonated within the startup community and has been adopted as a quick way to test ideas.

The application of Lean Startup to the development of MedTech has been explored in practice by de Jong (2015), who points out that the application of Lean Startup appeared as suitable despite being harder to apply when compared to other industries. Indeed, the MedTech sector is "complex, […], highly regulated, […], capital intensive, and has a long time-to-market" (de Jong, 2015).

Lean Startup can be a valuable approach in the early phases of product development as a way to explore different solutions, refine them and converge towards a "product/market fit" and a viable business model. However, it is not intended to support the detailed design phase. Another potential limitation to applying Lean Startup to the MedTech industry lies in the regulatory aspects. As pointed out in Hansen and Özkil's study (2020), one particularity of the MedTech sector is the need for validation before anything can be tested with humans. The validation process "is often long and expensive, so as soon as a product has been validated, the companies are reluctant to change the product, because it will have to be validated again" (Hansen and Özkil, 2020). Similar observations were brought up by de Jong (2015).

Another way of supporting the early phases of product development is through the use of Design thinking, discussed next in combination with user-centred design.

2.5 Design thinking and user-centred design for medical technologies

Design thinking shares some similarities with Lean Startup in their design approaches (Arandia et al., 2023). Both involve iterative processes focused on defining, prototyping and testing with users in order to collect real-world data and make decisions, which can be perceived as "business-oriented" decisions for Lean Startup and "design-oriented" decisions for Design thinking.

Design thinking can be described in short as "a user-centered approach to development and problem solving" (Mejtoft et al., 2022). The use of a user-centred design (UCD) method in the MedTech industry has been partly motivated by safety considerations (Martin et al., 2012). For instance, there have been examples of "bad designs" in the MedTech industry leading to device misuse. One of the several documented cases is self-injectors, but there are also examples involving software interfaces (Pillalamarri et al., 2018; Shariat and Savard Saucier, 2017). This is where Design thinking, and more broadly UCD and assimilated practices, come into play. By involving end users early in the development process through the use of different methods and tools, Design thinking and UCD aim to design safe MedTech that meets actual users' needs (Martin et al., 2012). Although Design thinking might add cost and time to the development, it fosters design changes when the cost of change is still contained, while increasing the end solution usability and acceptance through prototyping and testing (Fisher and Johansen, 2020). In terms of application, various studies have exemplified Design thinking and UCD on a wide range of MedTech and have reported "positive outcomes" (Oliveira et al., 2020). Through their systematic study, Oliveira et al. (2020) identified the "most common practices" of Design thinking, while also identifying their limitations, some of which are discussed in the next paragraph.

Although Design thinking and UCD seem to have demonstrated their potential for the development of MedTech, some limitations remain. Some are intrinsic to the processes and techniques involved, while others are extrinsic to them and instead are dependent upon industry practices and customs. Among the extrinsic limitations, Money et al. (2011) identified that manufacturers tend to base their design decisions on "individuals that will be most influential in making purchasing decisions for their products", relegating the patient to a second-class position. In line with this aspect, one particularity of MedTech development resides in the number and variety of stakeholders. It might be important to define each of them and their role around the product before applying UCD or Design thinking. In some cases, identifying the "main" end user can be challenging, on top of the divergence of concerns and the difficulty to align them in between patients and practitioners (Andersen, 2019; Money et al., 2011; Oliveira et al., 2020). Among the consequences, "ill-targeted or wrongly applied user centrism may also delay or threaten the outcome of a product development process" (Kuhl et al., 2020). Finally, an intrinsic limitation of Design thinking could be its lack of emphasis on regulatory requirements, leading Arandia et al. (2023) to question its use for the development of MedTech. As with the Agile approach, one way of overcoming this limitation would be to combine Design thinking with a synergistic approach. Menshenin et al. (2023a), for instance, explore its combination with Systems engineering, an approach described in the next section.

2.6 Systems engineering and model-based systems engineering for medical technologies

Systems engineering (SE) is often defined as an interdisciplinary approach, partly based on systems thinking, "a way of thinking that enables better understanding and designing of complex phenomena" (Haberfellner et al., 2019; INCOSE, 2015). Although it has a certain "plan-driven" aspect, SE is distinguished here from the Systematic approach by a greater emphasis on the systemic aspect, which can be reflected in the implemented processes and methods. Given that perspective, the operationalization of the SE approach is often implemented in pairs with V-model and model-based systems engineering (MBSE) practices (Guérineau et al., 2022). This scheme is adopted by Mishra and Behdinan (2023) to contextualize their research on multidisciplinary design optimization for "medical mechatronic products". Other works identified in the literature focus in particular on SE or MBSE, which are discussed in the next paragraph.

