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INTEGRATING AGILE PRACTICES IN MEDICAL DEVICE HARDWARE DEVELOPMENT

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ABSTRACT

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This thesis explores the integration of Agile project management practices into medical device hardware development, with a focus on risk mitigation strategies. The purpose was to examine how Agile principles, typically used in software development, can be adapted to meet the strict regulatory and safety requirements of hardware-based medical projects. The research was conducted through a qualitative approach, combining a descriptive literature review with thematic analysis. The study used a mechanical CPR machine development project as a contextual reference to assess practical implementation challenges and benefits. Results demonstrate that Agile methods, when tailored to comply with standards such as ISO 13485 and ISO 14971, can support iterative development, early risk detection, and better alignment between technical teams and regulatory expectations. The findings suggest that Agile can enhance flexibility and efficiency in medical hardware development without compromising compliance or quality.

Keywords Agile development, medical device hardware, ISO 13485, ISO 14971, CPR machine

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ABBREVIATIONS

Agile	Adaptive Group of Iterative Lightweight Engineering
CPR	Cardiopulmonary Resuscitation
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JIRA	A project management tool for Agile tracking
LUCAS	Lund University Cardiopulmonary Assist System
MDR	Medical Device Regulation (EU)
PFMEA	Process Failure Mode and Effects Analysis
QMS	Quality Management System
R&D	Research and Development
RMF	Risk Management File
RMP	Risk Management Plan
RPN	Risk Priority Number

SOP	Standard Operating Procedure
XP	Extreme Programming (an Agile framework)

1 INTRODUCTION

Development of medical devices is an important industry with direct impacts on patient health and overall healthcare effectiveness. Medical device development is an extremely broad field, varying from diagnostic imaging technology to life-support devices such as ventilators and defibrillators. Ongoing medical technology innovation has made it possible to develop more effective and less failure-prone medical devices, eventually improved patient outcomes and reduced mortality rates. However, the production and development complexity of these devices has numerous challenges from regulatory compliance, risk, and quality evaluation.

The regulatory compliances for the development of medical devices are stringent, with global standards such as ISO 13485 (Quality Management System) providing exhaustive quality assurance guidelines to producers (International Organization for Standardization, 2016, p. 1). In addition, there is the methodical risk management system available in ISO 14971 across the lifespan of the device (International Organization for Standardization, 2019, p. 14). The standard also establishes comprehensive guidelines for manufacturers that enhance safety, performance, and risk management. These regulations aim to protect patients by ensuring that medical devices undergo strict quality and performance standards before being introduced into the market. But adhering to these standards can significantly extend the development process and add layers of complexity into the process. (Cooper & Sommer, 2016, p. 169.)

Traditional project management techniques such as the waterfall model were historically the normal paradigm of medical device development due to their serial nature. However, this rigid process usually leads to long development cycles, delays in regulatory approval, and difficulties in responding to evolving market needs. As the healthcare industry

moves towards more efficient and responsive processes, Agile methodologies are needed as the leading candidate for development streamlining while being compliant. (Beck et al., 2001, p 1.)

Agile methodologies have been conventionally developed for software engineering, where iterative development, rapid prototyping, and continuous user feedback are salient aspects of the process. However, their application to hardware development, particularly medical device hardware development, is still an emerging field of study. Agile practices are more agile and flexible, enabling faster iteration, inclusion of feedback, and enhanced collaboration among multidisciplinary teams (Pikkarainen et al., 2012, p. 5). These practices can reduce the time to market and improve product quality but present particular challenges when implemented in physical hard-ware, including regulatory documentation, compliance testing, and long manufacturing cycles.

One example of Agile's applicability in medical hardware development is the CPR machine project, which is a combination of hardware and software integration. This project involved large-scale safety assessment, iterative prototyping, and compliance to ISO 13485 and ISO 14971 standards. Agile methodology worked remarkably well in segregating potential hazards in the initial stages of development and promoting collaboration between clinicians, engineers, and regulatory organizations. By studying this case, this study will analyze how Agile concepts can be modified to enhance quality, shorten development cycles, and optimize efficiency in meeting medical devices with high regulatory requirements.

