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Between Innovation and Regulation

A Study on New Product Development of Medical Devices

Master's thesis in Management and Economics of Innovation

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Abstract

The majority of medical device companies fail to generate sufficient returns for their investors and need more efficient, user-oriented, and faster New Product Development (NPD) processes while pressure from regulatory requirements is increasing. In Europe, the Medical Device Regulation has increased the regulatory burden for medical device companies, thereby prolonging the time to market for new devices. At the same time, user needs, regulations, and technologies are continuously changing, increasing the need for flexible, efficient and fast NPD processes. This thesis explores the NPD processes currently employed by medical device companies, the contemporary challenges they face, and the actions used to address these challenges in practice. The study places particular emphasis on fulfilling user needs and shortening time to market while maintaining regulatory compliance. The qualitative interview study is based on 29 semi-structured interviews with practitioners across 15 medical device companies and two consultancy firms active in the medical device sector.

The findings show that a hybrid model, where a governing stage-gate process is combined with agile elements and/or V-model logic between the gates, is the most common approach for NPD of medical devices. The six main challenges identified are: regulatory burden and extensive quality management system, environmental and organizational changes, securing and translating user needs, inefficient and short-term oriented prioritization processes, organizational and cultural barriers, and software-specific complexity. The thesis concludes that medical device companies can improve NPD through six practical recommendations: front-load before design control, organize for cross-functional execution to reduce time to market, keep the quality management system lean, be closer to users and observe behaviors, prioritize in a structured way and protect exploration, and assign responsibility and follow-up on deliverables. This study provides six practical recommendations for balancing innovation and regulation in NPD and for improving user-needs fulfillment and time to market without compromising compliance.

Keywords: Cross-Functional Collaboration, Fuzzy Front End, Medical Device, MDR, New Product Development, Prioritization, QMS, Time to Market, User Needs

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Abbreviations

AIMDD - Active Implantable Medical Device Directive
FFE - Fuzzy Front End
IEC - International Electrotechnical Commission
ISO - International Organization for Standardization
MDD - Medical Devices Directive
MDR - Medical Devices Regulation
MDSW - Medical Device Software
NPD - New Product Development
R&D - Research and Development
QMS - Quality Management System
TTM - Time to Market

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1 Introduction

This chapter introduces the background of the medical device industry and the research problem, as well as the purpose, objectives, and scope and limitations of the thesis.

1.1 Background

New Product Development (NPD) of medical devices is inefficient. The lifespans of medical device technologies are short, and NPD is expensive and carries a high risk of technological failure (Marešová et al., 2020). Only a few medical devices reach commercial success, and the vast majority of medical device companies fail to generate sufficient returns for their investors (Marešová et al., 2020; Goldenberg & Gravagna, 2018). Traditional NPD processes used in the industry are neither dynamic nor tactical enough to ensure successful development (Goldenberg & Gravagna, 2018). Efficient NPD processes are crucial for medical device companies to develop new medical devices in a resource- and time-effective manner. It is also central to securing the requirements of different stakeholders (Marešová et al., 2020), which have drastically grown in number (Goldenberg & Gravagna, 2018). The focus of medical device companies is, however, mainly on regulatory compliance without ensuring a process that is both resource- and time-effective (Marešová et al., 2020).

This seems to be particularly evident in Europe, where several medical device companies have placed great focus on meeting the requirements of the Medical Device Regulation (MDR), Regulation (EU) 2017/745, since its introduction (Carl & Hochmann, 2024). The MDR was published in 2017 and came into force on 26th May 2021, replacing the predecessors Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD) (European Commission [EC], 2020). The regulation's stated intent is to strengthen patient safety and create a more robust and transparent regulatory framework for medical devices while still supporting innovation (Regulation (EU) 2017/745). A major difference from the predecessors is that MDR is directly applicable EU law whereas MDD and AIMDD were only directives (Becker et al., 2019). For individual EU Member States, that leeway for individual transposing of the directives is gone, thus creating a more harmonized legislative environment (Granlund et al., 2021). EU Member States can still have complementary national laws, but the MDR creates a common bottom line.

The MDR does not specify the technical methods for becoming compliant with the MDR (Francesconi et al., 2025). International bodies such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) provide international mandatory and guiding standards that support compliance with regulations like MDR. ISO 13485:2016 (Quality Management), ISO 14971:2019 (Risk Management) and IEC 62304:2006 (Medical Device Software) are all standards supporting compliance with the MDR (Francesconi et al., 2025). The nested and complex cluster of legislation and standards makes it unsurprising that medical device companies have reported that the information related to the MDR is fragmented (Huusko et al. 2023), and a lack of clarity regarding the new requirements (Carl & Hochmann, 2024). The complexity increases the cost in the industry, weakens the innovativeness, and could potentially hinder development, approval and market access of medical devices (Bermann et al., 2024), a concern for medical device companies and society.

In practice, the MDR has raised regulatory expectations throughout the entire product life cycle (Carl & Hochmann, 2024). This includes stronger requirements for clinical evidence and investigations, stricter post-market requirements, more extensive technical documentation (EUDAMED), and mandatory identification and traceability system through unique device

identification (Carl & Hochmann, 2024). New requirements for clinical evidence and investigations have forced medical device companies to redo clinical testing in order to maintain market access for all devices, regardless of novelty, implying extensive work (Ladd, 2023). The greatest burden for medical device companies related to MDR, at least in the orthopedic aids industry, is the additional workload for technical documentation (Carl & Hochmann, 2024). A comparison between two surveys at the introduction of MDR and two years later, indicated that several medical device companies struggle to meet the increased requirements of documentation (Carl & Hochmann, 2024). Due to the extensive regulatory work and financial burden, medical device companies have reported a reduction of their portfolio and withdrawal of medical devices from the EU market (EY, 2025; Carl & Hochmann, 2024).

At the same time, software is increasingly embedded in every aspect of medical devices (Gordon & Stern, 2019), where Software as a Medical Device (SaMD) has an expected compounded annual growth rate of 10.7-19% until 2032-2035 (Allied Market Research, 2024; Navistrat Analytics, 2025; Roots Analysis 2025; UnivDatos, 2024). Agile software development methodologies typically include frequent iterations, rapid testing, fast user feedback and regular updates over time, which is far from traditional hardware development optimized for stable requirements and infrequent releases (Gordon & Stern, 2019). The hardware-oriented regulatory requirements of the MDR are inherently in conflict with agile software development. Software-driven devices create specific challenges and opportunities for innovators and regulators, including issues related to software development processes, safety, security, data collection, and privacy (Gordon & Stern, 2019). Agile implementation in one medical device organization showed that agile practices often must be integrated with more plan-driven elements to meet regulatory expectations, rather than simply replacing traditional development approaches (McHugh et al., 2014).

In addition, the predecessor MDD did not include as many software products and applications as MDR does (Becker et al., 2019). The term “standalone software” is no longer used by MDR where software should now be classified and qualified on its intended use (MDCG 2019-11 Rev.1). Software that fulfills the definition of a medical device according to (EU) 2017/745, is called Medical Device Software (MDSW) in MDR and SaMD by practitioners. Software that is not MDSW can still be included in the MDR legislation if it is an accessory to a medical device (MDCG 2019-11 Rev.1), often referred to as Software in a Medical Device (SiMD) (Gordon & Stern, 2019). Any updates to the design or the intended purpose that are significant are all subject to a new conformity assessment and a new EU certificate issued by a notified body for MDSW in those risk classes (MDCG 2020-3 Rev.1). Class Im (Measurement Function), class Is (Sterile), class Ir (Reusable Surgical Instruments), all class II and all class III devices require a notified body’s conformity assessment procedure (Becker et al., 2019). Notified bodies are designated by EU Member States and responsible for the conformity assessment and certification, where one example of a notified body is RISE MNB (EC, n.d.b; Research Institutes of Sweden [RISE], n.d.). Moreover, bug fixes, cybersecurity updates, and cosmetic updates are usually not considered significant, but any safety- or performance-related features are (Läkemedelsverket, 2025a). In many cases where the updates are considered a significant change, the medical device is considered as a new product and must undergo a new conformity assessment and CE certification. In summary, agile software development with its continuous modifications is in conflict with MDR as it sets barriers for the methodology (Granlund et al., 2021).

Meanwhile, several studies have reported that medical device companies are failing to meet user needs, despite the fact that meeting those demands is the main purpose of a medical device (Chen et al., 2023). These companies are advised to consider key factors as early as possible to satisfy customer needs (Chen et al., 2023). Excluding customer interactions during the development phase exposes the risk of producing a device that is not in demand. According to Basit et al. (2017), agile NPD may provide value more rapidly, mitigate failure risks, and adapt to customer feedback through fast iterations. Another top priority for medical device companies is reducing time to market (TTM) (Hartung, 2026), which is defined as the time between the conception of an idea and its market launch. Besides the obvious patient benefits, it creates a competitive advantage for the company (Hartung, 2026). A quick TTM can determine the commercial success of a medical device, as longer development cycles may result in missed opportunities and higher development costs (Hartung, 2026). Additionally, Hartung (2026) emphasizes the importance of fast development cycles that do not compromise regulatory compliance.

According to a report commissioned by the European Commission, 45% of the medical device companies interviewed prioritized compliance practices over innovation, and 27% reported canceling the development of new medical devices due to MDR (EY, 2025). The MDR has certainly posed challenges for medical device companies in developing new products, particularly for MDSW. The MDSW industry is growing and naturally favors agile NPD. However, there is a mismatch between the agile NPD methodology and the MDR's hardware-oriented legislation, hindering the straightforward implementation of agile NPD. On the other hand, the agile methodology has been reported to be more beneficial than the traditional waterfall methodology, not just for software development (Basit et al., 2017). Agile NPD offers a faster TTM (Hartung, 2026; McHugh 2015), and customer involvement in development is a key aspect of the agile manifesto (Basit et al., 2017), two critical factors in medical device NPD. Medical device companies must find more efficient NPD practices that balance compliance and innovation, as traditional processes have been too inefficient (Goldenberg & Gravagna, 2018). As MDSW becomes more common and agile NPD offers benefits related to user involvement and shorter TTM, it is relevant to investigate which NPD processes medical device companies currently employ and which have proven successful. Thus, this thesis aims to first identify the currently used NPD processes in medical device companies. Second, to identify challenges in the NPD, particularly regarding fulfilling user needs, and reducing TTM, while ensuring compliance. Third, to identify what solutions have been successful addressing these challenges and what more can be done.

1.2 Purpose and Research Questions

This thesis aims to identify the current new product development processes employed by medical device companies, present the challenges they face, examine how these challenges are successfully addressed, and explore what more can be done. The results of this thesis primarily contribute practical recommendations for improving new product development of medical devices and secondarily provide understanding of medical device companies' current ways of working and contemporary challenges. The thesis is guided by the following three research questions:

- RQ1: What new product development processes do medical device companies currently employ?
- RQ2: What challenges do medical device companies face in new product development, particularly with regard to fulfilling user needs, and reducing time to market, while ensuring regulatory compliance?
- RQ3: How do medical device companies successfully address these challenges in practice, and what more can be done?

1.3 Scope and Limitations

This report focuses on medical device companies in Europe with a focus on Sweden, including companies that develop both hardware and software for medical devices. The report takes into account the MDR and associated documentation and approval requirements, as these factors directly impact the manner in which development work can be executed in practice. However, the report's primary focus is not on the regulation itself. Instead, MDR is regarded as a factor that influences the application of innovative development practices.

The report's primary focus is on work methods and development processes. It examines how companies plan and manage development work, how different functions collaborate (e.g., R&D, Quality, and Regulatory), and how user needs and requirements are identified and met during development. A key theme is how companies can integrate new practices in their operations to become more time- and resource-efficient, develop better devices, and secure user needs. The report does not evaluate clinical outcomes or the medical performance of particular products. It focuses on how development work is carried out and how innovation-oriented ways of working can be used within the medical device regulatory environment.

2 Previous Research

Previous research provided knowledge of and insight into the research landscape before the thesis interviews were initiated. This section clarifies what has already been discovered and what remains to be discovered, offering insight into this study's contributions. While prior studies have identified various challenges in New Product Development (NPD), they tend to concentrate on a particular issue, which this thesis does not. There is a research gap, particularly regarding studies based on interviews with practitioners. This thesis differs from Shah's (2024) literature review on why NPD of medical devices fail, the most comparable research, in that it is based on numerous practitioner interviews and focuses specifically on Time to Market (TTM) and user needs.

2.1 Challenges and Recommended Actions

Shah's (2024) literature research on why NPD projects of medical devices fail and how to overcome those challenges found five challenges, illustrated in Figure 1.

Figure 1: The five major reasons why NPD of medical devices fail (Shah, 2024).

2.1.1 Inadequate Risk Management

Inadequate risk management is a major reason why the NPD of medical devices fail. Failures often arise from an inability to foresee and mitigate risks early in the development process (Shah, 2024). The author emphasized the importance of initiating risk management early on, as overlooking risks can lead to more significant problems later in the process. Shah (2024) emphasizes integrating risk management with product design and development, as well as with design inputs and user needs. Otherwise, these elements may be incorporated too late. It is also important to consider compliance with regulatory standards to ensure that the functionality and usability of the manufacturing process meet regulatory requirements (Marešová et al., 2020). Risks should be continuously monitored and reviewed during development. Clear communication about their roles is necessary to mitigate potential project failure, and stakeholders should be involved (Marešová et al., 2020).

2.1.2 Regulatory Hurdles

Regulatory hurdles, such as the complexity of regulatory requirements and high overhead costs, can put projects at risk of failure (Shah, 2024). Adapting to regulatory changes can also significantly impact the NPD of medical devices. Shah (2024) states that engaging with regulatory institutions to improve regulatory orientation and proactively adapt to future compliance is an essential strategy for success.

2.1.3 Change Management Issues

Shah (2024) emphasizes the importance of change management, a topic that is often overlooked. According to Shah (2024), proper change management incorporates human, technical, and organizational perspectives when introducing new development processes. The author emphasizes engaging with stakeholders throughout the process, from conceptualization to deployment. Employees and business units often resist change, which can severely impede effective implementation. This is consistent with the findings of Ojha (2023), Lepmets et al. (2016), and Colomo-Palacios et al. (2020), who also highlighted resistance to change and organizational culture as barriers to implementing new processes, in their cases agile new product development (NPD). Overcoming this resistance requires transparent communication, effective onboarding, and inclusive decision-making. Another hurdle is adapting to regulatory and market changes (Shah, 2024). The author asserts that projects must be agile and adapt swiftly to be successful, and they must have change management mechanisms in place to monitor external changes.

2.1.4 Market Misalignment

Market misalignment occurs when there is an incorrect device-user needs fit (product-market fit) and has been reported to be the biggest risk (Marešová et al., 2020; Shah, 2024). Insufficient market research during development, poor translation of user needs, and inadequate competitive analysis in the short and long term can lead to market misalignment when the product is released. Failing to adapt to shifts in market trends, technology, and user needs can also contribute to market misalignment (Marešová et al., 2020; Shah, 2024). According to Shah (2024), as development cycles surpass years, projects must remain flexible to meet requirements at launch. Market misalignment can be mitigated through rigorous market research, proactive development processes, ongoing stakeholder involvement, and competitive and regulatory analysis (Shah, 2024). Cooperation between developers and users is also an effective mitigation measure (Marešová et al., 2020). Shah (2024) emphasizes the necessity of a cross-functional approach to effectively coordinate the necessary disciplinary contributions. Proper risk detection and prevention can save significant time and development costs (Marešová et al., 2020).

Access to healthcare professionals and patients has also been identified as a significant challenge (Haarmann & Holler, 2024). A low response rate results in a considerable amount of time spent acquiring interviewees, writing personalized requests and follow-up emails, and finding suitable candidates (Haarmann & Holler, 2024). Furthermore, objectively determining user needs is often challenging because the biases of market researchers can influence interviewees' answers and, consequently, the interpretation of user needs. A lack of training and experience on the part of the interviewer can result in misinterpretations or an inaccurate translation of the interviewee's real needs (Haarmann & Holler, 2024). According to the authors, recommended actions include accessing the right users, addressing their key needs, and testing if the device meets user needs early on. Education and practice are essential for understanding user needs and the attributes for which they are willing to pay (Haarmann &

Holler, 2024). The authors suggest designating employees to regularly collect user needs so they can improve and eventually ensure the effective translation of user needs.

2.1.5 Communication Breakdown

Inadequate communication is a critical factor that leads to development failure (Shah, 2024). According to the author, cross-functional teams often face communication barriers due to differences in terminology, priorities, and objectives. Poor communication among device developers, end users, and the marketing department can lead to delays or rejections (Marešová et al., 2020). Miscommunication with regulatory bodies can lead to delays or rejections. Inadequate communication with stakeholders can result in poor engagement and misaligned expectations. User engagement is often overlooked, which can result in unmet user needs and an inadequate fit between users and devices (Shah, 2024). To overcome communication breakdowns, Shah (2024) suggests that organizations should implement structured communication strategies that ensure continuous stakeholder engagement.

3 Theoretical Frameworks

This chapter includes the regulatory process a device takes from idea to finished product, New Product Development (NPD) processes, and relevant concepts and theories for understanding NPD of medical devices.

3.1 Regulatory Process of a Medical Device

This chapter walks through the main steps from idea to finished product from a regulatory standpoint. The chapter is grounded in Läkemedelsverket's (2025b), the Swedish Medical Products Agency, description of the process from idea to finished product and Figure 2 shows the overview of the regulatory process of a medical device provided by Läkemedelsverket (2025b).

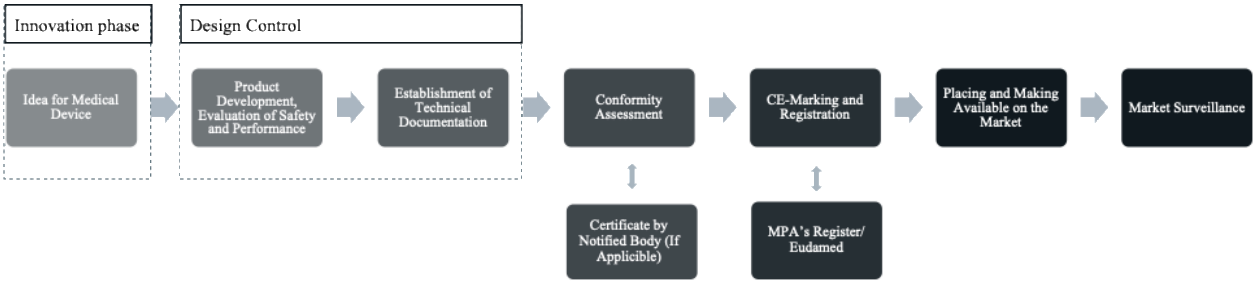

Figure 2: Overview of the process from idea to finished product (Läkemedelsverket, 2025b). Note: Innovation Phase and Design Control are added to the original figure as they are of high relevance to the thesis.