Application of SE to MedTech development has been explored by a handful of researchers (Coe, 2019; Menshenin et al., 2023b). Similar to the use of UCD, the increasing number of safety issues and reporting of tragic incidents in patient care involving medical device software motivated Fu (2011) to advocate the use of "modern software engineering and systems engineering practices". In a similar perspective, pursuing "built-in safety from the beginning", Malins et al. (2015) illustrated through activity diagrams how ISO-14971 – Risk management for medical devices – can be integrated within

the technical processes and systems life-cycle of ISO-15288 – Systems and software engineering. Therefore, in addition to complexity, the use of SE in the MedTech industry is driven by the imperative of ensuring safety and compliance with regulatory bodies. At a lower level, these aspects can be supported by MBSE (Haberfellner et al., 2019; INCOSE, 2007). Applied to MedTech development, MBSE can, for example, help with bidirectional traceability between successive models, from requirements to the detailed design and validation contributing to building the design history file (Mishra and Behdinan, 2023). In a similar vein, Corns and Gibson (2012) demonstrate in part how MBSE can be implemented and benefit MedTech development using SysML static diagrams.

SE strengths can be appreciated when dealing with complex problems in a regulated environment with multiple stakeholders and safety-critical concerns, such as those encountered in the MedTech industry. Criticisms of SE usually lie in its perception as being "heavyweight" and therefore opposed to the Agile approach. Because of the "plan-driven" aspects, it can be perceived as rigid and not capable of adapting to changing requirements, a point that has been partially addressed in the revision of the VDI-2206 standard and its V-model (Graessler and Hentze, 2020). In an effort to overcome some of its limitations, SE has also been considered in the context of hybridization, discussed in the following section.

2.7 Hybrid approaches and processes for medical technologies

In the context of this article, hybridization is about combining two (or more) approaches or processes to achieve a higher level of performance in product development. The resulting value is expected to be much higher than if each were utilized separately (Arandia et al., 2023; Guérineau et al., 2022).

As seen in section 2.2, a potential research direction for bridging the gaps between Agile and regulatory bodies' requirements could be its hybridization with other approaches, mostly envisioned through the systematic approach and process models (Alsaadi et al., 2019; Cawley et al., 2010; Karrenbauer et al., 2019). Examples of Agile hybridizations include the integration of Scrum within the Waterfall model (Schidek and Timinger, 2021), and variants of the Agile-V-model (Arandia et al., 2023; Mc Hugh et al., 2013).

Agile has also been combined with Lean for the development of MedTech in work by Glazkova et al. (2019). This hybridization was further refined in their subsequent article with the formalization of the sprints and the Lean principles employed, as well as the addition of CE elements to the proposed framework (Glazkova et al., 2022). The latter is structured around six sequential phases, supported throughout by the Quality management system (QMS). The phases of "planning", "design concept", "design & development" and "pre-production" are based on sprint adaptations, while part of the "pre-production", "design transfer" and "production" phases rely on CE. Lean principles mainly focus on long-term knowledge gain, traceability and improved communication. The latter is also fostered by the "Scrum ceremonies", the "joint design sessions", as well as by "systems engineering methods for interface management and integration" (Glazkova et al., 2022). SE has also been considered for hybridization, one of which is discussed below.

Like Agile and Systematic approaches, SE and Design thinking can initially be perceived as being opposed to each other. SE is described as a "systematic and analytic problem-centric approach", while Design thinking is presented as "a creative and emphatic solution-centric approach" (Menshenin et al., 2023a). Expanding on prior research, Menshenin et al. (2023a) demonstrate the potential value of their combination and propose an SE-based framework for MedTech development that integrates elements from SE, Design thinking and Agile. Design thinking is mainly implemented through methods and tools that are mapped to SE activities. The proposed framework enables different solutions to be explored during the early phases of development, while relying on a systemic approach that acts as the backbone throughout the development process.

After having reviewed six distinct product development approaches and processes and their hybridizations for MedTech development, the next section focuses on the opportunities to explore new approaches and processes.

3 Medical technology development: opportunities to explore new approaches and processes

The previous section has presented six existing approaches and processes identified from the scientific literature, providing an overview of product development for MedTech. From the corpus analyzed, two main observations stand out, which are discussed in the following paragraphs.

First, the research on the development of smart MedTech, which combines hardware and software components, is relatively new and explores diverse approaches (Coe, 2019; Glazkova et al., 2022, 2019; Mishra and Behdinan, 2023; Schidek and Timinger, 2021). For instance, Mishra and Behdinan (2023) and Coe (2019) propose the use of an SE-based approach, while Glazkova et al. (2022, 2019) explore the Lean-Agile combination. Schidek and Timinger (2021) focus their research on the hybridization between Scrum and Waterfall. This divergence in the proposed approaches is an opportunity to expand research on smart MedTech development.