The other significant aspect of Agile in medical device development is its ability to respond to rapidly evolving industry demands. With advancing artificial intelligence, robotics, and personalized medicine, quicker and more adaptable development processes are more necessary than ever. Traditional development systems lag behind such technological ad-

vancements, whereas Agile models encourage a culture in which continuous improvement, cross-functional collaboration, and immediate decision-making drive innovation.

Also, Agile allows early identification and reduction of risks, essential in medical device manufacturing. Risk analysis and hazard evaluation are essential components of ISO 14971, and the developers are required to strictly evaluate and manage risks associated with their devices. The high frequency of testing and validation in Agile seamlessly integrates with these requirements, and companies may find it easier to comply with international safety standards without compromising on development speed.

While it can be of benefit, putting Agile into place in medical device hardware design comes with its problems. Government authorities have a propensity to require heavy documentation, formal validation processes, and predestined design controls, all of which can clash with Agile's low-documentation ethos. Therefore, applying Agile methodologies for application within the formal, compliance-based sphere of medical device manufacturing is combining Agile principles with governmental best practice. This research will analyze best practices and implementation strategies for optimizing the utilization of Agile in the medical device industry, including suggestions on how organizations can implement Agile effectively while fulfilling compliance obligations. Medical device development is a part of healthcare in the modern world that enables improvement in diagnostics, treatment, and patient care. However, the manufacturing process of such products is regulated to a great extent and requires adherence to extremely stringent standards such as ISO 13485 (Quality Management System) (International Organization for Standardization, 2016, p. 1) and ISO 14971 (Risk Manage-ment for Medical Devices) (International Organization for Standardization, 2019, p. 14). These regulations ensure that these medical devices must meet at least minimum safety and performance criteria before they can be licensed for clinical use. Despite significant technological progress, the

development of medical hardware remains complex and time-consuming due to lengthy documentation, stringent risk management steps, and regulatory challenges. (Cooper & Sommer, 2016, p. 168.)

Agile methods, initially created for developing software applications, have been adopted in many industries due to their emphasis on flexibility, collaboration, and iterative process (Beck et al., 2001, p 1). However, the use of Agile methods in hardware development, particularly in the production of medical devices, is still an innovative area of study. The imposition of longer iteration cycles, physical prototyping constraints, regulatory compliance requirements, and documentation hurdles that take time to overcome inhibit smooth adoption of Agile (Pikkarainen et al., 2012, pp. 5-6). Despite these challenges, the iterative approach of Agile, continuous feedback loops, and risk analysis based decision-making can arguably increase medical hardware development efficiency without undermining regulatory compliance.

A case example that best shows how Agile is essential in medical device development is the CPR machine project that includes both hardware and software integration. The development of the machine entailed rigorous safety assessments, repeated testing, and ISO 13485 and ISO 14971 conformity. From this case, this study will explore how Agile approaches can be adopted to enhance quality, reduce development cycles, and enhance collaboration while making certain that the device conforms to strict medical standards for safety.

1.1 Research Gap and Problem

Whereas Agile methodologies have become standard in software development, applying them in hardware-based industries such as the manufacturing of medical devices has been uncharted ground. Much of the existing work is concentrated on Agile deployment within software envi-

ronments and does not talk much about its application to hardware projects subject to regulatory requirements. Most significant of all, in healthcare where documentation, compliance, and safety are paramount considerations, little empirical evidence exists regarding how much Agile can peacefully coexist with standards such as ISO 13485 and ISO 14971. There exist also limited operational models demonstrating how Agile can be integrated with hardware iteration cycles, compliance documentation, and risk management in real-world medical hardware projects.

This lack of dedicated research presents a hurdle to organizations seeking to adopt Agile practices in medical device hardware development. Traditional waterfall-based methodology is typically preferred due to its linear, document-focused nature that is appealing to regulatory needs. This methodology, however, typically results in long development lifecycles, reduced flexibility, and reduced response to new requirements or feedback. The key problem that this research is addressing is how to implement Agile practices in increasing development effectiveness, product quality, and regulatory compliance in medical device hardware projects. This study aims to fill the research gap by investigating best practices and implementation approaches grounded in the literature and a case study of a mechanical CPR machine project.