3.1.1 Idea for Medical Device

The first stage includes investigations of the device attributes and purpose which are the basis for determining whether the device is classified as a medical device and which class (Läkemedelsverket, 2025b). The purpose of the device is partly deduced from the marketing, the labeling and instructions for use. Two devices that look similar may have different regulations to comply with depending on the earlier mentioned factors (Läkemedelsverket, 2025b). A medical device can be many things such as software, apparatus, instrument, implant etc. To be classified as a medical device, it must have at least one of the functionalities below (Läkemedelsverket, 2021):

- *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*
- *Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability*
- *Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state*
- *Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.*

After the device is classified as a medical device, the device should be classified into a risk class in accordance with MDCG 2021-24 Rev.1 (Läkemedelsverket, 2019). The basis of the

classification is its intended use, but several aspects need to be considered (Läkemedelsverket, 2025b).

3.1.2 Design Control

Läkemedelsverket (2025b) does not explicitly mention design control as a step but the steps: product development, safety and performance evaluation, and establishing the technical documentation are commonly referred to as design control. Under design control, manufacturers convert the idea to a medical device that ensures compliance: safe to use, achieves claimed performance for its intended use, and can be manufactured and supplied to the market (Läkemedelsverket, 2025b). The manufacturer must present evidence in the technical documentation, so the conversion from idea to compliant device is possible.

Zhang and Cresswell (2016) described design control more thoroughly, presenting it as a series of connected and documented steps that link user needs to a finished and controlled product. Figure 3 illustrates the overview of the design control steps according to Zhang and Cresswell (2016).

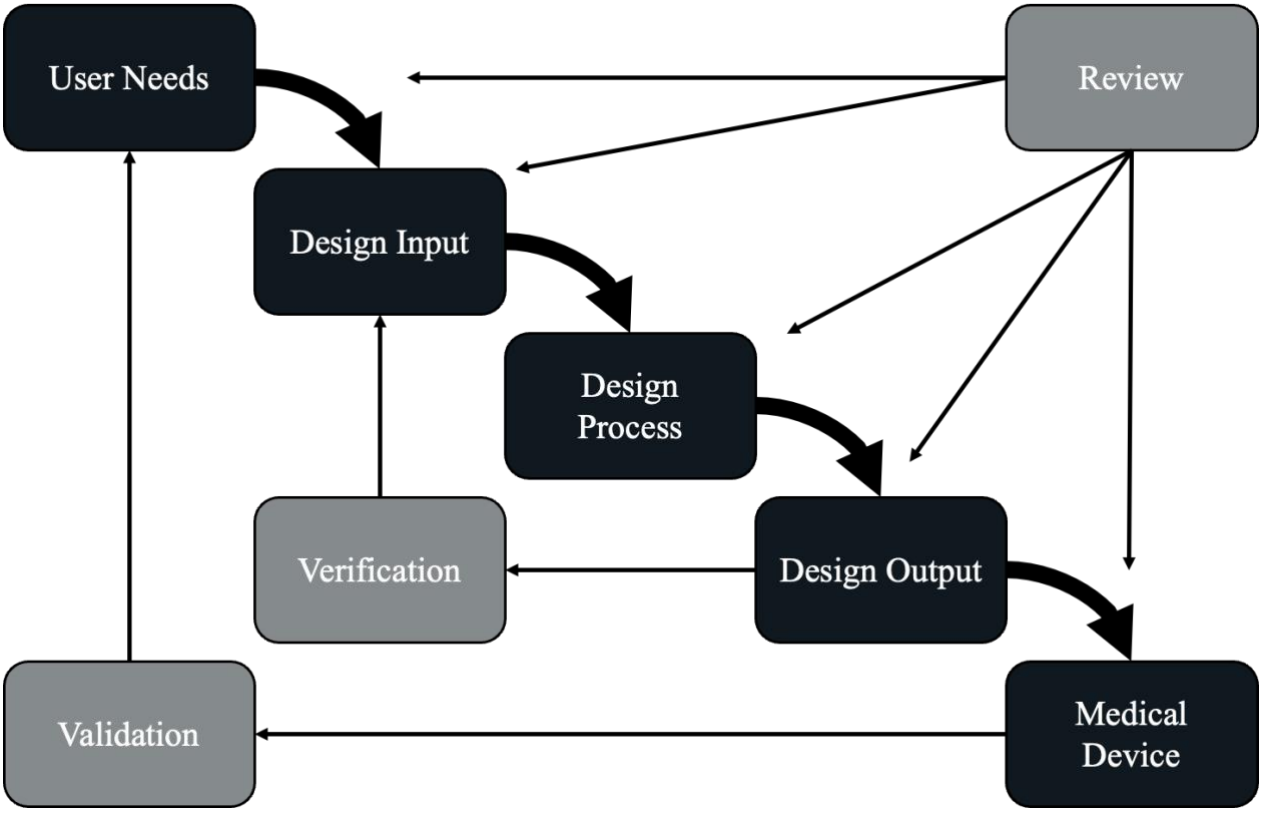

Figure 3: Overview of the design control steps (Zhang & Cresswell, 2016)

The process typically begins with design and development planning where the company defines the project scope, responsibilities, milestones, review points and how verification and validation activities will be carried out. This is followed by design input, where user needs, intended use, regulatory requirements and relevant technical requirements are translated into clear and reviewable specifications. Based on these inputs the company then develops design outputs, meaning the drawings, specifications, software descriptions, manufacturing information and other deliverables that describe the product in enough detail to allow evaluation and realization. Throughout the process, formal design reviews are carried out to assess progress, identify problems, handle incomplete or conflicting requirements and decide whether

the project is ready to move forward. The next core steps are design verification and design validation. Verification is about checking that the design outputs actually meet the design inputs, in other words that the product has been designed correctly against the specified requirements. Validation instead focuses on whether the finished device meets user needs and intended use in actual or simulated use conditions, meaning that the right product has been developed. After this, design transfer ensures that the approved design is correctly translated into production specifications and can be manufactured in a controlled and repeatable way. Design control also includes design changes which means that modifications must be reviewed, documented and approved so that traceability is maintained and unintended consequences are avoided. Taken together, these steps show that design control is not only about final testing but about maintaining a traceable chain from planning and requirements to evidence, transfer and controlled change throughout the whole development process.

3.1.3 Conformity Assessment

During this stage, the manufacturer assesses whether the technical documentation about intended use, design, manufacturing etc. meets requirements from regulations and associated standards (Läkemedelsverket, 2025b). For some risk classes, a notified body is engaged in the assessment of technical documentation, and sometimes the Quality Management System (QMS). MDR regulates what must be included in a company's QMS and how the company continuously must work according to it, update it, improve it etc. (Läkemedelsverket, 2024). The intent of the QMS is to ensure compliance with MDR in the most efficient way for the specific company. It is the company which must transpose the regulatory requirements and decide how they shall work to ensure compliance, describe it in their QMS and evaluate if they work in accordance with their QMS (Läkemedelsverket, 2024). The QMS should be in accordance with ISO 13485 and other international guiding standards (Läkemedelsverket, 2024).

If the company works in accordance with their QMS, then the notified body issues a "Declaration of Conformity" (Läkemedelsverket, 2024). However, this does not mean that the device is ready for CE-marking (see section 3.1.4 below), and it is the manufacturer's responsibility that the device meets the regulatory requirements. Further, if changes are made to the design, production process labeling etc. the manufacturer must update technical documentation and assess if the change affects compliance of the device.

3.1.4 CE-Marking and Registration

Once the declaration of conformity has been issued either by the company itself or a notified body, it can be CE-marked (Läkemedelsverket, 2025b). The CE marking informs users that the manufacturer ensures that the device is manufactured in compliance with regulations and is safe to use in accordance with the instructions for use.

3.1.5 Placing and Making Available on the Market

When the CE-marking and registration have been made, the device can be placed on the EU market if it complies with national laws (Läkemedelsverket, 2025b). For example, in Sweden all instructions for use and labeling must be written in Swedish.

3.1.6 Market Surveillance

When the device has been placed on the market, post-market surveillance must be done (Läkemedelsverket, 2025b). It includes having a plan and process how to collect, analyze and act on data relevant to how the device is used, how it works and performs. Additionally, the manufacturer must compare performance with similar devices on the market. If any new

information about the safety, performance, usage of the device comes up, assessment and action may need to be taken to ensure compliance. The technical documentation must also be updated on those occasions. This implies that the manufacturer has responsibility for the entire device lifecycle (Läkemedelsverket, 2025b).

3.2 Process models

Product development is the overall design-and-development process (DDP) that companies use to turn needs, technologies and limitations into a real product. As Wynn and Clarkson (2018) emphasize in their discussion of process models, one of the main difficulties is that these processes are usually new and complicated, and involve many rounds of iteration. Because of this, planning must allow for uncertainty, repeated work and learning along the way. It cannot be treated as a simple step-by-step path. Different types of process models exist, and each serves a different purpose. Some describe what actually happens in development, some recommend "best practices" and others help analyze how different choices affect performance. This means organizations should choose the model that fits their planning situation and what decisions they need to make.

In practice, companies often need more than one model at the same time. A common setup, again consistent with the argument made by Wynn and Clarkson (2018), is to use a simple high-level phase model for governance and decision points while also using more detailed models that help teams coordinate daily tasks. Wynn and Clarkson (2018) argue that no single model can represent every aspect of a development process. Instead, the real value comes from selecting and combining different perspectives based on the situation, such as how new the work is, how tasks depend on each other, how much iteration is expected and how many parts of the organization are involved.

According to Guzik (2023), modern product development research shows that companies choose different strategies for creating new products depending on how much uncertainty they face and how ambitious the project is. Some companies use a more structured plan-driven approach, while others choose more flexible methods that let them quickly adjust when customer needs change, or market conditions fluctuate. Guzik's (2023) review explains that NPD models differ in how detailed they are and when they are useful. Newer approaches like agile product development and open innovation, have become popular because they help teams deal with uncertainty, get faster feedback and improve both the quality of ideas and how well the product fits market needs.

Having a process model does not automatically mean it will be used successfully. Tzortzopoulos et al. (2004) conducted research on process model implementation showing that failures often happen when the model does not fit the organization's real situation or when "soft" factors, such as motivation, agreement among team members, collaboration, and how daily routines evolve, are not handled well. The main lesson for planning is that adopting a new process should be seen as a change management effort. This means giving people clear roles, offering training, and reinforcing new ways of working, rather than merely introducing a new flowchart or checklist. Model implementation shows that failures often occur when the model does not support how work is actually carried out.

Product development involves many different functions in a company, so the team aspect is very important. Jassawalla and Sashittal's (1999) research on cross-functional teams shows that collaboration does not automatically happen just because people from different areas are put together. Real collaboration develops over time through certain team milestones and practiced

behaviors. For planning, this means organizations should actively build routines that support cross-functional teamwork. These include having shared goals, clear and open communication, and agreed upon ways to handle conflicts. Coordination cannot simply be assumed to happen on its own.

3.2.1 Stage-Gate

The stage-gate model is a structured way of organizing product development into several clear phases where each phase ends with a decision point. At these decision points the project is reviewed before it is allowed to continue. This helps organizations evaluate progress, risks and resource needs during the development process. As Wynn and Clarkson (2018) explain, process models are useful because they create structure, support planning, and help coordinate work between different parts of an organization. In that sense, stage-gate can be understood as a high-level process model that gives management a clear overview of how development moves forward and when key decisions need to be made. This makes the model especially useful in settings where control, traceability and formal follow-up are important. Figure 4 illustrates the stage-gate model taken from Wynn & Clarkson (2018).

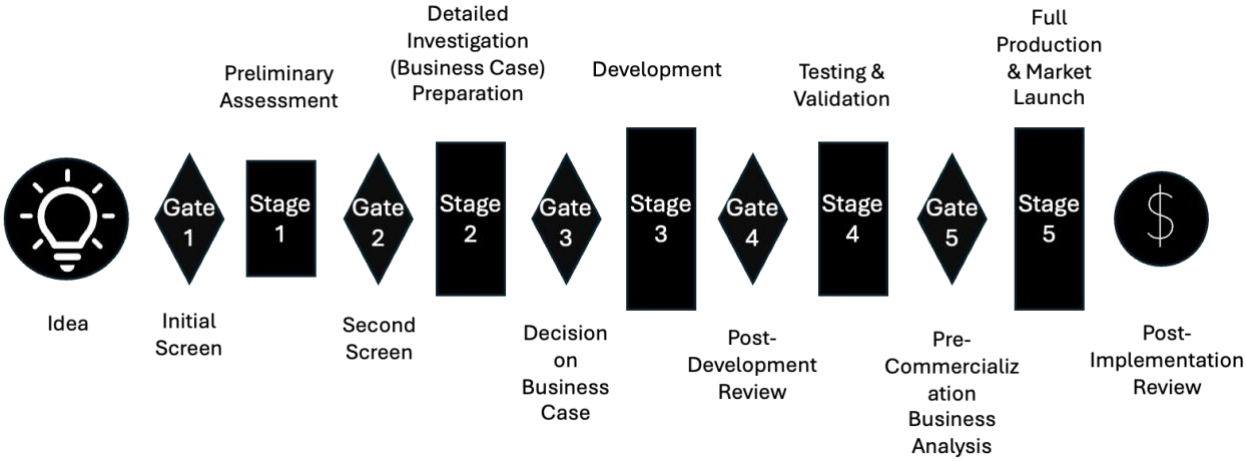

Figure 4: Overview of the stage-gate model (Wynn & Clarkson, 2018)

3.2.2 Waterfall

The waterfall model is similar to the stage-gate model as there are defined steps and clear gates for the process (Cooper, 2025). However, the structured approaches differ: stage-gate is more iterative and flexible than the waterfall method, which follows a more rigid and linear process. Once a phase has begun, the waterfall method does not allow for going upstream, back to the previous phase (Cooper, 2025). Stage-gate on the other hand does and includes risk assessment and a go or no-go decision at each gate which is absent in waterfall. Additionally, stage-gate naturally implies more cross-functional collaboration whereas waterfall model is more siloed (Cooper, 2025).

3.2.3 Agile

Hron & Obwegeser (2022) explain that agile product development in software is an approach designed to handle uncertainty by learning quickly. It does this through short feedback loops, frequent integration of new code and regularly updating priorities based on what we learn from working versions of the product. Instead of trying to follow a fixed plan perfectly, agile teams focus on adapting fast and responding to new information. This is especially useful when requirements are likely to change as stakeholders see and test early versions of the solution. Research shows that agile methods are almost never used exactly as described in the official frameworks. Scrum (agile framework for NPD), for example, is often adjusted to fit real-world

needs such as handling dependencies, meeting documentation or governance requirements or working with teams at different experience levels.

Dikert et al. (2016) explain that when agile involves more than one team, coordinating all the teams becomes one of the biggest challenges. In these situations, the organization's overall architecture and rules often shape how agile works more than the team level ceremonies do. Research on large-scale agile transformations consistently shows that teams struggle with coordinating work across groups, working with departments that are not agile and managing quality requirements that affect the whole system. At the same time, successful transformations usually have strong leadership support, a clear purpose for the change and organizational setups that make it easier for teams to work together. For planning in a multiteam environment, there is a clear need for ways to handle dependencies between teams, a shared rhythm for integrating work, agreed upon architectural guidelines and defined processes for how agile teams interact with functions like quality, regulatory compliance and operations.

McHugh's (2015) academic research on agile in medical device software development generally agrees that the key challenge is not how long a sprint is but how well teams integrate required regulatory documents and evidence into an iterative way of working. McHugh's (2015) studies show that agile can fit within medical device lifecycle rules if teams treat documentation, traceability and risk controls as essential development outputs, not just paperwork done afterward. In this view each iteration delivers both working software and the evidence needed for audits with the amount of formality adjusted based on risk and the software's safety classification. This approach aligns with the idea of "continuous compliance," where the development process is set up so compliance documentation is created step by step during the project, instead of being pieced together at the end.

According to Atzberger and Paetzold (2019), agile planning for medical devices that include both software and hardware has to deal with the fact that these two parts develop at different speeds. Software can usually change and improve quickly but hardware takes longer because it depends on prototyping, suppliers, lab testing and preparing for manufacturing. Research on agile hardware development shows that these limits make it hard to use the same sprint rhythm for every subsystem. The practical solution is not to drop agile but to use different development speeds for different parts. Software and digital tools, like simulations, or interface mockups, can iterate often. Meanwhile hardware follows a slower build and test cycle with planned moments where everything syncs up. This means planning must clearly define how work from different subsystems will come together in integrated builds, how stable interfaces will be kept during development and how integration tests will be arranged so the team can learn quickly without causing unnecessary disruptions.

Walrave et al. (2022) explain that because regulated medtech development requires both investment control and formal decision points, many organizations choose a hybrid governance model that mixes agile execution with structured oversight. The Agile-Stage-Gate approach is relevant because it allows teams to work iteratively within each phase while still passing through higher-level gates where leadership reviews progress, allocates resources and evaluates risks. For medtech products that combine software and hardware this hybrid model is particularly suitable. It aligns naturally with important system milestones such as architecture freeze, design verification readiness, readiness for clinical or usability evaluations and release readiness within the constraints of a quality management system and functional approval.

3.2.4 V-Model

According to Wynn and Clarkson (2018) the V-model is a structured development model that shows how different stages of development are linked to corresponding testing activities. On the left side of the model, the product is gradually defined through steps such as identifying needs, setting requirements and developing the design. On the right side, these steps are matched with testing and evaluation activities where the product is checked and validated step by step. In this way the model creates a clear connection between what is planned early in the process and how it is later verified. According to Wynn and Clarkson, process models like the V-model are useful because they create structure, support planning, reduce the risk of missing important steps and improve communication between different functions involved in development. This makes the V-model especially relevant in regulated industries where traceability, documentation and verification are important parts of the development process. Figure 5 presents the V-model where CI stands for configuration item, taken from Wynn & Clarkson (2018).