The second observation is that an important part of these process models has been adapted to comply with the regulated environment. This highly regulated environment is one of the hallmarks of MedTech development and ensures the efficiency and safety of such products. Device classification plays a pivotal role in the regulations and is an indicator of the level of risk for users. The higher the risk level, the more stringent the regulatory requirements on the development process (Santos et al., 2012; Tsai et al., 2023). For example, the manufacturers of Class II and Class III devices are obliged to implement and sustain procedures "to ensure that specified design requirements are met" (FDA, 1997). These procedures address a wide range of development activities and documents, including design and development planning, design input, design output, design review, design verification, design validation, design transfer, design changes, and the design history file. As a result, "generic" process models need to be adapted to comply with the regulatory bodies' requirements, as well as with the MedTech sector specificities, some of which were briefly presented in the introduction. Various researchers have pointed out the need for specific approaches and processes for the development of MedTech (Menshenin et al., 2023a, 2023b; Santos et al., 2012; Slattery et al., 2022). Hybridization is one way to achieve this.

Both observations invite researchers to explore approaches and processes adapted to the specificities of smart MedTech. A research direction is introduced in the next section, exploring Agile and SE hybridization, two approaches discussed extensively in the literature for multidisciplinary products.

4 Agile Systems engineering for medical technologies development

An excerpt from Zamith and Gonçalves (2018) particularly resonates with our intention where "the ultimate goal should be to find a development model able to comply with regulations and standards, but also provides enough flexibility and ability to react to change". The first part of the sentence could be supported by an SE – or Systematic – approach, while the second part, seeking flexibility, would refer to Agile, leading to the idea of exploring the hybridization between Agile and SE.

Part of the rationale for implementing SE and Agile over other approaches also resides in the fact that smart MedTech can be abstracted as "multidisciplinary products" – as discussed in the introduction – opening up a wider corpus of literature. In fact, SE and Agile have been the subject of extensive research in this field (Guérineau et al., 2022), as has their hybridization (Mabrouk et al., 2018; Mule et al., 2020). Hybridization of SE and Agile is not new and has been the subject of a number of studies (Stelzmann, 2012), but seems to have received only limited attention in the context of MedTech (Karrenbauer et al., 2019). That lacuna is the stimulus for a proposed research direction exploring the hybridization of SE and Agile for the development of smart MedTech, as explained next.

4.1 Agile Systems engineering hybridization: a continuum

The hybridization of Agile and SE can take various forms. One way of representing these possibilities would be along a continuum with SE approach on one end, Agile on the other, and the different possibilities of their hybridization in-between. One half would encompass predominantly SE-based hybridizations, whereas the other half would be predominantly Agile-based hybridizations. In the middle there could be a theoretical 50/50 Agile-SE hybrid approach. In more concrete terms, the "predominantly SE-based" side could contain process models such as the V-model-Scrum, integrating Scrum in a V-model, while the "opposite" could be described as a Scrum-V-model, with mini-Vs within each sprint. These two process models have been discussed by Karrenbauer et al. (2019) and are part of their two strategies proposed for MedTech development.

Along that continuum, the hybridization that could be best suited for a smart MedTech would need to be identified. In the context of this article, the research intention is driven by finding a balance between compliance with regulatory bodies and flexibility in order to cope with external changes. Multiple factors come into play, including technical and organizational complexity, multiple stakeholders, required traceability, and a strong focus on requirements management. As discussed in the last paragraph of section 2.6, SE can be a good fit for the development of smart MedTech. The combination of systems thinking, the decomposition-integration principle, and system modelling implemented through MBSE helps to tackle the increasing product development complexity. In addition, SE is in line with the factors listed above, gearing the hybridization towards a predominantly SE-based approach. Regarding the process model, Mc Hugh et al. (2013) presented several arguments in favour of the V-model. These include its compliance with regulatory requirements, and its ability to support traceability, verification, and validation. Although the V-model may be perceived as inflexible and unsuitable for accommodating evolving requirements, the new VDI-2206 partially addresses these limitations (see section 2.6). Additionally, when combined with Scrum, these limitations can be further mitigated. As a result, the proposed hybridization explores the combination of SE and Agile through a V-model-Scrum process model, which is explained in the following section.

4.2 Agile Systems engineering for the development of medical technology: V-model-Scrum

As discussed in the previous section, different hybridizations of Agile Systems engineering exist along a continuum. In the context of smart MedTech, an Agile-SE approach operationalized by a V-model-Scrum process is proposed. Depicted in Figure 1, this V-model-Scrum process is presented in detail below.