1.2 Research Questions

1. What are the key challenges in implementing Agile methodologies in medical device hardware development?
2. What are the advantages of adapting Agile methodologies to enhance quality and ensure safety in medical device hardware development?

1.3 Research Model and Structure of the Thesis

This qualitative case study adopts thematic analysis methodology in the exploration of embedding Agile practices within medical device hardware development. This research seeks to comprehend theme and pattern through literature, standards, and case-based experience. Development of a mechanical CPR device serves as an exemplar to direct, presenting a realistic view of the mechanism by which Agile can coexist with regulatory compliance such as ISO 13485 and ISO 14971. By thematically exploring relevant and industry specific literature, understand the best practices to adopt Agile frameworks to development of medical devices hardware.

The thesis has five main chapters. Chapter 1 sets out background information, establishes the research gap and problem, and sets out the principal questions and the scope of study. Chapter 2 addresses literature on project management in controlled environments, Agile methodologies, risk management strategies, CPR device development, and regulation. Chapter 3 presents an overview of the research methodology, such as the thematic analysis procedure and data sources used. Chapter 4 sets out results and discussion according to thematic interpretation. Finally, Chapter 5 provides conclusions, practice implications, and recommendations for further research. The figure 1 below illustrates the general framework of the thesis.

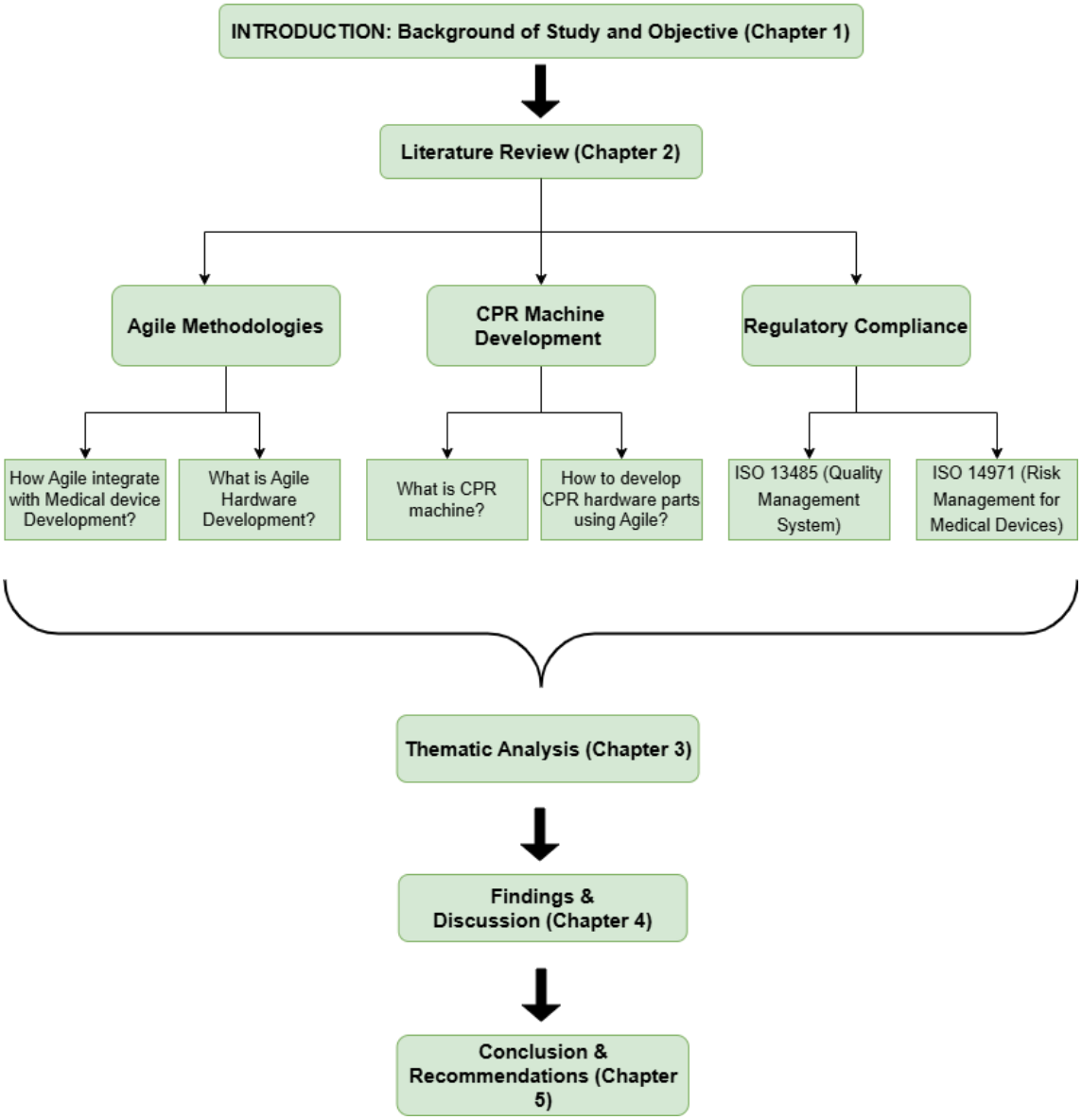

Figure 1. Structure of Thesis

1.4 Definitions

To ensure clarity and consistency throughout the thesis, several key concepts and terms used in the research are defined below:

- **Agile Methodologies**

Agile is a group of principles and practices aimed at enhancing flexibility, collaboration, and continuous improvement in project development. Agile frameworks such as Scrum, Kanban, and Extreme Programming (XP) are based on iterative development, stakeholder involvement, and frequent feedback loops. (Beck et al., 2001, p 1.)

- **Agile Manifesto**

The Agile Manifesto, published in 2001 by a group of software developers, defines four values and twelve principles that guide Agile methodologies. The values place emphasis on:

1. individuals and interactions over processes and tools,
2. working software over comprehensive documentation,
3. customer collaboration over contract negotiation, and
4. responding to change over following a plan.