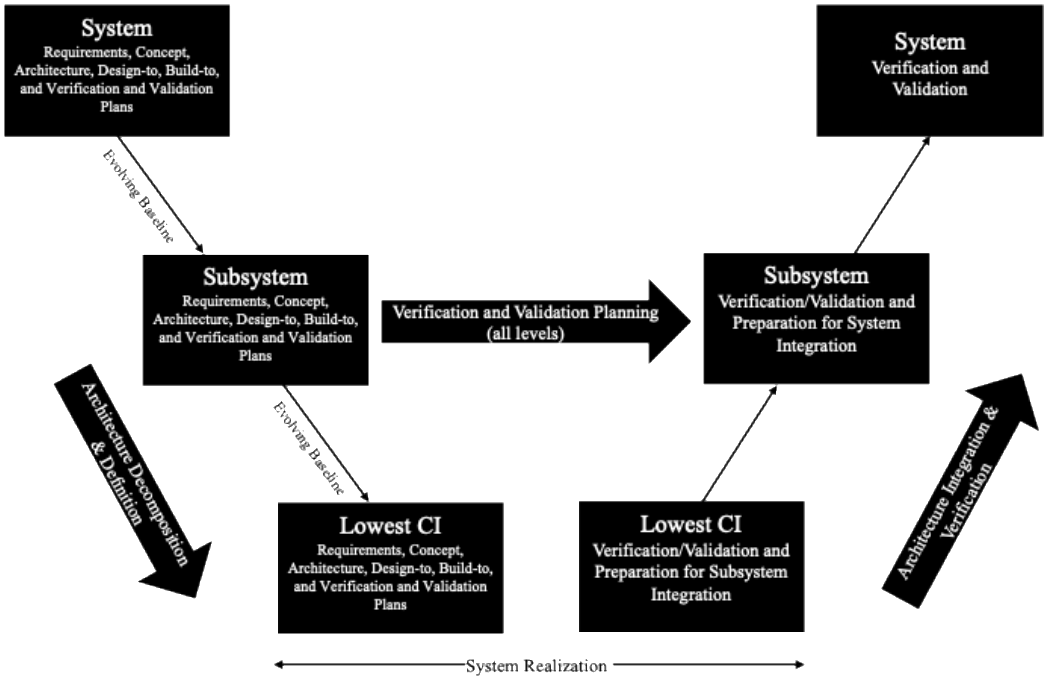

Figure 5: Overview of the V-model (Wynn & Clarkson, 2018)

3.2.5 Stanford Biodesign

Chua et al. (2024) describe Stanford Biodesign as a needs-driven innovation framework for healthcare innovation and medical technology development. The framework is built around three main phases, identify, invent and implement. In the identify phase unmet clinical needs are found through clinical immersion, observations and discussions with healthcare professionals and patients. In the invent phase possible solutions are created and evaluated. In the implement phase the selected solution is prepared for product testing, commercialization and use in healthcare.

The framework is relevant for medical device development because it starts with the clinical problem rather than with a technical solution. Chua et al. (2024) explain that the Stanford Biodesign framework helps innovation teams develop new medical products by focusing on unmet patient needs, multidisciplinary teamwork and practical implementation. The review also

shows that the framework has been used across several medical fields and that products developed with this approach can improve patient care.

A central strength of Biodesign is its focus on clinical immersion and observation. By observing real healthcare settings, innovation teams can better understand user needs, workflow problems and practical limitations. Chua et al. (2024) found that clinical immersion helped innovators identify unmet needs and understand clinical situations more deeply. The framework also encourages multidisciplinary collaboration between people with medical, engineering and business backgrounds, which can improve both creativity and feasibility during development.

3.3 Concepts and Theories

This chapter introduces concepts and theories necessary to understand and explain patterns found in the empirical analysis.

3.3.1 The Fuzzy Front End

The Fuzzy Front End (FFE) is defined as the beginning of an innovation process and is critical for the success of new product development (Ferreira et al., 2017). The FFE is the phase before NPD and is the most predictive indicator for NPD success (Markham, 2013). Markham (2013) showed that the FFE performance impacts TTM, financial performance, market penetration and success of the product. The initial process may involve several actors where the idea is generated from creative or rational thinking (Ferreira et al., 2017). Innovation management is thus a crucial activity for innovation and business opportunities (Ferreira et al., 2017). FFE activities are central as they may increase the probability of successful commercialization. FFE creates an ideal starting point for an innovation where an in-depth understanding of the problem is coordinated to foster concept development. Several studies have shown that improving the FFE enhances the chances of successful development (Ferreira et al., 2017). Activities in the FFE are by nature experimental and chaotic.

Khurana and Rosenthal (1997) emphasized the importance of an enabling organizational structure in the FFE, adequate identification of customer needs, and the need for a well-developed product concept for successful NPD. Ajamian et al. (2001) defined five front-end elements: opportunity identification, opportunity analysis, idea genesis, idea selection, and concept and technology development. Opportunity identification is the first phase where organizations identify opportunities, where the methodologies and sources used constitute the essence of this element. From the identification, additional information needs to be gathered about the business and technology opportunity and includes making an initial market assessment. Idea genesis is where the idea matures and is developed through many iterations. Direct contact with customers and cross-functional collaboration often enhances this activity, where the output is a more developed description of the product concept. Idea selection is where the organization chooses the most promising ideas, where decisions based on financial return are often at best just a wild guess. The authors argue that more tailored models are needed during the FFE as ideas must be allowed to grow despite having high uncertainty. The last element, concept and technology development, includes business case development and is based on the estimates of the technology, market, user needs, etc.

3.3.2 Time to Market

Time to market (TTM) refers to the timing of when a new product is introduced to the market. For technology-based products this decision is important because companies often operate under high uncertainty, fast technological change and strong competition. Lint and Pennings

(1999) explain that companies face a strategic choice between launching early to gain competitive advantage and waiting to reduce uncertainty before making large market-introduction investments.

A fast TTM can be valuable because early market entry may help a company build market share, shape customer preferences and stay ahead of competitors. However, Lint and Pennings (1999) also show that entering too early can be risky if the market, technology or customer acceptance is still uncertain. Waiting can give the company more information and reduce the risk of investing in the wrong product or market. The TTM decision is therefore not only about speed but about choosing the right timing for launch.

This is especially relevant for medical device development, where market introduction often requires large investments in production, regulatory work, documentation, clinical evidence and marketing. If a company launches too late, it may lose competitive opportunities. If it launches too early, it may face costly rework, weak user acceptance or regulatory problems. Lint and Pennings (1999) argue that uncertainty can be reduced through actions such as test marketing, phased rollout, early market feedback, strategic alliances and cooperation with other actors.

3.3.3 Cross-Functional Collaboration

Cooper and Kleinschmidt found in 1995 that one critical success factor for new product development is cross-functional collaboration. Cross-functional collaboration has also been proven to have positive complementary effects on innovation in product design, development and product engineering, but negative effects on marketing (Love & Roper, 2009). Cross-functional collaboration is thus not suited for all elements of NPD. For the medical device industry, traditional silo-based organizational structures in NPD have become inadequate for developing more complex devices, particularly for innovation, managing risk and decreasing TTM (Whitmore, 2025). NPD of medical devices requires input and collaboration from regulatory, market, engineering, and clinical perspectives. It has been shown that if these perspectives are integrated early and throughout the project, safety, usability and compliance are improved (Whitmore, 2025). Cross-functional collaboration has also emerged as an effective TTM-reduction measure. It enables concurrent engineering, where the alternative is sequential and not as efficient at handling issues early on (Whitmore, 2025).

Cross-functional collaboration is, on the other hand, not straightforward to implement. An appropriate organizational structure is needed to align incentives and ensure a shared objective; otherwise, the collaboration structure may become inefficient and trigger conflicts (Whitmore, 2025). McDonough (2000) found that the three most important success factors for cross-functional collaboration are establishing goals, team leadership and cooperation. The author highlights that the factors could be interrelated, as establishing clear goals can enhance cooperation, as can effective team leadership.

3.3.4 Change Management

Change management is referred to as the process of changing an organization’s direction, structure and capabilities to adapt to the changing environment (Todnem, 2005). As changes in organizations happen continuously, it is essential that organizations have adequate processes for managing such change (Oakland & Tanner, 2007). Kotter’s (2007) eight-step methodology is a traditional, yet relevant change management model. The first step is to establish a sense of urgency in the organization, where employees need to be informed about why a change is needed and what will happen if the change is not implemented. Without motivation, employees

will not help (Kotter, 2007). The second step is to build a strong enough guiding coalition to lead the change and encourage collaboration within the coalition. Not all will buy into the change, but it is important to get enough people to support it and be committed to the same goal. The third step is to create a common vision of the change, which preferably should be easy to communicate and appealing to stakeholders.

The fourth step is to communicate that vision and do it to a large enough extent, which Kotter (2007) argues is sometimes underdone by a factor of ten. The fifth step is to empower others to act on the vision, where obstacles to the change are removed. If a system or structure undermines the vision, it needs to be removed. The sixth step is to plan for and create short-term wins, which includes making performance improvements visible, recognizing and rewarding employees pursuing the change. The seventh step is to consolidate improvements and continue changing, as it is easy to fall back into old habits. Organizations should hire, promote, and develop employees who support the vision and avoid declaring victory too early, as change takes years, not months. The eighth step is to institutionalize the new approaches and develop the necessary means to ensure the sustainability of the change.

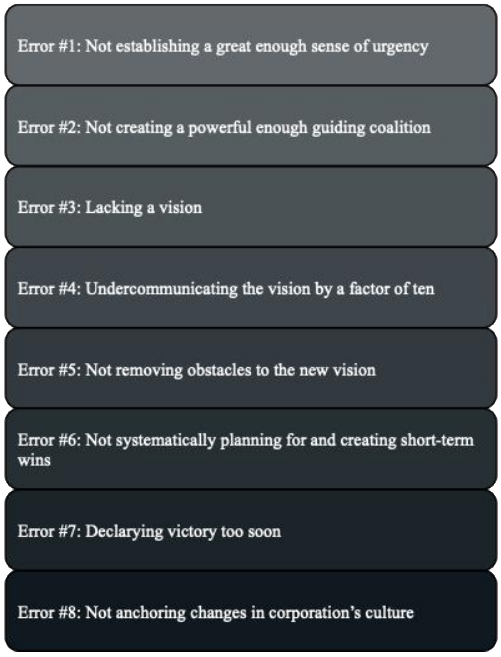

Figure 6: Kotter's (2007) eight errors in poor change management

3.3.5 Project Portfolio Management

Organizations struggle with resource allocation across projects despite employing different methodologies (Martinsuo, 2013). The coordination and control of multiple projects competing for the same resources is called project portfolio management (Martinsuo, 2013). Holistic project portfolio management approaches have been developed and can be seen as the governing approach to manage product development. Traditionally, successful firms have had a structured rational decision-making approach to assessment, allocation and decision making (Martinsuo, 2013).

In the medical device sector, the most common approach to determining if a project should proceed is based on a financial evaluation (Johal et al., 2008). It is often a combination of payback analysis and a discounted cash flow analysis. Johal et al. (2008) stated that the methodologies are easy to understand and use and provide clear and consistent decision criteria for projects. However, the tendency to undervalue projects and to prematurely close projects with negative net present value has been reported to be a limitation by practitioners (Johal et al., 2008). The net present value was often calculated at the concept phase or after a phase of basic research.

3.3.6 Ambidexterity

Ambidexterity of an organization is commonly understood as the balance between exploitation and exploration, where firms must simultaneously make use of existing knowledge while also pursuing new opportunities (Raisch et al., 2009). Being ambidextrous therefore requires both an internal and external focus, as well as the ability to continuously adapt and reconfigure existing capabilities to meet changing requirements. O'Reilly (2011) defines this as the ability to sense shifts in the external environment and to seize these opportunities by adjusting both

tangible and intangible assets. Chen (2017) further categorizes ambidexterity into three types: contextual (where employees can choose between exploration and exploitation), sequential (where the two are separated over time), and structural (where different units are responsible for each). Chen argues that the most effective form is a combination of these, referred to as dynamic ambidexterity.

Furthermore, ambidexterity has been shown to positively influence firm performance (Raisch et al., 2009) and is often described as essential for long-term survival in environments characterized by change (O'Reilly, 2011). However, the benefits of ambidexterity are not universal. Siggelkow & Rivkin (2005) demonstrate that the effectiveness of organizational structures depends on the external environment, showing that in stable and complex environments, hierarchical structures are more suitable. In such contexts, the need for exploration is limited, and therefore ambidextrous organizations may not be advantageous, as the coordination costs associated with balancing exploration and exploitation may outweigh the benefits. This is particularly relevant in highly regulated environments, where stability reduces the need for continuous exploration. Thus, while O'Reilly (2011) emphasizes ambidexterity as critical for long-term survival, this primarily applies to dynamic environments, whereas in stable settings the need for exploration is significantly lower.

4 Method

This chapter outlines the methods employed in this thesis, including the research strategy and process, interview selection, data analysis, generalizability, and ethics. The aim is to enable research reliability, replicability, and validity through transparency and guiding principles.

4.1 Research Strategy

This thesis has explored the experiences of practitioners in medical device companies within an MDR environment and in conjunction with complementary international guiding standards. Thus, the emphasis has been on the words that describe those experiences. The most suitable research strategy for this thesis was qualitative, as it emphasizes words over numbers (Bell et al., 2022). Theory generation from observations is usually associated with qualitative research, a process known as induction (Bell et al., 2022). However, this thesis was also based on existing theories, particularly different NPD-processes. Abduction was thus deemed to be an appropriate approach for this thesis and is defined as the generation of new concepts or theories derived from both existing theories and empirical observations (Tavory & Timmermans, 2012). Researchers should enter the field with the best possible knowledge and improve this understanding alongside the research process (Tavory & Timmermans, 2012). Instead of theories solely emerging from observations without any preconceived predispositions, new concepts are developed based on puzzling of empirical materials (Tavory & Timmermans, 2012). Abduction does not limit itself to the explanatory limitation of existing theories, rather it can extend and refine the theories available (Tavory & Timmermans, 2012). Abduction includes both inductive and deductive strategies, but this thesis has to a larger extent been conducted inductively than deductively. For instance, Stanford Biodesign was incorporated into the theoretical framework after it emerged as relevant in the interviews, illustrating how the study moved abductively between empirical findings and theory.

Qualitative research strategy was particularly appropriate when answering the experiences and standpoints from participants. This thesis identified the views of key informants on a specific topic, which justified the use of this strategy (Hammarberg et al., 2016). One advantage of this strategy was its ability to support researchers' understanding of complex contexts (Basis & Pollalis, 2018), which was necessary for such a complex cluster of legislation and dependencies as the medical device sector. The research objectives required in-depth knowledge, which the qualitative research strategy facilitated. As the research strategy included analysis and interpretations conducted by the researchers, there was a risk of subjectivity (Basis & Pollalis, 2018), as everyone has their own perceptual filter in which they perceive the world (Buchanan & Huczynski, 2019). The difficulty to replicate was another concern as the strategy was relatively unstructured and based on the researchers' creativity (Bell et al., 2022). However, almost no strategy is completely straightforward to replicate. The generalizability of the qualitative interview study was improved by interviewing 29 respondents across 17 companies, though the purpose was not to derive complete generalization by statistical significance. As Bell et al. (2022, p. 636) explain "(...) it is the quality of the theoretical inferences that are derived from qualitative data that is crucial to the assessment of generalization.". Bell et al. (2022) also shed light on the challenge of lack of transparency, as it is difficult to understand what the researchers did and how they came to their conclusions. This chapter demonstrates how transparency was ensured and how subjectivity was mitigated, which is further discussed in this thesis, along with generalization of findings.

4.2 Research Process

The research process of this thesis was structured to enable the researchers to understand the complexities of medical device NPD and derive practical recommendations based on the findings. This included an exploratory phase of industry practices, active legislation, and international guiding standards, as well as previous studies. Theories were explained from these standpoints to create an extensive theoretical framework on which the selection of interviewees was based.

The next phase was data collection, which involved conducting numerous semi-structured interviews. The final phase was the exploitative phase, in which thematic analysis was conducted. When theoretical saturation was achieved, practical recommendations were formulated. This accurately resembles the main steps in qualitative research described by Bell et al. (2022), which are iterative in nature. Through conceptual and theoretical work, research questions were formulated more precisely, and further interviewees were selected for additional data collection. Thus, there was no clear distinction in which phase the thesis was in, as it was an iterative process. Research questions typically evolve as data is collected and literature is read (Bell et al., 2022), which happened in this thesis as well. Figure 7 presents an overview of the research process.

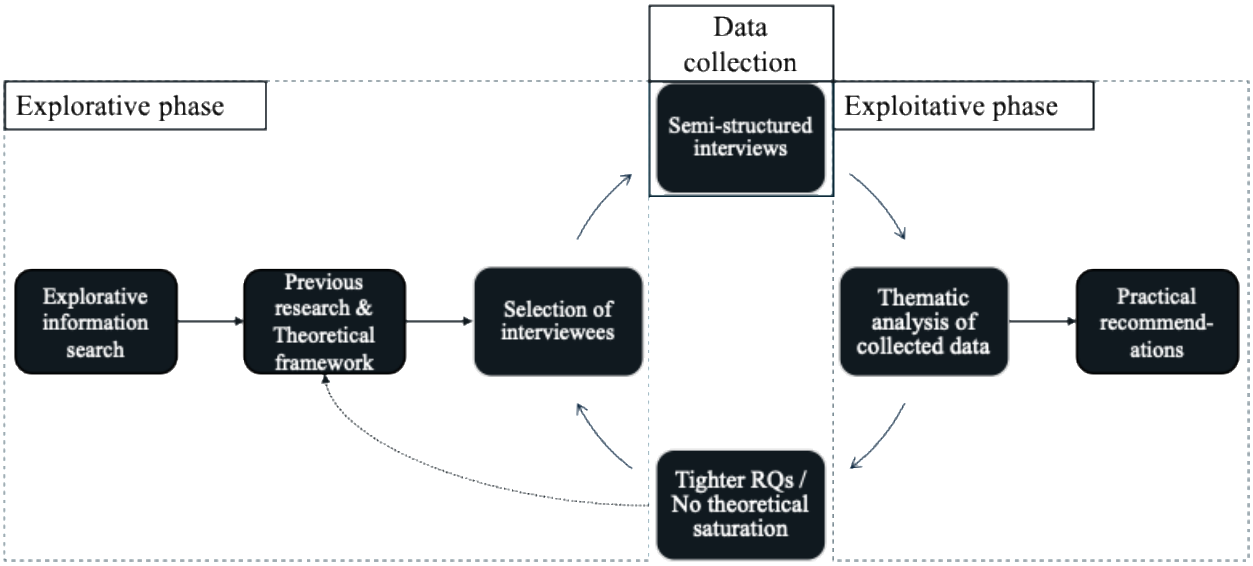

Figure 7: Overview of the thesis' research process

4.3 Explorative Phase

The explorative information search was conducted by searching through Google Scholar, Chalmers Library and Google using keyword searches, as presented in Table 1. Exploring older scientific articles on the perspectives of how the NPDs of the industry formed and how legislation developed and changed revealed industry dynamics. Covering the MDD and AIMDD of the era before the MDR, as well as searching for differences between the directives and the regulation, provided a solid knowledge foundation. Exploring newer scientific articles, the MDR, reports, and grey literature provided up-to-date perspectives from different stakeholders and a holistic industry landscape, although some sources were more trustworthy.