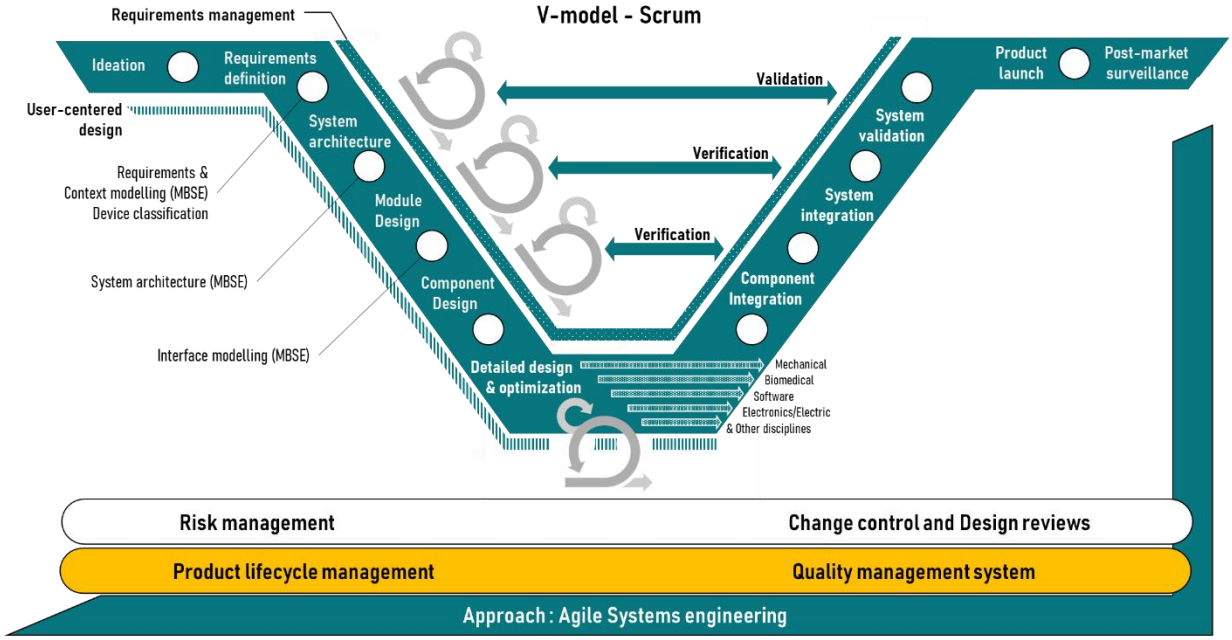

Figure 1. Proposal of a V-model-Scrum process to support the development of smart medical technologies

From left to right, the V-model-Scrum starts with an ideation phase. This pre-development phase can be conducted using innovation-oriented practices including Design thinking or the Lean Startup approach to quickly iterate and determine the product concepts that will be investigated during the development phase. The development phase starts with the requirements definition, during which the requirements and context are modelled. Context modelling can be used as a checklist to feed the requirements, and includes, for instance, identifying stakeholders, regulatory agencies, reimbursement procedures, existing intellectual property, and relevant standards. In addition, the device classification and an associated certification strategy should be established at this step. This is also where the V-model-Scrum begins to differ from a traditional V-model by leveraging Scrum, and more specifically its sprint-based structure, to lead the decomposition. A set of high-level requirements constitute a first sprint backlog leading to an initial system architecture. Once the system architecture is "mature" enough, the subsequent sprint backlog for the module design can be established and the sprint can begin. In turn, when a module is released and the interfaces are fixed, the succeeding sprints can begin for the component design. Concurrently, the second sprint for the system architecture begins with a sprint backlog that includes a lower-level set of requirements, leading to a new increment of the system architecture. This increment's results feed into the subsequent module design sprint to be refined, and so on.

This sprint-based decomposition enables a certain flexibility in requirements management. The latter, adopted from the new VDI-2206 standard, is integrated throughout the development process. Complementarily, MBSE is utilized to support the modelling steps on the downward side of the V-model and is "an indispensable prerequisite for the use of Agile concepts" (Haberfellner et al., 2019). MBSE enables traceability between the different models, which in turn can help to assess the impact of a change in requirements and in its implementation.

On the lower part of the V-model, the detailed design and optimization step focuses on physical models and simulations of the different components. Mechanical, biomedical, software, electronics and electric developments are running concurrently, in an incremental and iterative manner driven by successive sprints. The sprints can be conducted using cross-functional teams to ease communication and solve problems as they arise. Conversely, if there are separate teams for each discipline, shorter sprints should be preferred to improve the communication. In parallel, from the ideation phase to the detailed design and optimization step, UCD is implemented as a way to integrate feedback from users to maximize the adoption, usability and safety of the final solution.

The ascending side of the V-model-Scrum adopts the steps of traditional V-models, namely unit testing and integration, as well as verification and validation. Finally, the process model is extended to include product launch and post-market surveillance, thereby considering pre-development, development, and post-development phases.

The lower part of Figure 1 mentions the risk management process (*e.g.*, ISO-14971), as well as change control and design review procedures. A Product lifecycle management (PLM) system and a QMS are also included. The PLM system focuses on the management of technical data, records and their traceability, enabling the creation and updating of the design history file. Complementarily, the QMS supports the quality assurance and documents all the procedures required by regulatory bodies throughout the development process.

5 Discussion and research perspectives

The proposed research direction is a preliminary work on the joint application of SE and Agile approaches to smart MedTech. Investigating a predominantly SE-based hybridization is in line with recent research advocating the use of SE to support the development of MedTech (Menshenin et al., 2023a; Mishra and Behdinan, 2023), along with research on the integration of Agile in regulated environments (Haberfellner et al., 2019; Karrenbauer et al., 2019). Although the research leverages literature on MedTech and multidisciplinary product development, the process model faces unique limitations that could be addressed by the following research perspectives.