Though originally designed for software development, these values eventually influenced hardware and regulated industry projects through their focus on flexibility, continuous delivery, and customer-centric workflows. (Beck et al., 2001, p 1.)

- **ISO 13485**

ISO 13485 is an international quality management standard specific to the medical device industry. It specifies requirements for a quality system to exhibit its capability to supply medical devices that consistently meet customer and regulatory needs across the product lifecycle. (International Organization for Standardization, 2016, p 1.)

- **ISO 14971**

ISO 14971 details the application of risk management to medical devices. It presents a structured approach to the identification of hazards, risk estimation and evaluation, and the implementation and monitoring of risk controls. (International Organization for Standardization, 2019, p 14.)

- **Medical Device Hardware Development**

This entails the design, prototyping, and production of physical medical devices and their electrical, mechanical, and electronic subsystems. Development must adhere to international safety and performance standards and often includes embedded software components.

- **Regulatory Compliance**

Regulatory compliance is the process of adhering to legal, safety, and quality standards such as ISO 13485, ISO 14971, and FDA or MDR regulations. Compliance ensures that medical devices are safe, function as intended, and are cleared for use in their intended markets.

1.5 Limitations of this Study

This study directly addresses the application of Agile methods to medical device development, which is hardware-oriented. It does not address software-only projects or general Agile acceptance in non-regulated environments in any great depth. While much of Agile philosophy is shared between hardware and software projects, the constraints, iteration timing, and regulatory burden are very dissimilar with hardware development, and this justifies a restricted scope.

The research primarily deals with compliance to global standards such as ISO 13485 and ISO 14971, as well as U.S. FDA and European MDR

requirements. Differences between regulatory regimes in different regions are not studied in detail. Although these standards have broad acceptability, individual jurisdictions may have additional documentation or approval requirements, which are outside the scope of this thesis.

Another limitation lies in the case study data. The study relies on a single CPR machine development project to illustrate the challenges and benefits of adopting Agile in a regulatory-driven hardware setting. While the case provides real-life observations, the findings may not fully extend to different classes of medical devices or organizational configurations.