Table 1:Keywords used in the explorative information search.

Keywords	Agile software development, Agile new product development, IEC 62304, ISO 13485, ISO 14971, MDD, MDR, Medical device, Medical device software, New product development, Notified body, Software as medical device, Software in medical device

This thesis employed two purposive sampling methodologies: theoretical sampling and snowball sampling. Theoretical sampling was controlled by the researchers and was based on emerging theories. New perspectives and gaps derived from previous data collection were complemented by new data collection based on anticipated learning opportunities. Bell et al. (2022) highlight its iterative nature, in which the point at which sampling should stop is based on theoretical saturation. Theoretical saturation is achieved when no new categories emerge, the existing categories are fully developed, and the relationships between them are established (Bell et al., 2022). Theoretical sampling was supplemented by snowball sampling, in which interviewees proposed relevant individuals to be interviewed by the researchers. In turn, new interviewees were asked to recommend others who had not yet been interviewed, and this process was repeated until theoretical saturation was achieved. Snowball sampling was deemed to be appropriate to generate several interviewees within a single company as they most often were a part of the same network, which the sampling method is strong at generating (Parker et al., 2019). LinkedIn was used to find suitable respondents.

This thesis conducted interviews with multiple employees at different levels across several companies. These interviewees were selected to capture variation across medical device development contexts, including large and mid-sized medical device companies, recently organizationally transformed firms, and a management consultancy firm, enabling the study to compare contexts and challenges. Interviewing numerous medical device companies and two consultancy firms in the sector allowed a broad understanding of challenges and action taken in the industry from different perspectives. The total number of interviews conducted was 29, which was enough to reach theoretical saturation. 26 of the interviews were with employees working in Sweden, 2 from Italy and 1 from Denmark. 5 interviewees were at President/Vice President level, 14 at Senior Director/Director level, 9 at Senior Manager/Manager level, and 1 was a Product Owner. Origin and titles are not linked to each interviewee to ensure confidentiality. Anonymous companies, company type, department, and interview duration are presented in Table 2.

Table 2: Overview of interviews conducted where R&D stands for research and development, and PD stands for product development.

#	Anon. company	Company type	Department	Duration
1	Company A	Medical device company	R&D/PD	30 Min
2	Company A	Medical device company	Business development	45 Min
3	Company A	Medical device company	Program management	45 Min
4	Company B	Medical device company	Project management	45 Min
5	Company C	Software consultant company	Software development	45 Min
6	Company D	Medical device company	R&D/PD	45 Min
7	Company D	Medical device company	R&D/PD	45 Min
8	Company E	Medical device company	Product management	45 Min
9	Company F	Medical device company	R&D/PD	45 Min
10	Company G	Medical device company	R&D/PD	45 Min
11	Company H	Medical device company	R&D/PD	45 Min
12	Company H	Medical device company	R&D/PD	45 Min
13	Company I	Medical device company	Product management	45 Min
14	Company J	Medical device company	Product owner	45 Min
15	Company J	Medical device company	Innovation	30 Min
16	Company K	Medical device company	R&D/PD	60 Min
17	Company K	Medical device company	Project management	60 Min
18	Company L	Medical device company	R&D/PD	30 Min
19	Company L	Medical device company	R&D/PD	30 Min
20	Company L	Medical device company	R&D/PD	30 Min
21	Company L	Medical device company	R&D/PD	30 Min
22	Company M	Medical device company	R&D/PD	30 Min
23	Company N	Medical device company	R&D/PD	30 Min
24	Company N	Medical device company	R&D/PD	30 Min
25	Company N	Medical device company	R&D/PD	30 Min
26	Company O	Medical device company	R&D/PD	45 Min
27	Company P	Management consultant company	Life science	60 Min
28	Company P	Management consultant company	Life science	60 Min
29	Company Q	Medical device company	Product management	45 Min

4.4 Data Collection

A semi-structured interview approach was used because it allowed participants to share extensive information and details (Bell et al., 2022). Semi-structured interviews include several predetermined questions that are largely asked with similar wording. What sets a semi-structured interview apart from a structured one is that it gives interviewees the leeway to steer their answers in a desired avenue. Interviewers may also ask follow-up questions based on topics brought up by the interviewee, covering new areas of interest that were not thought of beforehand. Bell et al. (2022) emphasize that some structure is needed to conduct cross-case comparisons, which was done to some extent. A completely structured interview was also not appropriate for this thesis because follow-up questions were necessary to gain the in-depth knowledge needed to achieve the thesis's objectives. The interview guide used for the medical

device companies and the software consultancy company is presented in Appendix 1 - Interview Guide - Medical Device Companies and Software Consultant Company, while the interview guide used for the management consultancy company is presented in Appendix 2 - Interview Guide - Management Consultant Company.

There are both pros and cons to video/audiorecording and notetaking. Video/audiorecording has several benefits, such as the ability to rewatch the interview unlimited times, examine how the interviewee expressed themselves more thoroughly, and quote them, as well as the ability to free oneself from the limitations of human memory. However, videorecording can intimidate respondents, who may limit their answers (Bell et al., 2022), which can be the case for audiorecording as well (Bernays et al., 2019). In cases where the subject is of particular sensitivity, it could be expected that these tendencies were amplified. This thesis used notetaking to mitigate the risk of limited answers, as practitioners' unfiltered opinions were very valuable for the research questions, particularly when things were not working. Notetaking also reduced confidentiality concerns and lowered the perceived risk of being "on record," which helped create a more relaxed interview setting and encouraged more open, experience-based reflections. Notetaking is considered the best method when recording an interview would likely affect its content (Bernays et al., 2019). One interview was almost canceled due to the confidentiality of the company's core practices, which highlighted the importance of ensuring the best possible anonymity for transparent answers. This was best achieved by not recording the interviews. The performance of traditional notetaking was continuously evaluated and found to have worked very well, despite the difficulty of ensuring exact citations. Several interviewees appreciated the transparency regarding how anonymity was secured and the fact that only notes were taken. Two interviewers were present at all interviews, with one responsible for the conversation and the other responsible for notetaking, which enabled more time and focus on each activity. Post-interview discussions were always conducted and included key takeaways, as well as anything that was unclear or improperly cited. The note-taker asked clarification questions when they could not follow the conversation to ensure the notes were complete.

4.5 Exploitative Phase

As Figure 7 shows, the exploitative phase included data analysis and practical recommendations. This section covers data and thematic analysis, as well as the reliability and validity of the findings and the ability to generalize them to cases outside the sample.

4.5.1 Data Analysis - Thematic Analysis

This thesis used thematic analysis, which involves clustering data based on recurring themes (Bell et al., 2022). Themes may be clustered based on several factors, but they were primarily based on repetition, the most common categorization factor (Bell et al., 2022). Repetition refers to both in-case and cross-case repetition; the latter was emphasized more. However, Bell et al. (2022) conclude that repetition alone is insufficient for categorization, as identified themes must be relevant to the research questions. Thematic analysis has a broad range of applications and is useful in qualitative and quantitative settings (Braun et al., 2017). It is particularly well-suited for analyzing interviews, which, together with the methodology's general flexibility, was the reason for its selection. As an abductive approach to the data was used, the data were examined both from a bottom-up and a top-down perspective, as recommended by Braun et al. (2017). Regarding the bottom-up perspective, however, researchers never start from a clean slate (Braun et al., 2017), and perhaps particularly when also employing a top-down perspective. Coding the data was primarily based on explicit meanings, as is often the case with an inductive approach, which the thesis primarily employed. Decoding based on implicit meanings required

a solid understanding of the topic, often with a deductive approach where theories guide the decoding of implicit signals. Theories were not used to a large enough extent that implicit decoding was suitable, particularly as videorecording was not used.

The six-step thematic analysis method by Braun et al. (2017) was used, which included familiarization, coding, theme development, reviewing, defining themes, and producing the report. The *familiarization* step provided an overview of a large amount of data, offering a broad understanding of the analysis. Braun et al. (2017) emphasize the importance of properly conducting this initial step, as overlooking it may negatively impact the rest of the analysis. The main goal of this exploratory phase was to generate provisional analytical ideas (Braun et al., 2017). *Coding* involved the systematic creation of labels attached to the source of the data. The labeling had a broad focus, and the relevance to the research question was the determining factor in whether the data needed to be coded. This phase was equally about organizing participant observation and data reduction, and good coding includes precisely enough details so that the researcher did not have to revisit the original source to understand it. Braun et al. (2017) highlight the iterative nature of this process, noting that codes captured later in the process often have greater clarity.

Theme development first involved examining the codes and then clustering them into meaningful patterns (Braun et al., 2017). The authors underscore the importance of a central organizing concept, which is an idea or concept that frames a theme. This concept enabled a clear distinction between what the theme referred to and which codes belonged to it. Cross-case clustering was emphasized in this phase. Great themes are described by Braun et al. (2017) as distinctive and, preferably, mutually exclusive and complementary, with their own central organizing concept. However, there is a trade-off between the exclusivity and connectedness of themes, so one should not focus on one or the other (Braun et al., 2017). Greater themes emerged during the latter part of the analysis as the first iteration of themes was more content based instead of insights. *Reviewing* involved examining whether the candidate themes captured the meanings of the collected data and worked in relation to each other and the research questions. If not, another round of clustering was done. *Defining themes* involved writing an analytic narrative grounded and supported by data and themes (Braun et al., 2017). The goal was to ensure the clarity, cohesion, quality, and accuracy of the analytics. Themes needed to be diverse and rich, allowing for more than a few lines of analysis; otherwise, they were dropped or placed as subthemes. Subthemes provided another important perspective on a theme and had the same central organizing concept. *Producing the report* was the phase where researchers zoomed out and connected the theoretical framework, previous research, background, etc., all together, and used data extracts as either illustrative quotes or analytic discussions of properties (Braun et al., 2017). Figure 8 presents the data analysis process.

Figure 8: Representation of data analysis phases based on Braun et al. (2017)

4.5.2 Generalizability, Reliability and Validity

According to Mason (1996), generalizability, reliability, and validity are criteria that can be used to depict the quality and potential of qualitative research. Generalizability refers to the transferability of the research's findings to cases outside the research's sample. The purposive sampling method also improves transferability by sampling a broad variety of participants that cover the most important aspects. As Bell et al. (2022) explain, the quality of the theoretical

inference derived from the data determines the transferability of the findings. Nevertheless, the thesis addresses the extent to which the findings can be generalized beyond the sample in 7 Conclusions**.**

Reliability is defined as the consistent repeatability of research outcomes (Bell et al., 2022). In other words, if the research were to be conducted again, would the results remain the same? The reliability of the thesis was improved by ensuring transparency through detailed description of the entire process. However, the thesis is limited by the anonymity of the interviewees, which could hinder repeatable consistency. Furthermore, validity refers to whether the research examined the intended phenomenon (Bell et al., 2022). As the thesis conducted interviews within medical device companies, the validity is deemed to be more than sufficient as the research examined the intended phenomenon.

4.6 Ethics

Ethical considerations were addressed to this thesis due to its qualitative nature and reliance on interviews with practitioners working in regulated medical device companies. The study was conducted in accordance with generally accepted ethical principles for social science research, including respect for persons, informed consent, confidentiality and responsible data handling (Bell et al., 2022).

4.6.1 Data Management

Participation in the study was entirely voluntary, and all interviewees were informed in advance about the purpose of the research, how the data would be used, and the interview guide. Informed consent was obtained prior to each interview, either in written or verbal form depending on the interview format. Given the regulatory sensitivity of the medical device industry, particular attention was paid to confidentiality and anonymity. Interviewees' names, roles and organizations were anonymized in all written material. Interviewees were free to withhold proprietary, confidential or commercially sensitive information and were not pressured to share anything. When examples or quotes were used, they were presented in a way that prevents identification of individuals or organizations. All interview notes were securely stored and only accessible to the authors and the supervisor and were handled in compliance with applicable data protection regulations, including the General Data Protection Regulation (GDPR). Personal data were limited to what was strictly necessary for the research purpose and were deleted after completion of the thesis.

Finally, the authors strived for integrity and transparency throughout the research process. This included accurately representing participants' perspectives, avoiding misinterpretation and clearly distinguishing empirical findings from analytical interpretations. The study aimed to contribute knowledge that benefited both academia and practitioners without causing harm to individuals or organizations involved.

4.6.2 Use of AI

The use of AI in this thesis was limited to language recommendations regarding grammar and formulations. Any language recommendation first had to be approved by the authors, who verified that the content's message was correct before adoption. The AI tools used were ChatGPT and DeepL. Sensitive or confidential information, such as that from interviews, was not processed with AI.

4.6.3 Social Factors

Medical devices are shaped by what people and healthcare systems need. In the EU, the population is aging, which puts more pressure on healthcare and long-term care services (Eurostat, 2026). This tends to increase demand for medical technology that supports older patients and works well in long-term care situations. Chronic (long-term) diseases are another strong driver. The European Commission (n.d.a) highlights that non-communicable diseases, such as cardiovascular disease, diabetes, chronic respiratory diseases, and cancer, make up a large part of the disease burden in EU countries. Because these conditions often require ongoing treatment and follow-up, there is a growing need for devices and digital solutions that help with long-term monitoring and management.

Trust also matters a lot in medtech. EU medical device rules require manufacturers to demonstrate that devices are safe and perform as intended. In practice, that pushes companies to work in a structured way with documentation, risk management, and careful control of changes during development and after the product is released (Regulation (EU) 2017/745).

According to the Medical Device Coordination Group (2020), privacy and cybersecurity are increasingly important, especially for connected devices and software. Under the GDPR, health data is treated as sensitive personal data and has stricter requirements for how it can be processed and protected (Regulation (EU) 2016/679). On top of that, EU guidance for medical devices makes it clear that cybersecurity should be handled as part of the product's safety and risk management work, not as an "extra" added late in the process.

4.6.4 Ecological Factors

Sustainability is becoming more relevant for medical devices too. According to Directive 2012/19/EU, medical devices can affect the environment through material choices, manufacturing, transport, energy use and end-of-life disposal, especially when they contain electronics that can become e-waste. EU law on waste electrical and electronic equipment (WEEE) aims to reduce environmental and health impacts by improving collection and treatment of e-waste.

Environmental rules can also influence design decisions. For example, the EU's RoHS rules restrict certain hazardous substances in electrical and electronic equipment, which can affect which materials and components are allowed (Directive 2011/65/EU). The EU is also pushing for products to be more sustainable across their whole life cycle (Regulation (EU) 2024/1781). The Ecodesign for Sustainable Products Regulation (ESPR) sets a framework for ecodesign requirements, supporting goals like better durability and circularity.

5 Empirical Analysis

The empirical analysis is based on 29 interviews conducted across 17 companies. The chapter is divided into current new product development setup, challenges, and proven solutions and what more can be done, matching the thesis' research questions.

5.1 Current New Product Development Setup

This section describes how the interviewed medical device companies currently organize their product development processes. Despite differences in company size, product type, and regulatory class, a set of recurring patterns emerged. Most companies rely on a stage-gate structure as the foundation of their development process, often incorporating agile or iterative elements. Some have introduced newer frameworks to strengthen their early-phase innovation work. Cross-functional collaboration has become increasingly common, though its implementation varies. Overall, the results suggest that the industry is primarily plan-based, yet is also experimenting with more flexible, user-driven approaches. This chapter is linked to research question one:

What new product development processes do medical device companies currently employ?

5.1.1 Hybrid Model with Stage-Gate as Backbone Process is Dominant

The most common way of working across the interviewed companies is best described as a hybrid approach, combining different models at different levels (A, B, D, E, F, G, I, J, K, L, M, N, O, Q). Interviewee 17K explicitly referred to this hybrid setup as best practice. In most cases, a stage-gate model forms the backbone, with V-model and/or agile elements embedded within the gates. Nearly all companies described some form of gated process in which development progresses through defined phases, each ending with a review or decision point before the project is allowed to continue. Where the process was not explicitly referred to as stage-gate, it was instead described as a waterfall model. Respondents 4B and 11H highlighted that design control steers the whole development process and is incorporated into the stage-gate structure. The findings suggest that the stage-gate model primarily functions as a governance and decision-making layer, providing structured checkpoints for evaluating progress, allocating resources and ensuring compliance.

Stage-gate facilitates communication

Interviewees 6D, 11H, 22M and 29Q emphasized that the gate structure facilitates communication, both internally and externally, by providing a shared understanding of project status and expectations. Interviewee 14J even mentioned the stage-gate model as a requirement from the management board for reporting purposes, while others (4B, 11H) highlighted that it ensures that critical steps are not missed, though at the cost of reduced flexibility. The number of gates and the level of formality vary across companies, with some maintaining lean structures and others, particularly larger organizations, adding additional gates or additional processes at stages over time. In contrast, the stage-gate backbone is less present in early exploratory phases, where more flexible approaches such as Stanford Biodesign are used (H, N). Interviewee 9F described that company F has a stage-gate backbone model that integrates different types of complementing models depending on product characteristics. An observation is that the logic of the stage-gate model can conflict with the desire to work in parallel and iterate (11H), creating a structural tension between control and speed.

5.1.2 Agile Elements and V-Model within Stages are Common

Most companies apply agile elements within stages, such as sprints, iterative work, backlogs, etc. though not always referred to as working in an agile way. Pure agile development, in the textbook sense with Scrum ceremonies, self-organizing teams and feature-complete deliveries every sprint is not practiced by any of the companies interviewed for their overall product development. Respondent 5C even claimed that using Scrum in a pure form is not possible. However, agile elements are widely used, particularly for software development where teams working with software largely used agile methods. The degree to which agile practices are adopted varies significantly, from companies that barely touch agile to those that run most of their day-to-day engineering work in sprints. Interviewee 8E stated that their development teams work in three-week sprints planned by the product manager and the development manager is responsible for ensuring technical decisions. The interviewee acknowledged that it is hard to have something fully ready after three weeks but still felt that the agile approach gave good control over large and complex projects by forcing the team to break things down and prioritize. Interviewees 20L and 18L told that they work in quarterly sprints with backlogs, demos and retrospectives, essentially running an agile cadence.

Agile offers short-term flexibility but sometimes comes at the cost of the long-term direction.
At company G the shift toward agile was driven by a need to respond faster to a changing competitive landscape, particularly pressure from Asian manufacturers entering the market with lower-cost products. They restructured their entire development process over the past year to be more agile, moving away from long slow projects. Interviewee 10G wanted to become more agile as it enables flexibility and changes create opportunities. However, interviewee 18L pointed out that the agile teams do not think far enough ahead, which creates tension with the long-term project commitments that leadership needs to make toward investors and regulators. Respondent 8E has also experienced working in agile teams is not suitable for every team and mentioned the combination of long development cycles and agile development as a struggle as rework has to be done. Respondent 18L added that working in agile teams does not suit every team and it requires a specific type of task.