A likely next step would be to refine the high-level process and specify each step for the different disciplines and expertise gravitating around such a development, aiming to reach a similar level of detail as the process model of Pietzsch et al. (2009). This refinement could be conducted through interviews and workshops with different experts from the MedTech sector. Once a higher level of detail is achieved, the process model could be exemplified in a "lab" setting before being implemented in industrial case studies. A parallel research direction would investigate the selection process alongside the Agile-SE hybridization continuum to explore other possibilities, such as a predominantly Agile hybrid approach, or other process models, including a Scrum-based process with "mini-Vs" (Karrenbauer et al., 2019). A selection process would be able to address the wide variety of products in the MedTech sector from low to high risk and subsequently tailor a corresponding process. Finally, the research domain of smart MedTech development is still relatively new and would benefit from the knowledge transfer of adjacent research, including research in other highly regulated fields.

6 Conclusion

Healthcare systems across the globe are facing numerous challenges, and smart MedTech may be part of the solution. The Covid-19 pandemic further highlighted the critical importance for countries to develop and maintain sovereignty in the development of MedTech with a degree of autonomy and responsiveness. The proposed research is positioned in this perspective and aims to support the development of smart MedTech from a methodological standpoint. This heavily-regulated field strongly constrains the development process which requires multiple adaptations. This paper contributes to the existing knowledge by reviewing six current approaches and processes for MedTech before exploring the hybridization of Agile-SE. An adapted V-model-Scrum process model is suggested for operationalization, supported by different practices such as MBSE or UCD. This preliminary work lays the groundwork for future research directions in the field of smart MedTech development.

References

Alsaadi, M., Lisitsa, A., Khalaf, M., Qasaimeh, M., 2019. Investigating the Capability of Agile Processes to Support Medical Devices Regulations: The Case of XP, Scrum, and FDD with EU MDR Regulations, in: D.-S. Huang et al. (Eds.), Lecture Notes in Computer Science. Springer International Publishing, pp. 581–592. doi:10.1007/978-3-030-26766-7_53

Andersen, T.O., 2019. Large-scale and long-term co-design of digital health. Interactions 26, 74–77. doi:10.1145/3356252

Anderson, K.M., Grasman, S.E., Ayoub, K., Introne, S., Smithwick, K., 2011. Using lean product development to speed time to market for medical devices. 61st Annu. IIE Conf. Expo Proc. 1–7.

Arandia, N., Garate, J.I., Mabe, J., 2023. Medical Devices with Embedded Sensor Systems: Design and Development Methodology for Start-Ups. Sensors 23, 2578. doi:10.3390/s23052578

Beck, K., Beedle, M., Van Bennekum, A., Cockburn, A., Cunningham, W., Fowler, M., Grenning, J., Highsmith, J., Hunt, A., Jeffries, R., Kern, J., Marick, B., Martin, R.C., Mellor, S., Schwaber, K., Sutherland, J., Thomas, D., 2001. Agile Manifesto http://agilemanifesto.org/iso/fr/principles.html (accessed 2.12.24).

Cawley, O., Wang, X., Richardson, I., 2010. Lean/Agile Software Development Methodologies in Regulated Environments – State of the Art, in: Abrahamsson, P., Oza, N. (Eds.), Lecture Notes in Business Information Processing. Springer Verlag Berlin, pp. 31–36. doi:10.1007/978-3-642-16416-3_4

Chen, C., Ding, S., Wang, J., 2023. Digital health for aging populations. Nat. Med. 29, 1623–1630. doi:10.1038/s41591-023-02391-8

Coe, M., 2019. Robust Systems engineering for medical device design.

Cooper, R.G., 2011. Winning at New Products: Creating Value Through Innovation, 4th ed. Basic Books.

Corns, S., Gibson, C., 2012. A model-based reference architecture for medical device development. 22nd Annu. Int. Symp. Int. Counc. Syst. Eng. INCOSE 2012 8th Bienn. Eur. Syst. Eng. Conf. 2012, EuSEC 2012 4, 2731–2740. doi:10.1002/j.2334-5837.2012.tb01457.x

Davey, S.M., Brennan, M., Meenana, B.J., McAdam, R., 2011. Innovation in the medical device sector: An open business model approach for high-tech small firms. Technol. Anal. Strateg. Manag. 23, 807–824. doi:10.1080/09537325.2011.604152

Davis, K.M., 2012. Decreasing time to market for a medical device: New methods for the product development process. Missouri University of Science and Technology.