2 LITERATURE REVIEW

This chapter provides a comprehensive overview of the published literature on Agile project management in regulated environments and specifically for the development of medical device hardware. The production of medical devices is where technology march and regulatory oversight intersect. With the growing need for faster, more agile product development particularly in healthcare traditional project management techniques have been wanting when it comes to meeting rapidly accelerating technological changes and shifting user needs. In this context, the Agile process has emerged as a welcome option due to its iterative nature, stakeholder emphasis, and adaptability. Its implementation in safety-critical and regulated environments such as medical device hardware development, however, carries unique challenges that must be met with particular regard for conformity, documentation, and risk management.

2.1 Project Management in Highly Regulated Development Environments

In sectors such as healthcare, aerospace, and pharma that have intense regulation, project management is crucial so that technically sophisticated products not only become compliant with the regulations but also satisfy the technical specifications. The medical devices sector, for instance, faces stringent global standards that not only demand compliance, quality assurance and risk management, but traceability at a high level and documentation at an enormous scale throughout the development phase. Legacy project management approaches, especially linear such as Waterfall, are well-liked in these environments because they are formal, milestone-based, and are in line with expectations of regulation. They also align with quality frameworks such as ISO 13485, which are centred on document control, formal design review, and gated phase transition.

However, with increasing product complexity especially with software embedded in products, electronics, and human-machine interfaces the limitations of traditional project management have become apparent. The rigid, sequential nature of Waterfall models can stifle innovation, delay the recognition of risk, and diminish responsiveness to feedback from stakeholders. In addition, when user needs change throughout development or when iterative testing is required for usability or safety validation, linear methods can be cumbersome and inflexible. This has raised growing interest in more flexible methods such as Agile, even within regulated development contexts. But applying Agile in these kinds of contexts is a subtle balancing act between flexibility and rigid compliance a balancing act that is explored in greater depth within the sections below.

2.2 Agile Methodologies in Regulated Medical Device Development

Agile methodologies have significantly shaped modern software engineering by introducing practices that focus on flexibility, user interaction, and iterative development. Originally formalized by the Agile Manifesto (Beck et al., 2001, p. 1), the paradigm revolves around adaptive planning, early delivery, and continuous improvement qualities that have been tremendously successful in dynamic software environments. Frameworks such as Scrum, Extreme Programming (XP), and Kanban have gained popularity because they emphasize realization of real value to users through small, working product increments. (Dingsøyr et al., 2012, pp. 1213–1215.)

However, the application of Agile to the highly regulated world of medical device development is not entirely problem-free. While Agile encourages quick iterations and fewer upfront specifications, the medical device industry is governed by strict regulations for safety, performance,

and compliance. Organizations in this sector have to contend with regulatory concerns such as traceability, detailed documentation, and validated risk management elements that do not necessarily align with Agile's minimal documentation culture. Traditional software process models like Waterfall have been the de facto standard for regulated environments due to their linear, phase-based flow and explicit documentation milestones (Royce, 1970, p. 1). These satisfy the requirements of regulatory bodies by producing traceable deliverables and predictable outcomes. Boehm and Turner (2005, p. 30) state that such models allow auditing and verification more easily. However, their rigidity has the effect of leading to delayed feedback, costly modification, and weak responsiveness to evolving stakeholder needs.

Agile methods, by contrast, promote iterative development, with teams reacting continuously to feedback and changing requirements. Denning (2016, p. 3) points out that such responsiveness facilitates the discovery of risks early and allows for changes in design before major issues arise. McHugh et al. (2014, p. 770) also point out that incremental delivery in Agile fosters stakeholder involvement, enabling developers to iterate features based on real-time feedback. This can be particularly valuable in medical device development, where it is important to remain close to the requirements of the end-users for safety and usability.

Despite these advantages, regulatory environments impose a series of limitations that make full uptake of Agile difficult. Among the most often expressed concerns is the perceived conflict between Agile's limited documentation and the extensive records required by regulatory authorities like the U.S. Food and Drug Administration (FDA, 2020, p. 3) or the European Commission under the MDR framework (European Commission, 2017, p. 5). Agile developers typically document "just enough" for development and communication purposes, but medical device regulations require rigorous traceability from initial user requirements through design, implementation, verification, and validation. (Torkar et al., 2011, p. 1111.)