Organizational structure and culture must be in place for effective agile elements implementation.
Interviewee 19L described how company L had attempted agile approaches three or four times but moved away from it each time. The main problem was the financing model where projects are funded based on a promise to deliver the specific function the business case was built on as that was the basis of the funding. Agile development might land on a different solution than the one originally specified. The teams were measured on whether they delivered the promised function, not on whether the product was actually better. This mismatch between agile flexibility and project-based financing was seen as a barrier by respondent 19L. Interviewee 10G noted that getting long-tenured employees to adapt to the new way of working was a challenge and that writing an ISO-compliant development process that also works in an agile way is not straightforward. Creating the culture around agile principles was thus a struggle.

Agile works well for software but is harder to apply to hardware-heavy development though not impossible.
Interviewee 4B said they believed in stage-gate for products mixing hardware and software, with agile used specifically for the software parts. Interviewee 7B stated that the hardware followed the waterfall model while the software was developed using agile methods. This split approach where different parts of the product follow different development rhythms was

described by several companies. On the other hand, respondent 29Q reported that the agile methodology worked well for their hardware development

The agile user-centric approach with prototypes and short iteration cycles is often used, although its applicability varies across device types.
Respondent 3A reported validating user needs in the beginning with very simple prototypes, sometimes full-scale paper models, which are tested with users early on. The team travels to hospitals and invites users to the company's facilities to test concepts. This is done iteratively, refining the design based on what they learn. Company L starts by building a prototype in the lab and testing it with in-house clinicians. If all users make the same mistake during testing, the design is reworked. On the other hand, interviewee 12H reported prototyping as demanding and if a significant change is made, new production equipment is needed.

V-model is widely used.
Several companies also described the V-model as a complementary structure within the stage-gate framework, and interviewee 6D liked the V-model as it is easily combined with the regulations and has a clear structure. Agile elements can be incorporated within the V-model as respondent 6D reported. The V-model is widely used by practitioners and is one of the core processes in companies A, F and M.

5.1.3 Cross-Functionality has Become a Key Organizational Practice
Companies A, H, L and O described some form of shift toward involving more functions earlier in the development process, moving away from a model where R&D develops the product in isolation and then hands it over to production, quality, regulatory and commercial teams in sequence. Interviewee 21L described this shift as a fundamental transformation. Company L moved from a line organization where each function worked separately to a project-based structure where purchasing, production, sales, compliance and R&D are all part of the development team from the start. Respondent 21L explained that this was a deliberate change in mandate. Project leaders now have authority over line managers, which was a difficult cultural shift. Interviewee 2A also emphasized that getting the organization to work cross-functionally, involving all functions early in the project, was the most impactful change they had made. Previously, product development was something the technology team did and the project leader was seen as a technical administrator with limited authority. At company J cross-functional teams were described as working very well and as one of the best changes made in recent years. Interviewee 14J noted that having each person in the team carry only one role, rather than having multiple roles was an important success factor. The interviewee pointed out that the biggest challenge is conflicting goals between functions and that leadership and experience are critical to navigate these conflicts.

5.1.4 Early Innovation-Phase has Become Strengthened with Cross-Functional Emphasis
Interviewee 1A reported that a lot of work has been done to improve the early phase and that more remains to be done. Company N has also had a lot of work done to improve the innovation phase, as it has been a challenge before. Respondent 29Q mentioned that they also had introduced a new innovation phase. It's, like the others, purpose was to develop and test a concept before entering design control. Further, several companies (A, F, H, L, N, O) emphasized that cross-functional work is particularly important in the innovation phase, where a small team including R&D, sales, and other functions works together before the regulated part of the design control process begins. Interviewee 5C stated that hardware and software

developers work closely together, while Interviewee 7D stated that they do not work as cross-functionally in the beginning.

Innovation ideas often come from users.
Respondent 16K stated that 20 years ago, innovation often came from the R&D department, which is not the case today. The R&D department is much more cost-controlled and does not have the leeway it used to have. Interviewee 16K added that business cases are needed from the very beginning, and without them, securing seed funding is difficult. Interviewee 12H also mentioned the same phenomenon, that innovation is not coming from the R&D side any longer.

Stanford Biodesign has increased in popularity during the innovation phase.
A notable finding is that two companies (H, N) have adopted or are in the process of adopting the Stanford Biodesign framework for their early-phase innovation work. This framework is focused on deeply understanding unmet clinical needs before jumping into solutions, using structured observation, interviewing, and need characterization to identify the right problems to solve. Interviewee 3N described it as a design thinking-like process. It represents a shift away from technology-push development toward a more need-driven and iterative front end, matching the earlier finding of innovation ideas' origin from users. It also has several agile elements. This is most clearly reflected in how companies handle user needs, prototyping, and requirements management. The general pattern is that companies start with early, rough prototypes and gradually refine them through repeated rounds of feedback, testing, and adjustment. Respondent 24N emphasized the methodology's problem orientation, where advanced interviewing methods are used to identify the core problem. Interviewee 24N added that they work according to similar principles as agile development, but that the methodologies are different. To illustrate Stanford Biodesign, the interviewee mentioned that it is like peeling an onion, layer by layer, and in that sense, it is somewhat similar to stage-gate. Respondent 24N also emphasized the importance of starting with the most urgent problem first.

Interviewee 12H described building on the principle of starting from customer needs rather than from a technical idea, working through a gated innovation phase that involves needs identification, concept development, and iterative validation with users before the project enters the regulated design control process. The idea is that by the time a project enters formal development, the concept should already be robust and well validated, reducing the risk of expensive changes later.

Different innovation processes for incremental and radical development.
Company N explained that the company has two different processes: their established process, which is essentially a stage-gate model for developing products in areas they already know, and a newer Stanford Biodesign-inspired process for exploring new and unfamiliar areas. Interviewee N3 described working on radically innovative projects where the team conducted 180 in-depth interviews at 27 hospitals in 6 countries, using the Stanford Biodesign methods to identify pain points and build the foundation for a new business area.

5.1.5 Strengths within the Current Process

Even though challenges dominated much of the interview material, interviewees also pointed to strengths of their current way of working. These strengths are closely tied to the regulatory environment in which the companies operate and reflect years of refinement within Quality Management System (QMS).

Regulatory compliance is achieved as a rule
A clearly recurring strength was the level of regulatory control built into the development process. Most companies described their stage-gate or V-model structure as well aligned with the requirements of MDR, ISO 13485, and IEC 62304. Interviewee 3A explained that they almost always pass notified body audits because they understand what is expected and have built it into their way of working. Respondent 25N described the regulatory department as a strength in itself, noting that their team saw the MDR coming and had prepared the company well before it came into force.

Documentation processes are well established
Documentation practices, while often described as burdensome, were also seen as a mature strength. Interviewees 6D, 8E, 20L, and 22M explained that they document continuously as the project progresses, and respondent 3A explained that they know in advance what questions will come up during audits, so they rarely have to redo work at the end. Another interviewee described how they reuse documents and templates across projects, which speeds up the work without compromising the content (5C). Several companies have invested in tools, templates, and dedicated documentation leaders to improve the quality of their technical files. One interviewee emphasized that even if the documentation workload is heavy, their process ensures that nothing gets missed, which gives the company confidence when moving into clinical testing or launch.

Verification and validation are well incorporated activities
Verification and validation were also described as strengths in several interviews (2A, 10G, 19L, 22M). One software-focused company said that their validation process, built around subjective clinical review by in-house experts combined with measurable technical criteria, is one of the best-functioning parts of their development. Another company highlighted that they test prototypes early and often using in-house clinicians, hospital partners, and advisory boards, which allows them to catch problems before design freeze. Across the interviews, there was a shared view that when V&V activities are taken seriously and planned into the process from the start, they provide confidence that the final product is safe, effective, and ready for the market.

5.2 Challenges

Generating sufficient return on investment for investors over time is critical for the survival of an organization. For medical device companies, continuously maintaining existing products and producing new ones are two core activities for company survival. The thematic analysis has resulted in some broad categorical challenges, with accompanying underlying challenges, which are presented below. This chapter is linked to research question two:

What challenges do medical device companies face in new product development, particularly with regard to fulfilling user needs, and reducing time to market, while ensuring regulatory compliance?

5.2.1 Regulatory Burden and Extensive Quality Management System

The common denominator among all the interviews, except for companies G and D, was extensive TTM. Time and time again, the same point was made, even after interviewing 14 different medical device companies with a broad variety of devices, ranging from basic to the most complex and regulated, and with significantly different TTM. TTM has many causes and underlying problems like regulatory burden and extensive QMS, making it an obvious theme.

Regulatory burden is the main TTM bottleneck

The regulatory burden of clinical tests, documentation, and approvals has been reported to be the main bottleneck for reducing TTM (6D, 10G, 18&19L, 26O). The workload for simple products is reportedly too extensive. Companies also find it difficult to determine which class to place their product in (4E). There are complaints that the regulations and the accompanying international guiding standards, ISO 13485 and IEC 62304, are outdated and do not align with modern work practices (5C). According to the interviews, the standards are not clear enough, which leads to companies having different regulatory processes for the same regulations (6D). While the regulations and standards are said to be natural and logical in essence, they sometimes demand too much and have added requirements over time because something went wrong at some point (24N). This creates complex, lengthy processes and documentation that no one will read in the future (6D). Interviewee 20L claimed that there is a regulatory arms race between authorities. Interviewee 18L claimed that the regulatory burden is twenty times greater than it was twenty years ago, which makes projects take longer.

Regulatory ambiguity and sandbagging create extensive quality management system

The ambiguity of the regulations and international guiding standards leaves room for companies to interpret the requirements differently and implement them into their quality management system (QMS). Companies are reviewed based on their QMS by notified bodies, and the assessment is based on whether the company has done what is described in the QMS (14J). If the regulations and international guiding standards are interpreted excessively conservatively in the QMS, the notified body assesses whether the company has done what was said to be done, which makes the regulatory burden extensive. It has been said several times that companies are exceeding the necessary requirements (A, B, C, I, J), while company N said it was a strength of theirs. According to interviewee 1A, quality and compliance can become overly extensive if the interpretation is black and white. Respondent 12H highlighted the tendency called sandbagging, where everyone tries to minimize their own risk, which in the case of regulatory interpretation results in overly conservative interpretations of regulations, making the project difficult to execute. Interviewee 2A also mentioned that a QMS tends to grow with a company, and processes tend to take on a life of their own. Each time something goes wrong, the natural response is to add another step to the process (2A, 11H, 27&28P). Over time, the processes become overly extensive. Respondent 3A stated that a device does not need

to be designed for someone who weighs 270 kg and uses it every minute of every day. If the device is durable enough for extensive usage in reality, it should not be overengineered.

5.2.2 Environmental and Organizational Changes

Environmental and organizational changes are also identified as two underlying causes to delaying the product launch.

Changing environment causes delays

In the medical device industry, development cycles often span several years. Over time, regulations, technology, and user needs change, causing the initial situation's conditions to change. One underlying factor of a long TTM is thus a changing environment. The longer the TTM, the more likely it is that these conditions will change, further delaying commercialization. Interviewee 25N stated that working with innovation in a highly changing environment is hard. Respondent 8E reported that they had multiple projects that exceeded their initial scope, and both regulations and user needs changed, causing them to rewrite documents. New technologies also emerged, adding features to the medical device, resulting in rework and delays. This was the case for company E, which had filed for and received approval of a patent that was deemed important enough to delay the project by years.

High employee turnover among top management increases TTM

Two interviews (20L, 24N) with long histories at each company suggested that employee turnover among top management is not beneficial for innovation. New roadmaps and decisions are made for innovations, but this is not ideal since innovations are long-term. New managers often want to reorganize and reprioritize, which may improve operations, but during the one-to-two-year transition, innovation slows down.

5.2.3 Securing and Translating User Needs

The most important aspect of a medical device development process is identifying and meeting user needs. The extent to which identifying and meeting those needs is challenging varies.

Inaccessibility to users hinders the securement of user needs

Company N clearly has a problem accessing users. Limited access to users and hospitals hinders close collaboration during development, which is a crucial factor for successful development, according to several interviewees (3A, 4B, 8E, 9F, 15J, 23&25N). Access to hospitals has become more restricted over the years, and an agreement is necessary for collaboration (24N). Developing a medical device without close collaboration makes it easy to develop the wrong product, which has happened at company E. Getting an agreement in place is a time-consuming process that increases TTM (23N, 24N, 25N). A lack of collaboration with clinicians and patients results in unmet and missed user needs (8E).

Lack of user involvement and poor translation of user needs can create mismatches between device and user needs.

The number one reason user needs are missed is a lack of user involvement and an inadequate data collection methodology. Respondent 14J reported developing a medical device that did not meet user needs because they were not present in the real world. Respondent 8E stated that they do not validate user needs as an integrated part of their process, unlike competitors. Competitors interviewed and observed their customers to identify unmet needs. Interviewee 22M stated that sometimes users are not aware that they have a problem because they are so used to having it. While company E did not continuously evaluate user needs, company M used this strategy to find business opportunities. Company E found that moving farther away from the customer by

going through a global distributor benefited them because their sales department did not have the global reach that the intermediary had. In addition, respondents 27P and 28P stated that medical device companies are often too far from users and lack the experience required to conduct market research properly. The translation from users' experiences to user needs and from user needs to technical requirements is poor and risks deviating too far from what actually emerged during interviews or observations.

Selling points are often overlooked and unknown, implying that user needs are not completely understood.
While the majority underscored the importance of validating medical devices with users early on, the interviews revealed that companies had overlooked user needs, which resulted in commercialization failure or rework. Some stated that addressing user needs was their greatest strength (2A, 10G, 19L, 22M), while others said they did not do so often enough (8E). Interviewees 27P and 28P stated that many medical device companies do not clearly understand their devices' selling points, implying that they do not know on what basis customers choose their specific device or why, making prioritization of resources challenging. Based on the experiences of respondents 27P and 28P, selling a device to a user without understanding the basis for their decision is rarely effective. Interviewee 13I claimed that they know their customers very well but had not investigated their devices' selling points.

5.2.4 Prioritization Processes are Inefficient and Short-Term Oriented

Since resources are scarce, they must be allocated wisely throughout the company. One interviewee clarified that prioritization means eliminating things, not ranking them.

Prioritization between projects and features is hard and time-consuming.
Prioritizing features has been identified as a difficult and time-consuming activity, yet an essential one for project leaders. During long development cycles, new user needs, technologies, and ideas will emerge, and some will be integrated into the project while others will not. Respondent 6D mentioned that prioritization is hard as resources are shared and that they have challenges with the prioritization structure. Interviewee 18L mentioned that there will always be new features to add to the device, but that eventually the budget and timeline will be at risk. This is the most difficult aspect, but it is crucial to staying within budget and schedule.

Current prioritization processes are inefficient.
Prioritization between projects was a challenge for company D, which had an unclear prioritization and ranking process. They, like other companies (G, N), had a forum where ideas were shared. However, their process needed to become clearer, a task on which they were currently working. Projects and features were often motivated by business potential, prioritizing opportunities with the highest return on investment and the shortest timeframe for commercialization. Prioritization was particularly challenging in new areas where company D was less familiar with the market. 20L argued that even if a new system were introduced, it would only provide limited improvement.

According to interviewee 16K, without proper business potential metrics, securing funding for a project is unachievable. Another interviewee highlighted the challenge of creating strong business cases as a bottleneck for TTM (11H). Another interviewee problematized the fact that they always had to make business cases for every project to secure funding (25N). They argued that if a business case is always required, there will be no room for the type of innovation needed to succeed in the industry. The vast majority of projects will not succeed, and only a

small minority will. It is not possible to have a business case every time, so companies must be willing to take risks. Thus, management must be aligned with such a risk-taking approach.

Short-term prioritization often comes at the long-term expense.
The classic exploration-exploitation trade-off emerged several times during the interviews, particularly among larger companies. Large companies have a portfolio of existing devices that require maintenance to remain on the market. According to one interviewee, the work burden of maintaining those products increases over time. According to several interviews, exploitation, which focuses on maintaining existing products, is always prioritized when resource conflicts occur. They cannot deprioritize existing products because cash flow would decline, resulting in fewer resources for innovation. Customers must always be prioritized. This aligns with interviewee 27P's and 28P's description of how the industry has changed: less radical innovation and a greater focus on incremental innovation among large companies. This may eventually become a significant problem when patents/intellectual property rights expire. One company reported that crucial patents will run out in the coming years, while the innovation pipeline remains limited.

Immature projects are entering design control
Interviewee 23N reported that immature projects enter design control and wanted to change that. Interviewee 1A stated that company A has worked a lot on the innovation phase to decide which projects to proceed with, but still needed to improve. Respondent 2A emphasized the same thing, stating that processing projects before design control has been the respondent's greatest learning. It creates a significant administrative burden if changes need to be made during design control (2A). Interviewee 14J also reported that projects enter design control too early and that there is a need for stricter entrance requirements. Interviewees 27P and 28P reported the same tendency of immature projects entering design control too early and the need for more mature projects before entrance.

5.2.5 Organizational and Cultural Barriers
Organizational and cultural barriers were reported in different settings across various companies but remain a significant challenge in many aspects.

Employees and business units have resistance to change.
Respondent 1A reported difficulty making people understand their organizational transition, in this case more towards a project-oriented matrix organization. Previously, line managers had a higher mandate than project managers, which changed with the transformation. This was hard to accept among line managers, and it is in general hard to change employees' mandates, according to the interviewee. After introducing a change, it is easy to fall back into old habits, which was the case for a company that had consultants implement the change (2A). Interviewee 21L also highlighted the tendency to fall back into old process habits after a while, where consultants had also been involved in driving change.

Conflicting goals create friction within cross-functional teams.
As mentioned before, several medical device companies have transitioned toward more cross-functional collaboration, which has introduced new challenges. Sometimes, different divisions have conflicting goals, priorities, or interests. According to interviewee 2A, setting division targets almost exclusively leads to interdivisional conflicts. The most common challenge with cross-functional teams is conflicting goals and this was mentioned several times as a reason why cross-functional teams fail (2A, 11H, 12H, 14J, 15J). Respondent 12H mentioned sandbagging as a challenge when working in cross-functional teams. Sandbagging occurs when

everyone tries to minimize their own risk, which makes projects difficult to execute (12H). One example could be the conservative interpretation of regulations that accompany international guiding standards to mitigate the risk of being accused of doing too little. This minimizes individual risk, but at the organization's expense, especially when the interpretation is overly conservative.