de Jong, J., 2015. Scientific Entrepreneurship in the Medical Technology Sector. Universiteit Utrecht.
Dunn, J., Runge, R., Snyder, M., 2018. Wearables and the medical revolution. Per. Med. 15, 429–448. doi:10.2217/pme-2018-0044
Eatock, J., Dixon, D., Young, T., 2009. An exploratory survey of current practice in the medical device industry. J. Manuf. Technol. Manag. 20, 218–234. doi:10.1108/17410380910929637
FDA Center for Devices and Radiological Health, 1997. Design control guidance for medical device manufacturers.
Fisher, M., Johansen, E., 2020. Human-centered design for medical devices and diagnostics in global health. Glob. Heal. Innov. 3, 1–15. doi:10.15641/ghi.v3i1.762
Flores, M., Glusman, G., Brogaard, K., Price, N.D., Hood, L., 2013. P4 medicine: How systems medicine will transform the healthcare sector and society. Per. Med. 10, 565–576. doi:10.2217/pme.13.57
Fu, K., 2011. Trustworthy Medical Device Software, in: Wizemann, T. (Ed.), Public Health Effectiveness of the FDA 510(k) Clearance Process: Measuring Postmarket Performance and Other Select Topics: Workshop Report. National Academies Press.
Glazkova, N., Fortin, C., Podladchikova, T., 2019. Application of lean-agile approach for medical wearable device development. 2019 14th Annu. Conf. Syst. Syst. Eng. SoSE 2019 75–80. doi:10.1109/SYSOSE.2019.8753825
Glazkova, N., Menshenin, Y., Vasilev, D., Fortin, C., 2022. MedTech Product Development Framework for Post-Pandemic Era. Proc. Des. Soc. 2, 1273–1282. doi:10.1017/pds.2022.129
Goevert, K., Schweigert-Recksiek, S., Tariq, B., Krischer, L., Lindemann, U., 2019. Agile development of a microtiter plate in an interdisciplinary project team. Proc. Int. Conf. Eng. Des. ICED 2019-Augus, 2139–2148. doi:10.1017/dsi.2019.220
Graessler, I., Hentze, J., 2020. The new V-Model of VDI 2206 and its validation. At-Automatisierungstechnik 68, 312–324. doi:10.1515/auto-2020-0015
Guérineau, B., Rivest, L., Bricogne, M., Durupt, A., 2016. Agile and Project-Planned Methods in Multidisciplinary Product Design, 13th IFIP International Conference on Product Lifecycle Management - PLM16. Columbia, SC, USA, pp. 108–118. doi:10.1007/978-3-319-54660-5_11
Guérineau, B., Rivest, L., Bricogne, M., Durupt, A., Eynard, B., 2018. Towards a Design-Method Selection Framework for Multidisciplinary Product Development, DESIGN CONFERENCE 2018. pp. 2879–2890.
Guérineau, J., Bricogne, M., Rivest, L., Durupt, A., 2022. Organizing the fragmented landscape of multidisciplinary product development: a mapping of approaches, processes, methods and tools from the scientific literature. Res. Eng. Des. 33, 307–349. doi:10.1007/s00163-022-00389-w
Haberfellner, R., de Weck, O., Fricke, E., Vössner, S., 2019. Systems Engineering. Springer International Publishing, Cham. doi:10.1007/978-3-030-13431-0
Hansen, C.A., Özkil, A.G., 2020. "You cannot test it before it is verified. when it is verified you cannot change it": prototyping challenges in industry, International Design Engineering Technical Conferences and Computers and Information in Engineering Conference IDETC/CIE2020. ASME, pp. 1–10.
Hood, L., Friend, S.H., 2011. Predictive, personalized, preventive, participatory (P4) cancer medicine. Nat. Rev. Clin. Oncol. 8, 184–187. doi:10.1038/nrclinonc.2010.227
INCOSE, 2015. Systems engineering handbook : a guide for system life cycle processes and activities, 4th ed. John Wiley & Sons, San Diego, USA.
INCOSE, 2007. Systems Engineering Vision 2020. San Diego, CA.
Karen, T., Mark, S., Amen, S., Matthew, T., 2018. Medtech and the Internet of Medical Things - How connected medical devices are transforming health care. Deloitte Cent. Heal. Solut.
Karrenbauer, J., Wiesche, M., Krcmar, H., 2019. Understanding the Benefits of Agile Software Development in Regulated Environments. Proccedings 14th Int. Conf. Wirtschaftsinformatik 832–846.
Kashani, K.B., Awdishu, L., Bagshaw, S.M., Barreto, E.F., Claure-Del Granado, R., Evans, B.J., Forni, L.G., Ghosh, E., Goldstein, S.L., Kane-Gill, S.L., Koola, J., Koyner, J.L., Liu, M., Murugan, R., Nadkarni, G.N., Neyra, J.A., Ninan, J., Ostermann, M., Pannu, N., Rashidi, P., Ronco, C., Rosner, M.H., Selby, N.M., Shickel, B., Singh, K., Soranno, D.E., Sutherland, S.M., Bihorac, A., Mehta, R.L., 2023. Digital health and acute kidney injury: consensus report of the 27th Acute Disease Quality Initiative workgroup. Nat. Rev. Nephrol. 19, 807–818. doi:10.1038/s41581-023-00744-7
Koivukangas, T., Lukkari, J., Haapola, J., Kohno, R., 2015. Streamlining medical device design development process from research laboratory to the market, International Symposium on Medical Information and Communication Technology, ISMICT. IEEE, pp. 98–102. doi:10.1109/ISMICT.2015.7107506
Kuhl, J., Sankowski, O., Krause, D., 2020. Investigation on methods and characteristics in medical device development. Proc. Des. Soc. Des. Conf. 1, 1969–1978. doi:10.1017/dsd.2020.95
Lie, M.F., Sanchez-Gordon, M., Colomo-Palacios, R., 2020. DevOps in an ISO 13485 regulated environment: A multivocal literature review, International Symposium on Empirical Software Engineering and Measurement. doi:10.1145/3382494.3410679
Liker, J.K., Morgan, J.M., 2006. The Toyota Way in Services: The Case of Lean Product Development. Acad. Manag. Perspect. 20, 5–20. doi:10.5465/AMP.2006.20591002
Lucke, L.E., Mickelson, A., Anderson, D., 2009. Proving experience speeds medical device time to market. Proc. 31st Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. Eng. Futur. Biomed. EMBC 2009 7057–7060. doi:10.1109/IEMBS.2009.5333371
Mabrouk, A., Penas, O., Plateaux, R., Barkallah, M., Choley, J.Y., Akrout, A., 2018. Integration of agility in a MBSE methodology for multidisciplinary systems design. 4th IEEE Int. Symp. Syst. Eng. ISSE 2018 - Proc. 1–5. doi:10.1109/SysEng.2018.8544425
Malins, R.J., Stein, J., Thukral, A., Waterplas, C., 2015. SysML Activity Models for Applying ISO 14971 Medical Device Risk and Safety Management Across the System Lifecycle, INCOSE International Symposium. pp. 489–507. doi:10.1002/j.2334-5837.2015.00077.x
Martin, J.L., Clark, D.J., Morgan, S.P., Crowe, J.A., Murphy, E., 2012. A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective. Appl. Ergon. 43, 184–190. doi:10.1016/j.apergo.2011.05.002
Mc Hugh, M., Cawley, O., McCaffcry, F., Richardson, I., Wang, X., 2013. An agile V-model for medical device software development to overcome the challenges with plan-driven software development lifecycles. 2013 5th Int. Work. Softw. Eng. Heal. Care, SEHC 2013 - Proc. 12–19. doi:10.1109/SEHC.2013.6602471