Further, company H had a sales employee incentive model based on expectations and whether they surpassed anticipated sales. This introduced the self-interest of keeping sales expectations very low. Getting funding for new business cases becomes challenging when sales actively reduce sales expectations. In company K, the sales department had significant influence over NPD, sometimes leading to drastic changes in project direction based on the sales department's perceptions of what is important. At company K, the sales function was said to have had too much power relative to R&D, leading to scope changes mid-project.

Poor collaboration across business units creates inefficiency.
While some have transitioned to cross-functional teams, others have not or have not done so to a large extent. Lack of cross-functional collaboration results in important perspectives not being considered during development, making later changes expensive (3A). One interviewee described a specific situation where R&D had developed a promising solution, but purchasing and production were not involved early enough to flag that the chosen components would be very expensive to source at scale or that the planned design was difficult to manufacture reliably. Changes at that stage required going back through parts of the design, updating documentation, and in some cases repeating verification activities, all of which pushed TTM out by months. Another interviewee described a similar issue, where regulatory and clinical teams were brought in late, meaning that key claims could not be supported by the evidence plan and had to be revised, again at significant cost. Interviewee 2A observed that cross-functional teams can unintentionally increase the number of processes because when everyone talks to everyone, each function tends to add its own steps and documentation requirements.

Unassigned tasks fall through the cracks.
In general, several interviewees reported challenges with activities that did not have an assigned responsible employee. According to interviewee 16K, people tend to take a step back and relax in those settings. Interviewee 20L provided a clear example: the research department would occasionally propose an idea for a medical device and hand it over to the product development department. In this case, the “valley of death” was the transfer of the project to the product development department, where many projects failed because no one was responsible for the transfer. Activities fell through the cracks because everyone had their own priorities and business-as-usual tasks, which dragged out the transfer process. This problem was organization-specific and did not come up during the other interviews. However, the general concern about activities with no assigned responsibility was often described in terms close to inaction. Interviewee 7D stated that they lacked having a person from the management team assigned to the projects. Currently, no one on the management team knew the inner workings of each project, which provided limited insight.

5.2.6 Software-Specific Complexity
Software development posed specific challenges that were not present to the same extent for hardware. Interviewees from software-heavy companies repeatedly described issues with module interdependence, validation across multiple platforms, and the mismatch between the pace of software development and the pace of regulatory review.

Unclear module interdependence causes rework
Respondent 9F described how software is built in modules, where the boundaries between modules are critical. A small change in one module can trigger unexpected effects in the others, and in medical technology, every significant change requires the whole product to be tested again. 8E also reported module interdependence as a challenge, where changes in one part of the software can require updates to the entire software package. Respondent 20L also emphasized module interdependence as something critical. Interviewee 9F emphasized that software is never really finished, as bugs continue to be found and new development is always ongoing. Yet the regulatory framework requires the team to know upfront what they want to build, because significant changes later in the process are very expensive to handle. This tension between the open-ended nature of software development and the requirement to lock down scope early was described as one of the hardest aspects of software work in a regulated environment.

Backlog and platform compatibility take time
Interviewee 10G mentioned that they develop software that must run on many different hardware platforms and administrative systems, which means that every change request triggers extensive validation across all supported configurations. The interviewee described this as the single biggest bottleneck in their process, noting that the decision of how much to validate and verify for each change is a difficult one that shapes the overall pace of development. Backward compatibility was also raised as a constraint. Company G wants to stay backward compatible with older parameter files already on the market, but this limits how far they can evolve the software without triggering further validation work.

5.3 Proven Solutions and What More Can Be Done

Medical device companies have introduced a broad variety of actions to mitigate and limit present challenges. Some have been more successful than others, and some can be done more. This chapter is linked to research question three:

How do medical device companies successfully address these challenges in practice, and what more can be done?

5.3.1 Front-Load before Design Control

The importance of catching as many issues as possible early has been highly emphasized by several interviewees (2A, 3A, 9F, 11H, 12H, 13J, 23N), which highlights front-loading with cross-functional teams as a key solution. Investing more time in the innovation phase before transitioning to design control offers several advantages and is said to reduce the time it takes to bring a product to market. First, the phase before design control is less regulated, allowing for more flexibility in terms of iterations, design changes, input from new users, etc. The development of any medical device is highly iterative, with frequent changes in design, which is significantly harder to do during the design control phase. Interviewee 2A said that a key takeaway is to sort out as much as possible before the design phase because the administrative burden increases significantly during design control. Another interviewee said that they had everything crystal clear before starting the development phase (9F). Every attribute of the device should be ranked (9F). For example, is it more important for a car to start quickly or drive fast? New user needs will conflict with older ones, and changes will become very expensive later in the process. The iterative approach is most visible and most effective in the early and middle phases of development, where the cost of change is still manageable.

Adapt projects to anticipated future needs and requirements to reduce rework and delays.
Respondent 9F emphasized the importance of future visioning, meaning that it is essential to have employees who can envision the future. When designing the device, it is important to consider mega trends, industry trends, regulations, technology, and user needs. Since development cycles occasionally span several years, setting the project on the right path from the beginning mitigates the risk of future rework and delays. Several interviewees described how they engage with institutions that establish regulations (B, L). This allows them to know what is about to be introduced and to influence regulations in the desired direction. As interviewee 18L emphasized, adapting to future regulations that have not yet been implemented is a way to mitigate rework and reduce the risk of delays. Company O explained that they decide very early what clinical and commercial claims the product needs to support, as these claims drive design choices, classification, and the required regulatory evidence. Aligning sales, regulatory, R&D, and clinical functions around the claim strategy at the start of the project reduces the risk of late-stage rework caused by sales promises that the device cannot legally support or by clinical studies that were set up to answer the wrong question.

Involve and iterate with users to secure user needs.
Front-loading is also essential to ensure that the medical device actually meets user needs. According to successful cases in interviews, the work should be highly iterative and close to the user. Testing module by module without overdeveloping is a winning concept. Interviewees 25N and 27P stated that testing an incomplete solution that one might be “ashamed of” is important for validating needs and the direction of development. Then, improvements can be made based on the input. Interviewee 25N drew a comparison to the massive project Millennium, which failed completely upon launch. According to the interviewee, this was largely because Millennium had not been validated or co-developed with users. They tried to

release a system that did not meet users' needs. The same company changed their innovation phase to a much more iterative one based on Stanford Biodesign. Interviewee 24N said it includes many iterations and observing users in real situations, not just listening to them. Advanced interview techniques helped them identify the core problem. The interviewee added that they always start with the most critical and important aspects first.

Use iterative sprint gates with killer questions to mature and filter innovation projects.
Company H worked in thirty-day sprints, using "killer questions" in a very iterative way. These were questions that needed to be answered by the end of the sprint, otherwise there was a risk of decommissioning the project. Although some leeway was given for delays or unanswered questions, the deadlines helped close projects in time and pursue only the most promising ones. The innovation phase is like a mini-project, and when it is successful, it results in a product description. Interviewee 12H mentioned that the innovation phase was the most challenging and crucial activity for a successful project. The requirements for moving on to design control should be strict so that only mature projects are approved (23N).

5.3.2 Organize for Cross-Functional Execution to Reduce Time to Market

Cross-functional collaboration was mentioned several times as a way to shorten TTM. Cross-functional collaboration enables early onboarding, commitment, and knowledge sharing among departments. It also enables concurrent engineering and collaborative design, resulting in a device that suits all functions. Respondents 1A and 2A noted that before the transition to a more cross-functional approach, everything was very sequential, which drove up lead times. Interviewee 1A claimed that minimizing TTM requires a cross-functional approach. This approach enhances collaboration, encouraging each function to take responsibility for their deliverables without blaming others for delays. In the early stages, the desired outcomes should be determined because they affect the design, classifications, etc. Collaboration between the market and regulatory sectors is essential for effective knowledge sharing. Otherwise, significant investments in work and resources can be wasted on fruitless standards and similar activities. Interviewee 2A claimed that, in many cases, customers do not value or understand some of the standards, making them unworthy of investment. Further, interviewee 5C claimed that the Quality Assurance/Regulatory Affairs (QA/RA) and production departments must be involved early on to ensure the device is testable and buildable. The purchasing department must also be included early on so that delivery lead times do not extend TTM. Respondent 2A reported that the result of the cross-functional transition was that all functions took shared responsibility for staying on schedule instead of blaming the previous function in a sequential handover chain. The interviewee noted that this led to shorter TTM and greater commitment in the early phases.

Create a common vision and goal to enhance cross-functional collaboration.
As discussed, division goals often result in conflicting interests, a frequently mentioned problem. An equally frequent solution is to establish a common goal. One metaphor mentioned by interviewee 15J is to imagine two people sculpting rocks: one is cutting stone, while the other is building a cathedral. There is a massive difference, though initially only psychological, which becomes physical over time. The interviewee talked about the importance of imagining the same look, smell, and impressions collectively as a team to move in the same direction. Further, interviewee 9F mentioned that great leadership is needed to leverage the potential of cross-functional teams, where leaders combine competencies and achieve synergies rather than conflicting goals. It is also crucial to get everyone on board before making a change and to ensure that everyone understands why the change must be made. This is particularly important

when implementing drastic changes, such as introducing a completely new process or restructuring the hierarchy.

Build and enforce cross-functional ways of working through long-term change management.
Respondent 21L reported that the cross-functional transition required step-by-step change management, including educating project leaders, raising their status, and getting line managers to understand that the project leader is backed by the management team. The interviewee emphasized that believing a new process has been implemented after six months means the work has only just begun, and that the organization has a natural tendency to slip back into old ways of working if consistency is not maintained. Company L had shifted from a line organization to a project-based, cross-functional structure, and described the change as something that took years rather than months. They started with a small project team, educated the project leaders, raised the status of the project leader role, and worked with line managers to ensure they understood that the project leader was backed by the management team. The interviewee underlined that after six months of implementation, the organization has only just begun the change. Without consistent reinforcement, the interviewee warned that the organization naturally slips back to the old way of working. Interviewees 1A and 21L emphasized that the organization has to be strict and enforce the changes in order to make them successful. Respondent 21L continued that consultants can help get a new process up and running in three months, but someone inside the organization has to carry it forward afterwards.

Examples of successful cross-functional structures.
Company I has recently undergone a structural change, as coordination and synchronization took too much time in their cross-functional setting. They divided the organization into different value streams that could independently create value for customers through new features or similar. Previously, employees had not designated time to each process, which increased coordination activities, while after the shift, employees had assigned time to specific value streams. The idea is that every value stream should have the resources to take an idea to commercialization without having to coordinate with other value streams to the same extent. Respondent 13I stated that this has decreased TTM but has come at the expense of the holistic perspective, which they are now working to improve.

Respondent 26O reported that they had added another layer of responsible project managers between the previous project manager and the different functions. Even if they worked cross-functionally before, the cooperation was significantly improved and more functions were engaged earlier in the development process, according to interviewee 26O. In this structure, they had also prolonged the timeframe during which the project manager is responsible for the device, extending it from launch to a period after launch when user feedback is collected.

Company P worked together with a medical device company that had one highly prioritized device project that had to be finished within a year. They conducted in-depth market research where they assigned a user experience coordinator responsible for securing user needs. User interviews and observations were carried out intensively over a short period, and decisions about what to include in the product were made quickly and backed by the management team. The interviewee described this as proof that when the right mindset, the right resources, and the right decisiveness come together, the organization can move much faster than its normal pace. The lesson for other companies, according to the interviewee, is that the speed of a project is often determined less by the process itself and more by how committed leadership is to be protecting it.

5.3.3 Keep Quality Management System Lean

To reduce unnecessary regulatory burdens, the QMS should only include absolutely necessary information. Interviewee 12H made this clear by stating that the QMS should only include the basic regulatory requirements. There should be guiding best practices that do not overcomplicate the regulatory burden or leave employees unguided, as detailed guidance is necessary in some areas. The same respondent said that the company had detailed Standard Operating Procedures (SOPs) and wanted to remove some of the detail. Furthermore, as described in the section on challenges, large corporations tend to add another activity to the process when things go wrong. This contributes to the decline in productivity. Interestingly, the same respondent had previously claimed that their current QMS was not detailed enough for some people because not everything is spelled out which causes them to get lost.

Create accessible process guidance through visual overviews, and employee education.
Company P emphasized the importance of creating space to have flexibility and within the QMS. They also emphasized the importance of having separate guiding documents outside the QMS. They further recommended educating employees on the process, claiming that this is not done properly, and making the process accessible to employees. A forty-page educational document does little to ensure that everyone receives the necessary overview of a company's processes. It is currently not emphasized enough that illustrating processes with figures and ensuring that employees understand them deeply, rather than just checking a box in a formal document, is important.

5.3.4 Be Closer to Users and Observe Behaviors

Co-development with the customer has emerged as a successful strategy for meeting user needs. 3A stated that user knowledge is the most important; if it is missed, everything falls apart. It should not be overlooked, and a systematic evaluation method should be established. This involves not only interviewing customers but also observing them and employing advanced interviewing methodologies. This may seem obvious, but according to one interviewee, this was not always the case. Creating a 1:1 scale prototype is also important so users can experience the future device as closely as possible, which interviewee 3A mentioned. Testing and iterating with digital twins came up in a few interviews. Some companies apply this approach, while others do not, sometimes due to limitations related to their devices.

Access to users is crucial and has been reported as a problem, especially at one firm. Hospital collaboration, in-house nurses and doctors, collaboration with external experts, and developing contacts with key opinion leaders have all been reported as ways to validate user needs and support co-development. While the sales department often receives complaints or proposals from users, nine out of ten of those are not considered real needs. The key to gaining access to hospitals is to engage with the right stakeholders (25N).

5.3.5 Prioritize in a Structured Way and Protect Exploration

The standard of prioritization of features is typically some form of forum, which has had varying levels of success. The success factor seems to depend on having the structure in place, the right employees active in the forum, and the mandate to act.

Dedicate time and resources to exploration.
The traditional exploration-exploitation trade-off is dealt with differently across companies. As exploration is necessary for a long-term innovation pipeline, cases where exploration is not doing so or deprioritizing it is considered a poor solution. Company N assigned fifty percent of

an employee's workload during two months to innovation work when assigned as an innovation manager. At company L, even if ten percent of the resources were assigned to innovation, this was the first area to be deprioritized when reductions were needed. The separation between exploration and exploitation is not implemented to a sufficient extent, where at least one company is expected to face major problems in the future due to a lack of innovation in the pipeline.

The right people and mandate are needed for efficient prioritization.
Several companies described structured ways of handling feature prioritization. A common approach is an internal forum or idea hub where anyone in the organization can submit an idea or feature proposal. The idea owner is then expected to motivate the proposal, typically with a one-page business case that is discussed with a management group or cross-functional committee, as described by company G. Respondent 10G described this process as a key mechanism for deciding which feature requests from OEM customers should be picked up and in what order. What separates forums that work well from those that do not, according to the interviewees, is whether the right people are in the room and whether they have the mandate to actually say no. Without that, the forum risks becoming a list-building exercise rather than a prioritization mechanism. Interviewee 18L emphasized that project managers need to say no more often instead of adding more features.

5.3.6 Assign Responsibility and Follow-Up on Deliverables

12H mentioned that the most impactful change they had implemented was assigning clear responsibility for resource planning. Company L, which had experienced problems related to the "valley of death," assigned a dedicated individual responsible for the transfer, which improved the situation, although it has not yet been fully resolved. Respondent 27P highlighted a general tendency to blame external factors rather than take ownership. Assigning responsibility has proven to be an effective solution when activities are not progressing as intended, as noted in the interviews, since individuals are less likely to underperform when accountability is clear. Following up on deliverables in combination with clear ownership has also been successful.

Company O described extending the responsibility of project managers beyond the development phase to include the period after launch, until initial customer feedback has been received. This means that the same team that develops the product is also accountable for its real-world performance. Combined with earlier involvement of multiple functions, this creates a continuous thread of ownership from concept to market feedback.

6 Discussion and Practical Recommendations

The discussion is based on the chapter 5.3 Proven Solutions and What More Can Be Done, as these insights represent the thesis's main contribution. By discussing the solutions, the current situation and the identified challenges are also addressed, but in a more practically useful context than if they were discussed separately. In this way, the study can be seen as an empirical complement to Shah's (2024) literature review, as it both confirms and extends Shah's findings through insights from practitioners. Each section concludes with a practical recommendation, and the six practical recommendations (PRs) are presented in Table 3.

Table 3: Overview of the practical recommendations

PR 1	Medical device companies should front-load critical user, technical, commercial, and regulatory learning before design control to reduce rework, improve device-user fit, and shorten TTM.
PR 2	Medical device companies should organize development around empowered cross-functional execution to reduce handovers, misalignment, late rework, and TTM.
PR 3	Medical device companies should keep the QMS lean by separating mandatory requirements from practical guidance to avoid unnecessary documentation burden and preserve flexibility.
PR 4	Medical device companies should involve and observe users throughout the lifecycle to improve requirement quality, device-user fit, compliance, and TTM.
PR 5	Medical device companies should protect exploration with dedicated resources and clear prioritization to prevent future innovation from being crowded out by urgent short-term work.
PR 6	Medical device companies should assign clear ownership for key deliverables and follow them up across phases to strengthen accountability and prevent tasks from falling between functions.

6.1 Front-Load before Design Control

The findings indicate that medical device companies should front-load critical user, technical, commercial, and regulatory learning before design control to reduce rework, improve device-user fit, and shorten Time to Market (TTM). This is because design control marks the point at which flexibility decreases and the administrative burden increases. Once a project has entered design control, design changes, requirement changes, and shifts in intended use become more expensive because they may affect documentation, verification, validation, risk management, and regulatory evidence. Therefore, the results suggest that medical device companies should resolve critical uncertainties before design control rather than carrying unclear user needs, weak claims, or unresolved technical assumptions into the formal development process.

This finding is consistent with the theoretical understanding of the Fuzzy Front End (FFE) presented by Ferreira et al. (2017) and Markham (2013). The FFE, in this thesis understood as the innovation phase, is characterized by uncertainty, iteration, and exploration, but it is also one of the most important phases for later product success, as found by Markham (2013). In regulated medical device development, this phase is even more critical because uncertainty that is not resolved early is not simply transferred into later development. Instead, it risks becoming formalized into requirements, documentation, and verification activities. If the original assumptions later prove incorrect, the consequences are larger than in less regulated industries. Front-loading should therefore not be understood as adding more work at the beginning of the project, but as shifting learning activities to the phase where learning is least costly.