McCaffery, F., Trektere, K., Ozcan-Top, O., 2016. Agile – is it suitable for medical device software development?, Communications in Computer and Information Science. pp. 417–422. doi:10.1007/978-3-319-38980-6_30

Mehrfard, H., Pirzadeh, H., Hamou-Lhadj, A., 2010. Investigating the Capability of Agile Processes to Support Life-Science Regulations: The Case of XP and FDA Regulations with a Focus on Human Factor Requirements, Studies in Computational Intelligence. pp. 241–255. doi:10.1007/978-3-642-13273-5_16

Mejtoft, T., Lindahl, O., Öhberg, F., Pommer, L., Jonzén, K., Andersson, B.M., Eklund, A., Wåhlin, A., Hallberg, P., 2022. Medtech innovation guide: an empiric model to support medical technology innovation. Health Technol. (Berl). 911–922. doi:10.1007/s12553-022-00689-0

Menshenin, Y., Pinquié, R., Chevrier, P., 2023a. New Product Development Process for Medtech Combination Products. Proc. Des. Soc. 3, 2795–2804. doi:10.1017/pds.2023.280

Menshenin, Y., Pinquié, R., Chevrier, P., 2023b. Defining a New Role of System Architect at the Product Strategy Stage of a MedTech Product Development Through the DSM-Based Method, in: 25th International Dependency and Structure Modeling Conference. pp. 116–122.

Mishra, S.R., Behdinan, K., 2023. Multidisciplinary Design Analysis and Optimization Framework for Regulatory Driven Medical Device Development. Proc. Des. Soc. 3, 2735–2744. doi:10.1017/pds.2023.274

Money, A.G., Barnett, J., Kuljis, J., Craven, M.P., Martin, J.L., Young, T., 2011. The role of the user within the medical device design and development process: medical device manufacturers' perspectives. BMC Med. Inform. Decis. Mak. 11, 1–15. doi:10.1186/1472-6947-11-15

Mule, S., Plateaux, R., Hehenberger, P., Penas, O., Patalano, S., Vitolo, F., 2020. A New Agile Hybridization Approach and a Set of Related Guidelines for Mechatronic Product Development, in: Nyffenegger, F., Ríos, J., Rivest, L., Bouras, A. (Eds.), Product Lifecycle Management Enabling Smart X. 17th IFIP WG 5.1 International Conference, PLM 2020. Springer, pp. 618–633. doi:10.1007/978-3-030-62807-9_49

Nyirenda, M., Loughran, R., McHugh, M., Nugent, C., McCaffery, F., 2023. Identifying Agile Practices to Reduce Defects in Medical Device Software Development, in: M. Yilmaz et al. (Ed.), Communications in Computer and Information Science. Springer Nature Switzerland, pp. 61–75. doi:10.1007/978-3-031-42310-9_5

Ocampo, J.U., Kaminski, P.C., 2019. Medical device development, from technical design to integrated product development. J. Med. Eng. Technol. 43, 287–304. doi:10.1080/03091902.2019.1653393

Oliveira, M., Zancul, E., Fleury, A.L., 2020. Design thinking as an approach for innovation in healthcare: systematic review and research avenues. BMJ Innov. 7, 491–498. doi:10.1136/bmjinnov-2020-000428

Pahl, G., Beitz, W., Feldhusen, J., Grote, K.-H., 2007. Engineering Design: A Systematic Approach. Springer London, London. doi:10.1007/978-1-84628-319-2

Pietzsch, J.B., Shluzas, L.A., Paté-Cornell, M.E., Yock, P.G., Linehan, J.H., 2009. Stage-gate process for the development of medical devices. J. Med. Devices, Trans. ASME 3. doi:10.1115/1.3148836

Pillalamarri, S.S., Huyett, L.M., Abdel-Malek, A., 2018. Novel Bluetooth-Enabled Tubeless Insulin Pump: A User Experience Design Approach for a Connected Digital Diabetes Management Platform. J. Diabetes Sci. Technol. 12, 1132–1142. doi:10.1177/1932296818804802

Ries, E., 2011. The Lean Startup. Crown Business, New York, USA.

Royce, W.W., 1970. Managing the development of large software systems. IEEE WESCON 1–9.

Ryan, B.L., Bray Jenkyn, K., Shariff, S.Z., Allen, B., Glazier, R.H., Zwarenstein, M., Fortin, M., Stewart, M., 2018. Beyond the grey tsunami: a cross-sectional population-based study of multimorbidity in Ontario. Can. J. Public Heal. 109, 845–854. doi:10.17269/s41997-018-0103-0

Santos, I.C., Gazelle, G.S., Rocha, L.A., Tavares, J.M.R.S., 2012. Medical device specificities: Opportunities for a dedicated product development methodology. Expert Rev. Med. Devices 9, 299–311. doi:10.1586/erd.12.3

Schidek, A., Timinger, H., 2022. Agilization of technical development processes for medical devices, 2022 IEEE 28th International Conference on Engineering, Technology and Innovation, ICE/ITMC 2022 and 31st International Association for Management of Technology, IAMOT 2022 Joint Conference - Proceedings. IEEE, pp. 1–9. doi:10.1109/ICE/ITMC-IAMOT55089.2022.10033297

Schidek, A., Timinger, H., 2021. Flexible Product Innovation Cycles for Smart Medical Devices, in: 2021 IEEE 6th International Forum on Research and Technology for Society and Industry (RTSI). IEEE, pp. 546–551. doi:10.1109/RTSI50628.2021.9597243

Shariat, J., Savard Saucier, C., 2017. Tragic Design: The Impact of Bad Product Design and How to Fix It. O'Reilly Media.

Shluzas, L.A., Pietzsch, J.B., Paté-Cornell, M.E., Yock, P.G., Linehan, J.H., 2009. The Iterative Nature of Medical Device Design, in: Norell Bergendahl, M., Grimheden, M., Leifer, L., Skogstad, P., Lindemann, U. (Eds.), Proceedings of ICED 09, the 17th International Conference on Engineering Design. Palo Alto, pp. 85–96.

Slattery, O., Trubetskaya, A., Moore, S., McDermott, O., 2022. A Review of Lean Methodology Application and Its Integration in Medical Device New Product Introduction Processes. Processes 10. doi:10.3390/pr10102005

Stelzmann, E., 2012. Contextualizing agile systems engineering. IEEE Aerosp. Electron. Syst. Mag. 27, 17–22. doi:10.1109/MAES.2012.6226690

Tsai, I.C., Wang, C. Da, Chen, P.T., 2023. Strategies for Medical Device Development: User and Stakeholder Perceptions. J. Healthc. Eng. 2023. doi:10.1155/2023/6724656

Zamith, M., Gonçalves, G., 2018. Towards an Agile Development Model for Certifiable Medical Device Software - Taking Advantage of the Medical Device Regulation, Proceedings of the 13th International Conference on Software Technologies. SCITEPRESS - Science and Technology Publications, pp. 132–140. doi:10.5220/0006861301320140

Zhang, X., Thomson, V., 2016. The impact and mitigation of complexity during product design. Int. J. Des. Nat. Ecodynamics 11, 553–562. doi:10.2495/DNE-V11-N4-553-562

Contact: J. Guérineau, École de technologie supérieure, Systems engineering department, 1100 Rue Notre-Dame Ouest, Montréal, QC, H3C 1K3, Canada, julia.guerineau@etsmtl.ca