The findings are in line with previous research, particularly the argument that medical device New Product Development (NPD) often fails when risks, user needs, and market requirements are addressed too late (Shah, 2024; Marešová et al., 2020; Haarmann & Holler, 2024). This is supported by the interviews, as early exploration before design control helps companies test

assumptions, understand user needs, and reduce uncertainty before formal development begins. The empirical findings show that successful companies use the early phase to clarify user needs, intended use, clinical and commercial claims, technical feasibility, and regulatory implications before the project enters formal design control. Several companies emphasized the need to work closer to users early in the process, not only by asking them what they want, but by observing their actual work practices and testing incomplete concepts. This is important because user needs are often hidden, tacit, or shaped by existing routines. Users may not always be able to articulate what they need, particularly if they have become accustomed to inefficient workflows. This supports the relevance of Stanford Biodesign, where clinical immersion and problem understanding are prioritized before solution development. In this thesis, the companies that had adopted more need-driven and iterative front-end practices appeared better positioned to identify the right problems before committing to a solution.

Front-loading should not be confused with locking all requirements too early or defining everything upfront before execution begins. A traditional interpretation of front-loading could lead companies to believe that all uncertainty should be eliminated before design control, but the findings suggest a more nuanced interpretation. The purpose is rather to reduce the most harmful uncertainty before design control while still allowing requirements to develop iteratively as knowledge improves. This is especially relevant for software and software-intensive medical devices, where requirements often evolve as prototypes are tested. A practical solution identified in the findings is to release requirements as an initial version and update them continuously during development, instead of treating the first requirement specification as final. Companies therefore need clear criteria for what must be clarified before design control and what can remain flexible. The most important elements to clarify early are those that are expensive or difficult to change later, such as intended use, major user needs, core claims, regulatory pathway, critical risks, system architecture, and feasibility of verification and validation. Less critical details can be allowed to evolve during development, provided that the process maintains traceability and controlled change.

Long TTM was one of the most recurring challenges in the interviews, where regulatory burden and late rework were central reasons for this. Since medical device development cycles often span several years, external conditions such as regulation, technology, market expectations, and user needs may change before launch. By clarifying the project direction early, companies reduce the risk of discovering fundamental problems after major investments have already been made. Front-loading therefore improves TTM not by making the first phase shorter, but by reducing avoidable loops in later phases.

Practical Recommendation
Medical device companies are recommended to use front-loading as a deliberate strategy to mature projects before entering design control. This means identifying and resolving critical issues early, aligning the project with anticipated future needs and requirements, iterating closely with users to secure real user needs, and using sprint-based gates with killer questions to mature, redirect, or stop innovation projects in time. Stanford Biodesign, which has been adopted by two of the studied medical device companies, may be a suitable methodology for structuring the innovation phase. Before the formal phase begins, companies should clarify intended use, core user needs, principal claims, regulatory pathway, critical risks, system architecture, and feasibility of verification and validation. By shifting learning to the phase where change is least costly, companies can enter design control with more consistent assumptions, reduce late rework, and shorten TTM without compromising compliance.

6.2 Organize for Cross-Functional Execution to Reduce Time to Market

Medical device companies should organize development around empowered cross-functional execution to reduce handovers, misalignment, late rework, and TTM. NPD of medical devices require input from R&D, quality, regulatory affairs, clinical, production, purchasing, marketing, and sometimes external healthcare actors. If these functions work sequentially, important constraints are discovered too late, and concurrent engineering becomes difficult. This creates rework, delays, and internal blame between departments. The results therefore indicate that medical device companies need to organize development around cross-functional execution rather than functional handovers.

The findings confirm previous research on the importance of cross-functional collaboration, but also add nuance regarding why it is particularly important in regulated medical device development. Previous research highlights that poor communication between functions, users, and regulatory stakeholders can lead to delays, misalignment, and development failure (Shah, 2024; Marešová et al., 2020). Similarly, Whitmore (2025) argues that medical device NPD requires early integration of regulatory, market, engineering, and clinical perspectives to improve safety, usability, compliance, and time to market. This study supports these conclusions, as the interviews show that cross-functional execution helps companies identify issues earlier, reduce handovers, and improve alignment between commercial, technical, and regulatory requirements. This is particularly important because decisions in medical device development are highly interconnected. For example, a design decision may affect manufacturability, verification, usability, regulatory classification, clinical evidence, and market claims. If regulatory, quality, or production functions are involved only after the design has matured, they may identify problems that require redesign. The findings therefore suggest that cross-functionality is not sufficient in itself. To reduce delays, rework, and misalignment, it must be supported by clear ownership, shared priorities, decision rights, and continuous involvement of relevant functions. Without these conditions, cross-functional teams risk becoming coordination forums rather than effective execution structures, which can allow the same problems found in silo-based organizations to remain.

The results also suggest that cross-functional collaboration shortens TTM through concurrent engineering, which confirms Whitmore's (2025) argument. Instead of waiting for one function to complete its work before the next begins, several functions can work in parallel around a shared project direction. This requires early onboarding and shared ownership. Interviewees 1A and 2A described how sequential processes created long lead times, while more cross-functional structures improved commitment and reduced the tendency to blame earlier functions for delays. This is important because TTM is not only a technical issue, but also an organizational issue. Delays often emerge from coordination problems, unclear ownership, and conflicting priorities between departments.

However, findings show that simply placing people from different functions in the same project does not guarantee effective collaboration, which is in line with Whitmore's (2025) argument that cross-functional collaboration is not straightforward to implement. McDonough (2000) found that establishing common goals, team leadership, and cooperation are central for effective cross-functional teams, which is also reflected in this study. Interviewee 9F emphasized that strong leadership is needed to combine competencies and create synergies rather than conflicting goals. The findings also indicate that conflicting functional goals often create inefficiency. For example, company H had sales commissions based on exceeding the

business case's anticipated outcome, which created incentives to lower the business case outlook and conflicted with the business case owner's objective. Even if individual functional goals are legitimate, the development process becomes fragmented if they are not integrated into a shared project objective. Cross-functional execution therefore requires clear roles, shared goals, decision rights, and project leadership with sufficient mandate to coordinate across functions, manage dependencies, and secure resources. If project leaders are responsible for progress but lack authority over resources and priorities, cross-functional execution becomes difficult. In this sense, cross-functional collaboration is not only about communication, but also about creating a common decision logic and an execution structure with real authority.

Change management is also crucial to get everyone on board before making a change and to ensure that employees understand why the change is needed, which is in line with Kotter's (2007) emphasis on motivation, communication, empowerment, and reinforcement. This is particularly important when implementing drastic changes, such as introducing cross-functional collaboration or restructuring the hierarchy, as company A did. The findings show that moving from a sequential or line-based structure to a cross-functional structure takes time and requires education, management support, and consistent reinforcement. Organizations tend to revert to old routines if the new way of working is not institutionalized, which corresponds to Kotter's (2007) argument that lasting change requires continuous reinforcement. In practice, this means that a new cross-functional process cannot be implemented only through a new process map. It must be supported by training, adjusted incentives, clear escalation paths, and management behavior that reinforces the new structure.

The results also suggest that there is no single best cross-functional structure. Different companies used different approaches, including value streams, additional project management layers, and project managers with extended responsibility after launch. These examples suggest that the specific structure should depend on the company's product complexity, size, and development context. For software-heavy products, smaller agile teams may be effective. For hardware-heavy or system-level products, a stage-gate or V-model backbone with cross-functional work inside each phase may be more appropriate. For companies with several product lines, value streams may reduce coordination needs, although this can come at the expense of a holistic perspective. The common denominator is not the exact structure, but that functions are integrated early and given shared responsibility for delivery.

Practical recommendation
Medical device companies are recommended to organize development around cross-functional execution rather than functional handovers, with clear ownership, shared project goals, decision rights, and a project leader with the mandate to coordinate across functions. Regulatory, quality, clinical, production, purchasing, and commercial perspectives should be integrated from the start so that work proceeds concurrently rather than sequentially and important constraints are identified before they create late rework. Companies should choose the cross-functional structure that fits their product complexity and context, such as value streams, or additional project management. However, the structure must be reinforced through long-term change management, including training, adjusted incentives, management support, and clear escalation paths, since cross-functional collaboration does not become effective only through a new process map. Cross-functional execution should be treated as a complement to front-loading, ensuring that early decisions are translated into coordinated action and that long TTM, late rework, and internal misalignment are addressed at an organizational rather than only a process level.

6.3 Keep Quality Management System Lean

Medical device companies should keep the QMS lean by separating mandatory requirements from practical guidance to avoid unnecessary documentation burden and preserve flexibility. This does not mean that the QMS should be weak or incomplete. Instead, it means that the QMS should include what is necessary to ensure compliance, safety, traceability, and product quality, without adding extra steps that do not create clear value. As interviewee 12H argued, the QMS should mainly include the core regulatory requirements, while more detailed best practices can be placed in separate guiding documents. Since the declaration of conformity issued by a notified body certifies that the company works in accordance with its QMS (Läkemedelsverket, 2024), writing too much into the QMS also creates more requirements that must always be followed and proven.

If regulations and international guiding standards are interpreted excessively conservatively in the QMS, the notified body assesses whether the company has done what it has stated it will do, which can make the regulatory burden more extensive than necessary. This is important because regulatory burden was found to be the main bottleneck for shortening TTM, which is in line with Shah (2024), who identifies regulatory hurdles as one reason why medical device development projects fail. Carl and Hochmann (2024) also describe how MDR has increased documentation work for medical device companies. However, the results of this thesis suggest that the problem is not only the regulation itself, but also how companies translate regulation into internal processes. Several companies were described as exceeding the necessary requirements (A, B, C, I, J). One reason for such conservative interpretations may be sandbagging, where functions, including QA/RA, add extra requirements, margins, or documentation to protect themselves from future criticism or uncertainty. By working cross-functionally with shared goals, companies can reduce this tendency, since regulatory, quality, technical, and commercial perspectives are aligned around what is actually necessary rather than what each function adds defensively.

In this sense, an overly detailed QMS can become a self-imposed obstacle. Companies may remain compliant, but the process becomes slower, heavier, and less flexible. As several interviewees reported, when something goes wrong, the natural response is often to add another activity, review, or approval step. However, this can gradually make the process harder to use and reduce productivity. The findings therefore suggest that companies should actively review, simplify, and remove unnecessary detail from the QMS instead of allowing it to grow without control. A lean QMS can therefore be understood as a way to manage increased documentation pressure without reducing compliance.

The discussion also connects to process model theory. Wynn and Clarkson (2018) argue that development processes should be chosen and adapted based on the situation, because no single model can capture every part of development. This is relevant for the QMS because the system should provide the required structure while allowing teams to adapt their way of working within that structure. A lean QMS can therefore support both control and flexibility by giving the organizations clear rules where they are needed, while avoiding unnecessary formalization where guidance, training, or best-practice documents would be enough.

The results also show that a lean QMS does not mean giving employees less support. Company P emphasized that companies should create space within the QMS and use separate guiding documents outside it. They also argued that employees need better education in how the process works. The solution is therefore not simply to remove content, but to separate mandatory requirements from practical guidance. Mandatory requirements should stay in the QMS, while

examples, templates, explanations, and best practices can be placed outside the QMS. In this way, employees can receive practical support without making every instruction part of the formal system that must be audited and followed in all situations.

Keeping the QMS lean is also relevant for TTM. Several interviewees described how extensive internal processes slow down development. If every change requires too many formal steps, approvals, and documents, development becomes less responsive. This is especially problematic for software and other fast-changing medical device technologies where learning and iteration are important. McHugh (2015) argues that agile methods can be used in regulated medical device software development if documentation, traceability, and risk control are integrated into the development work. A lean QMS fits this view because it does not conflict with compliance, but makes compliance easier to handle during development instead of becoming a separate administrative burden. However, this requires that employees understand how to apply the remaining rules, meaning that simplification must be combined with training and clear ownership.

Practical recommendation
Medical device companies are recommended to actively design the QMS as a strategic tool rather than a defensive document and limit it to the requirements that genuinely ensure safety, performance, traceability, and regulatory compliance. Detailed best practices, templates, explanations, and examples should be placed in separate guiding documents outside the QMS so that mandatory rules are clearly distinguished from practical guidance. Companies should periodically review and simplify the QMS to prevent uncontrolled growth, combine the lean structure with training, and resist the tendency to add formal steps after every incident. The second recommendation on cross-functional collaboration may also support this work, as shared goals and early alignment between functions can reduce overly conservative interpretations and defensive additions to the QMS. By doing so, companies avoid creating a higher regulatory burden than the regulation itself requires, while preserving compliance, flexibility, and the space needed for faster iteration and innovation.

6.4 Be Closer to Users and Observe Behaviors

Medical device companies should involve and observe users throughout the product lifecycle to improve requirement quality, device-user fit, compliance, and TTM. The findings indicate that securing user needs is challenged by limited access to users and hospitals, insufficient user involvement, poor translation of user needs into technical requirements, and overlooked selling points. These challenges can prevent companies from fully understanding the user context and the basis on which customers choose a device. The findings support previous research by Marešová et al. (2020) and Shah (2024), which identifies market misalignment as a critical reason why medical device NPD may fail. If user needs are not identified, interpreted, and translated correctly, the company risks developing a technically functional and regulatory-compliant product that still fails to create sufficient value for users. Since user needs are particularly uncertain in the early innovation phase, early user observation becomes central for improving design inputs before they are formalized (Ferreira et al., 2017; Markham, 2013).

The results also show that observing users in their real working environment can reveal needs that are difficult to capture through interviews alone. Users may not always be able to clearly express their needs, either because certain problems are taken for granted or because workarounds have become normalized in daily practice. This is consistent with Haarmann and Holler (2024), who argue that identifying user needs in medical device development is challenging because access to healthcare professionals and patients can be limited and because

user statements may be difficult to interpret objectively. The findings in this thesis suggest that observation can complement interviews by allowing development teams to see how devices are actually used, where inefficiencies occur, and how clinical workflows shape product requirements. Several interviewees also emphasized that user involvement should be iterative and occur before the solution is overdeveloped, for example by testing incomplete concepts or individual modules with users. In this way, observation and early prototype testing help companies move beyond stated preferences and instead understand actual user behavior.

Stanford Biodesign strengthens this argument by emphasizing that medical innovation should start with unmet clinical needs rather than with a predefined technical solution (Chua et al., 2024). Through clinical immersion, observation, and interaction with healthcare professionals and patients, development teams can gain a deeper understanding of the problem before deciding what solution to develop. Interviewees 25N and 27P emphasized that testing unfinished solutions can be valuable for validating both the user need and the direction of development before major resources are committed. Similarly, interviewee 24N described how a more iterative innovation phase based on Stanford Biodesign, including repeated iterations, user observations, and advanced interview techniques, helped identify the core problem before solution development. A more needs-driven approach can therefore improve product relevance, development efficiency, and the quality of early design inputs.

However, closer user involvement also creates practical challenges. Medical device companies operate in a regulated environment where user feedback cannot simply be translated into product changes without considering risk, documentation, verification, validation, and regulatory consequences. This means that user involvement must be integrated into the formal development process rather than handled informally. Design control theory is useful here because it highlights the importance of maintaining a traceable chain from user needs to design inputs, design outputs, verification, and validation (Zhang & Cresswell, 2016). The findings indicate that companies should not only collect user insights but also systematically document how these insights are evaluated, translated into requirements, and tested. Otherwise, valuable user knowledge may remain disconnected from the formal development process. This also supports an iterative approach to user involvement, where feedback is collected continuously but translated into requirements, risk assessments, documentation, and traceability in a controlled way (Hron & Obwegeser, 2022; McHugh, 2015).

The findings further suggest that companies should distinguish between different types of user involvement. Early in the process, the goal should be exploration: understanding workflows, pain points, unmet needs, and the broader clinical context. Later in the process, the focus should shift toward validation, testing whether the proposed solution actually meets user needs and intended use. This distinction is important because involving users late in the process may identify problems when the product concept is already difficult and expensive to change. Earlier involvement can instead prevent misalignment before major investments have been made. This aligns with previous research emphasizing that user needs should be considered as early as possible to improve customer fit and reduce development failure (Chen et al., 2023; Shah, 2024).

Closer user involvement can also reduce TTM, even if it initially requires more time and resources. At first glance, extensive user research, observation, and clinical immersion may appear to slow down development. However, the results indicate that insufficient understanding of user needs can lead to rework, unclear requirements, delayed decisions, and late-stage changes, all of which extend development time. From this perspective, early user involvement

should be seen as a TTM enabler rather than a delay. By improving the quality of early decisions, companies can reduce uncertainty and avoid developing features or solutions that later prove irrelevant. This is consistent with the idea that strong front-end work improves later NPD performance (Ferreira et al., 2017; Markham, 2013).

Finally, user closeness should continue after market introduction. Post-market surveillance under the MDR requires companies to collect and analyze information about how devices perform in real use. Rather than treating post-market activities only as compliance work, companies can use them as a structured source of user insight for future development. This can create a continuous learning loop where user feedback after launch informs product improvements, new opportunities, and future development projects.

Practical recommendation
Medical device companies are recommended to establish systematic routines for getting close to users and observing their actual behavior in the clinical environment, rather than only collecting stated preferences. User involvement should be planned as a continuous activity across the lifecycle, with exploratory observation, clinical immersion, and early testing of incomplete concepts or modules in the early phases, validation-oriented testing during design control, and structured use of post-market surveillance data as a source of learning rather than only as a compliance task. Insights from these activities should be documented and traceably translated into design inputs, requirements, and verification and validation activities. Treating user closeness as a TTM enabler rather than a delay allows companies to reduce uncertainty, improve requirement quality, and develop products that are clinically relevant, commercially successful, and compliant.

6.5 Prioritize in a Structured Way and Protect Exploration

Medical device companies should protect exploration with dedicated resources and clear prioritization to prevent future innovation from being crowded out by urgent short-term work. In this thesis, exploration refers to activities that search for new ideas, future technologies, user problems, new market opportunities, and possible future products. Exploitation, on the other hand, refers to selling, improving, and maintaining existing products, solving current problems, handling regulatory work, and delivering ongoing projects. Both are necessary. However, the results indicate that exploitation often wins when resources are limited, which connects directly to the empirical challenges of difficult prioritization, inefficient prioritization processes, short-term prioritization at the expense of long-term innovation, and immature projects entering design control too early.

This is particularly understandable in the medical device industry, where existing products require regulatory maintenance, documentation updates, quality work, post-market surveillance, and sometimes changes due to MDR. These tasks are urgent and directly connected to keeping products on the market, while exploration is more uncertain, long-term, and difficult to connect to immediate financial results. Since resources are scarce, prioritization must therefore mean eliminating activities, projects, or features, not only ranking them. This is important because adding too many projects or features risks stretching shared R&D, regulatory, quality, clinical, and management resources, which can increase TTM for all projects.

This connects to the theory of organizational ambidexterity, which describes the need to balance exploitation of existing knowledge and products with exploration of new opportunities (Raisch et al., 2009). O'Reilly (2011) argues that ambidexterity is important for long-term survival

because companies need to sense changes in the external environment and reconfigure their resources accordingly. The results from this thesis support this view. Medical device companies cannot only focus on today's products and today's regulatory demands. If they do, they may become efficient in the short term but weak in the long term. This is particularly relevant because medical device companies operate in a regulated but changing environment, where MDR-related demands, new technologies, changing user needs, and expiring patents or intellectual property rights make both control and exploration necessary. This also connects to front-end theory, as reducing early exploration may save resources in the short term but can create larger problems later in development when user needs, market fit, or technical assumptions prove incorrect (Markham, 2013).

The results show clear examples of how exploration becomes vulnerable when resources are limited. At company L, ten percent of the resources were formally assigned to innovation, but this was the first area to be deprioritized when reductions were needed. This indicates that exploration resources may need to be more clearly separated from ordinary project and maintenance work. If innovation resources are formally assigned but still easily reallocated to urgent exploitation tasks, exploration remains vulnerable in practice. In contrast, company N assigned fifty percent of one employee's workload to innovation work for two months when that person acted as innovation manager. This represents a stronger way of protecting exploration, because part of the employee's time was explicitly separated from regular responsibilities and dedicated to innovation work. This can be related to Chen's (2017) distinction between different forms of ambidexterity, as company L illustrates the weakness of innovation resources that remain too easy to reallocate, while company N shows a more sequential solution where a defined share of time is temporarily separated for innovation. These examples show that exploration needs more than verbal support or symbolic resource allocation. It must be protected through clearly separated time, responsibility, and management attention. However, such efforts need to be institutionalized rather than treated as temporary exceptions. The findings therefore suggest that companies that repeatedly deprioritize exploration risk weakening their future innovation pipeline.

The findings also show that prioritization forums can be useful, but efficient prioritization requires that the right people are present and that they have sufficient mandate to make actual decisions. Several companies used forums, idea hubs, or committees where ideas and feature requests could be submitted and discussed. For example, company G used a process where the idea owner prepared a short business case before the proposal was discussed with a management group or cross-functional committee. Interviewee 10G described this as a key mechanism for deciding which OEM customer feature requests should be prioritized. However, the results indicate that the success of such forums depends on whether the right people are present and whether they have the mandate to decide what should be prioritized, delayed, or rejected. Without this, the forum risks becoming a list-building exercise rather than a real prioritization mechanism. This also connects to interviewee 18L, who emphasized that project managers need to say no more often instead of continuously adding features. If companies cannot eliminate lower-priority activities, feature creep may occur, which risks increasing complexity, delaying projects, and threatening budget and schedule.

This is also related to project portfolio management. Martinsuo (2013) explains that organizations often struggle with allocating resources between competing projects. In medical device development, this becomes especially difficult because projects compete not only for R&D resources but also for regulatory, clinical, quality, and management resources. If too many projects or features are approved at the same time, TTM can become longer for all of them.

Therefore, prioritization should not only be about choosing attractive ideas. It should also be about limiting work in progress and making sure that the organization has enough capacity to deliver what it has already started. This is particularly relevant because respondent 6D described prioritization as difficult when resources are shared and the prioritization structure is unclear.

The findings further show that business case logic is necessary but can also create problems for early exploration. Projects and features were often motivated by business potential, with opportunities prioritized based on return on investment and short time to commercialization. This is understandable, especially when resources are scarce. However, uncertain innovation ideas may be difficult to justify with strong business cases too early. Interviewee 11H described the creation of strong business cases as a bottleneck for TTM, while interviewee 25N problematized that if a business case is always required to secure funding, there may be too little room for the type of innovation needed to succeed in the industry. Since most early innovation ideas will not become successful products, management must accept some risk rather than requiring every idea to be justified by a strong business case from the beginning. Thus, business potential is important, but an excessive reliance on business cases may leave too little room for uncertain but necessary exploration.

Early exploration should be allowed to remain open, creative, and uncertain, so that weak but promising ideas are not killed before they have had time to develop. This connects to Johal et al. (2008), who found that financial evaluation methods in medical device projects may undervalue early-stage projects and close them too soon. In the early phase, companies should therefore investigate user needs, future trends, technology options, and possible clinical problems without forcing every idea into a full product development project too early. However, exploration cannot remain loose indefinitely. If an idea starts to define intended use, product requirements, or safety-related claims, it must be transferred into the formal process with proper documentation, traceability, and risk management. If exploration is too loose for too long, important regulatory and technical issues may be discovered too late. A staged exploration process can therefore help companies balance flexibility and control. Early ideas can be evaluated with lighter criteria, such as user-problem strength, strategic fit, technical uncertainty, and possible regulatory pathway. Later, as the idea becomes more concrete, the evaluation can become more detailed and include business case, risk, clinical evidence needs, and regulatory workload. Such a staged process can help companies avoid both extremes, killing uncertain but promising ideas too early and sending immature projects into design control before they are sufficiently explored.

The results also suggest that companies should separate feature prioritization from exploration prioritization. Feature prioritization is often focused on existing projects or existing products. It asks what should be added, removed, or delayed. Exploration prioritization is different. It asks which future opportunities deserve protected time and resources. If both are handled in the same forum, urgent feature requests from current customers may dominate more uncertain innovation ideas. Therefore, companies may need a separate innovation forum or at least reserved agenda space where future-oriented ideas are reviewed on their own terms. This separation is important because short-term customer needs, regulatory maintenance, and ongoing product work often dominate when resources are scarce, while long-term exploration is easier to postpone.

Practical recommendation
Medical device companies are recommended to treat exploration as an organizational responsibility rather than a spare-time activity and protect it through structural means that cannot easily be eroded by short-term pressure. Companies should reserve a defined share of R&D capacity, dedicated roles, or recurring exploration sprints, and separate exploration prioritization from feature prioritization so that future-oriented ideas are not crowded out by current customer requests, regulatory maintenance, or ongoing product work. Prioritization forums should include the right people with sufficient mandate to make decisions about what should be prioritized, delayed, rejected, or stopped. Idea owners may be required to motivate proposals through short business cases before they are evaluated. However, early exploration should not depend only on strict business cases, since uncertain but strategically important innovation may otherwise be rejected too early. A staged evaluation logic should therefore be applied so that early ideas are assessed on user-problem strength, strategic fit, technical uncertainty, and regulatory feasibility, with stricter criteria introduced as ideas mature and transfer into the formal development and design control process. Management must also be aligned with the fact that exploration involves risk, since most early innovation ideas will not become successful products. Management must visibly defend these resources so that the company maintains a healthy innovation pipeline alongside its existing products and regulatory responsibilities.

6.6 Assign Responsibility and Follow-Up on Deliverables

Medical device companies should assign clear ownership for key deliverables and follow them up across phases to strengthen accountability and prevent tasks from falling between functions. The findings indicate that unclear ownership can make tasks fall between functions or phases, especially when several functions are involved and each function already has its own priorities and regular operational tasks. A first observation is that responsibility appears to shape behavior at the individual level. Interviewee 16K explained that employees may take a step back when tasks are not clearly assigned, while respondent 27P described a tendency for individuals to avoid being perceived as underperforming compared with their group. Respondent 27P also highlighted a tendency to blame external factors rather than take ownership, which further supports the need for clear accountability.

These observations suggest that visible deliverables and explicit ownership can strengthen accountability. At the same time, this tendency may also be explained by conflicting priorities. If no one has dedicated responsibility or allocated resources for a task, it risks being deprioritized in favor of other activities for which individuals are formally accountable. Assigning responsibility therefore has both a behavioral and a resource-allocation dimension. This is also reflected by interviewee 12H, who stated that the most impactful change they had implemented was assigning clear responsibility for resource planning. However, the employees who were assigned responsibility in the studied cases were not interviewed. The findings therefore reflect the perspective of decision-makers, not necessarily those carrying the responsibility. This limits the interpretation, since increased accountability may also increase pressure. Stronger responsibility structures should therefore be combined with sufficient resources, mandate, and support.

The findings also indicate that following up on deliverables is at least as important as assigning responsibility. Without follow-up, assigned responsibility risks becoming nominal rather than effective. Company O illustrates how follow-up can be designed in practice. In this case, the project manager’s responsibility was extended beyond the formal development phase and remained in place after launch until the first customer feedback had been received. This meant

that the same team that developed the product also remained accountable for its early real-world performance. As a consequence, the actions and decisions made during the project were indirectly followed up through customer feedback. This may encourage more responsible decision-making, since the consequences of earlier decisions become more visible over time and harder to attribute only to external factors. Combined with earlier involvement of multiple functions, this creates a more continuous thread of ownership from concept to market feedback. In this way, extending responsibility across phase boundaries closes the loop between decisions and their outcomes.

Assigning responsibility is also closely connected to how companies organize handovers between phases and functions. A standard process model with distinct stages and limited cross-functional collaboration may be more vulnerable to tasks falling between organizational boundaries. Company L, for example, had a clear separation between its research and product development departments. Interviewee 20L described this transfer as a "valley of death", where medical device ideas from the research department could fail to reach product development because no one had clear responsibility for the transfer. Activities therefore fell through the cracks, as employees had their own priorities and regular operational tasks, which delayed the handover. Company L later assigned a dedicated individual responsible for the transfer, which improved the situation, although the challenge had not yet been fully resolved. This suggests that handovers need both cross-functional involvement and a clearly assigned transfer owner. Cross-functional collaboration can increase engagement across functions and work as an onboarding mechanism into the project, which complements rather than replaces the need for clearly assigned ownership. Since company L described its current transition as not yet satisfactory, a clearer ownership structure combined with increased cross-functional involvement could further improve the handover between research and product development.

The results also suggest that assigned responsibility should not be limited to project leadership but extend to specific deliverables throughout the process. Several of the challenges discussed earlier in this thesis, including unclear user-needs translation and feature creep, can be partly understood as situations in which no single person held responsibility for ensuring that a particular deliverable was produced at sufficient quality. When responsibility is distributed across many people without explicit ownership, decisions tend to drift and important questions can remain unresolved until they become problems later in the development process. Defining responsible owners for specific deliverables, such as user-needs documentation, intended use, regulatory strategy, requirement specification, verification plans, and clinical evaluation, makes it clearer where progress should originate and where it should be followed up. This also relates to interviewee 7D's observation that projects lacked an assigned person from the management team, which limited management insight into the inner workings of each project. Clear ownership can therefore improve both project execution and managerial visibility.

In contrast to several of the other recommendations in this thesis, assigning responsibility was not explicitly identified as either a challenge or a solution in previous research, which makes this finding a complementary perspective on NPD in medical device companies. The contribution of this section is therefore not that responsibility is a new concept in NPD, but that the empirical material highlights its specific importance in a regulated and cross-functional environment. In medical device development, deliverables are often interdependent, and the cost of late discovery is high. This makes the combination of clear ownership and continuous follow-up particularly valuable as a mechanism for ensuring that earlier decisions translate into the documentation, evidence, and product characteristics required later in the process.

Practical recommendation

Medical device companies are recommended to assign clear individual ownership for key deliverables throughout the NPD process and follow up progress consistently. Responsibility should extend across handovers and formal phase boundaries, including the transition between research and product development and during the early launch period when the first customer feedbacks are received. Critical deliverables, such as user-needs documentation, intended use, regulatory strategy, requirement specification, verification plans, and clinical evaluation, should have an owner with sufficient mandate, resources, and cross-functional support. This reduces the risk of tasks falling between functions, strengthens accountability, improves management visibility, and ensures that early decisions remain visible and traceable to later outcomes.

7 Conclusions

The purpose of this thesis was to investigate the current New Product Development (NPD) situation and provide practical recommendations based on the findings. The thesis has provided several insights into NPD of medical devices: the current NPD processes employed, challenges, proven solutions, and what more can be done. The qualitative interview study was based on 29 interviews across 17 companies, supported by previous studies and theories. The thesis makes a practical contribution in the form of six practical recommendations for improving the NPD of medical devices. The recommendations can be applied individually, but they can also be used together, in which case they complement and reinforce one another. This thesis has also extended existing literature, particularly about the front-loading before design control and keeping the Quality Management System (QMS) lean.

To summarize the practical recommendations, medical device companies should strengthen the innovation phase before design control by working cross-functionally, focusing on user needs, and answering critical technical, commercial, user-related, and regulatory questions early on. This is particularly important for NPD of medical devices because the regulatory burden increases once the design control phase begins. This means projects should enter the formal development phase with a mature device-user fit, realistic time plans, clear selling points, and sufficient preparation for regulatory requirements. A structured, iterative approach such as the Stanford Biodesign model can support this process by testing simple concepts with users and using observations to better understand unarticulated needs. During design control and the rest of the NPD process, a governing structure, such as stage-gate or another formal governance structure, should be combined with execution-oriented methods, such as agile elements and the V-model. The workflow should remain cross-functional with common goals, aligned incentives, assigned responsibilities, and deliverables that are followed up on across phases. At the same time, the QMS should be lean, including only what is necessary to meet regulatory requirements. Overly conservative interpretations and unnecessary process complexity can increase the burden that companies create for themselves. Exploration should also be protected through dedicated resources and structured prioritization forums with the right people and sufficient mandate to make decisions. These actions can reduce rework, shorten time to market (TTM), improve prioritization, protect future innovation, and secure a stronger device-user fit without compromising compliance.

The contexts in which some medical device companies operate can be case-specific, such as limited access to users. This, however, mirrors the medical device industry's reality, where companies face different challenges depending on their context. Through the qualitative interview study approach, numerous perspectives have been shared, enabling insights into the current state of the industry. The study has mainly included decision-makers who have responsibility for development and medical devices, which may not fully reflect the researchers' and developers' perspectives on daily challenges and implemented solutions. On the other hand, accessing decision-makers usually provides the overarching insights that the study aimed to explore. The study has mostly included employees situated in Sweden, but as the companies are generally international and the MDR is active in the EU, similar results may be anticipated. This is also supported by the fact that the practical recommendations have strong support from previous studies and theories and are based on numerous interviewees across several international companies.

One enabler and limitation of this study is that data were collected through notes and not recorded, making the exact transfer from interviewees to data impossible. There is thus a risk that contexts were misunderstood. However, several mitigation strategies were employed. The

note-taking approach was an enabler for this study's in-depth findings, as some interviewees highly emphasized the importance of confidentiality for both the companies and themselves. The approach was deemed to be an enabler of this study's contribution, as the results would not have been achievable otherwise. Having access to their unfiltered opinions and experiences has been essential for the study. Future studies can investigate the implementation of the practical recommendations and thereby evaluate each element's impact on performance, for example regarding TTM and user needs fulfillment. Software-specific complexity is another area where future studies can extend and complement this study.

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Appendix 1 - Interview Guide - Medical Device Companies and Software Consultant Company

The study will examine the contemporary challenges that generally exist in the new product development of medical devices. A particular focus is on how user needs are met and how new product development is carried out in a resource- and time-efficient manner. The study also aims to map what is already being done today to address these challenges and how regulatory requirements are met. Finally, the study aims to develop concrete recommendations for how medical device companies can develop better devices in a more resource- and time-efficient manner, while meeting regulatory requirements.

1. Background and role
    a. Would you like to introduce yourself and your background?
    b. What are you responsible for at Company X?
2. Current situation: Product development in practice
    a. How would you describe product development today?
    b. What does the process look like from idea to launch?

Follow-up questions:

    c. Do you work according to a specific model? (Stage-Gate, V-model, Scrum, hybrid?)
    d. What works well in the process?
    e. What works less well?
    f. Impact on documentation?
    g. Clinical evidence?
    h. Change management/significant change?
    i. Collaboration with notified body?
    j. Time to market?
    k. Have you had to change your portfolio, priorities, or degree of innovation after MDR?
3. Agility and iteration
    a. How would you describe your working method - plan-driven, agile, or hybrid?
    b. Have you tried to implement agile methods?

If yes:

    c. What worked well?
    d. What did not work so well?
    e. How do you handle documentation in an iterative approach?

If no:

    f. What prevents you from working more agilely?
    g. Do you feel that agility is compatible with MDR?
4. User requirements and verification
    a. How do you identify user needs today?
    b. When in the process are users involved?
    c. How do you ensure that the product actually meets user requirements?

Follow-up questions:

    d. Do you work iteratively with user feedback?
    e. Are there any obstacles to working more iteratively?
    f. How are user requirements linked to risk management and regulatory documentation?
5. Resource and time efficiency

    a. What makes it difficult to meet user requirements in a resource- and time-efficient manner?
    b. Where do bottlenecks occur in the process?
    c. Are they regulatory, organizational, or technical in nature?
    d. How do you work to reduce time-to-market without compromising on regulatory requirements?
6. Future and potential for improvement
    a. If you could change one thing in your development process, what would it be?
    b. Which parts of agile working methods do you think could work better in your environment?
        i. Shorter feedback loops?
        ii. Time-boxing?
        iii. MVP thinking?
        iv. Cross-functional teams?
    c. What would be required organizationally for this to work?
7. Final reflection
    a. Is there anything important we haven't asked about?
    b. Is there anything you think is misunderstood about agility and MDR?
    c. Can we get back in touch if any questions arise?
    d. Is there anyone else at Company X we should talk to?

Appendix 2 - Interview Guide - Management Consultant Company

1. Background and role
    a. Could you briefly introduce yourselves and your background?
    b. What are you responsible for at Company X?
2. Current situation: Product development in practice
    a. How would you describe how product development has changed over the years?

Follow-up questions:

    b. Has any working model become more common? Has it changed for the better? Stage-Gate, V-model, Scrum, hybrid?
    c. Why?
    d. What works well in the process for medtech companies?
    e. Which parts do companies struggle with the most? Why?
3. Agility and iteration
    a. Have you tried to implement agile methods?

If yes:

    b. What worked well?
    c. What worked less well?

If no:

    d. What prevents you from working more agilely?
    e. Do you experience agility as compatible with the MDR?
4. User requirements and verification
    a. Do companies have problems with missed user requirements? How does this show?
    b. What causes it?
    c. How should one ensure that the product actually fulfills the user requirements?
5. Resource and time efficiency
    a. What makes it difficult to meet user requirements in a resource- and time-efficient way?
    b. Where do bottlenecks arise in the process?
    c. Have you helped a customer reduce time to market? How? What went well? What went less well?
6. Case
    a. Could you describe successful consulting cases?
    b. What was done?
    c. Why was it done?
    d. What went well?
    e. What could have gone better?
7. Future and improvement potential
    a. Which part of the development process is most important to get right? How should this be done?
8. Final reflection
    a. Is there anything important we have not asked about?
    b. Is there anything you think is misunderstood regarding agility and the MDR?
    c. May we contact you again if any questions arise?
    d. Is there anyone else at Company X we should talk to?

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