Stålhane and Myklebust (2014, p. 1133) highlight that traceability matrices, design history files, and risk management reports must be kept rigorously during the lifecycle of the product. Agile teams may struggle to meet these demands without supporting processes or tools. But this is not an insurmountable barrier. Agile can be adapted to accommodate documentation practice that addresses regulatory needs while preserving the benefits of iterative delivery.

One solution is the use of Application Lifecycle Management (ALM) tools like Polarion, Jira, or IBM DOORS. Such tools are able to automate traceability, generate compliance-ready artifacts, and map user stories to verification records in real time. Granlund (2016, p. 28) demonstrated how these types of tools bridge the gap between Agile workflows and audit requirements. For example, metadata in the product backlog can be leveraged to automatically create risk logs or validation summaries, satisfying regulators without disrupting Agile practices.

Organizational culture is the second significant barrier to Agile adoption in this industry. Most medical device companies are hierarchically structured, where decision-making follows formal channels and approval gates are placed at predetermined milestones (Campanelli & Parreiras, 2015, p. 88). Agile, however, promotes decentralized control, cross-functional teams, and self-organizing teams. Ghobadi and Mathiassen (2016, p. 430) argue that without a change in mindset and team structure, Agile initiatives are superficial, confined to task boards and buzzwords instead of deeper behavioral change.

To enable this cultural transformation, leadership cannot simply approve Agile but be directly engaged in its creation by building shared responsibility, and promoting Agile values such as transparency and continuous improvement.

Regulatory audits themselves are a key factor. Agile's emphasis on flexible change management must be counterbalanced with formal configuration control, versioning, and pre-defined acceptance criteria. Stålhane

and Myklebust (2014, p. 1134) propose the use of sprint reviews as formal gate checks where deliverables are assessed for compliance criteria. Suvvari (2020, p. 830) also proposes that the inclusion of risk assessment in sprint retrospectives and using automated reporting tools can strengthen both quality assurance and regulatory readiness. Figure 4 below illustrates the ISO 14971 risk management process, highlighting key phases such as risk analysis, evaluation, control, and post-production monitoring in alignment with regulatory expectations.

Figure 2. ISO 14971 Risk Management Process
(International Organization for Standardization [ISO], 2019, p. 14)

Fortunately, several regulatory frameworks and standards now accept Agile as a viable methodology if properly implemented. AAMI TIR45 (AAMI, 2016) provides specific guidance on how to map Agile to medical device standards, and IEC 62304 (IEC, 2015) explains how iterative processes can be harmonized with software lifecycle expectations. These

documents clarify that Agile is not inherently non-compliant, but it must be adapted to allow for traceability, validation, and design control.

2.3 Agile vs Waterfall in Medical Device Context

In medical device development, the selection of suitable project management methodology Agile or Waterfall is strategic in nature depending upon regulatory compliance, safety-critical requirements, and product complexity.

The Waterfall model has long been the default in safety-conscious industries. It is a strict, linear approach where each of the phases requirements, design, implementation, verification, and validation is completed before moving on to the next (Royce, 1970, p. 1). This approach supports formal quality control systems like ISO 13485 that demand meticulous documentation, official approvals, and traceability throughout development. Predictability of the model makes it more appealing to regulatory bodies that need traceable, transparent deliverables. (Boehm & Turner, 2005, p. 30.)

Waterfall's Traceable deliverables and detailed planning make audit and regulatory filing preparation straightforward. It ensures every stage of the development is approved and verified before proceeding, something critical for high-risk devices. This restrictiveness can be a problem in flexible development environments, however. The feedback delay associated with the model usually denies the early identification of design faults or usability issues (Torkar, Awan, & Alvi, 2011, p. 1110). Since changes become expensive and time-consuming once requirements are determined, countering new discoveries can be a slow, resource-intensive exercise.

Agile practices were created to overcome these limitations using the stimulation of adaptability and iterative development. Agile prioritizes working solutions, adaptable planning, and regular customer interaction

in the absence of rigid documentation (Beck et al., 2001, p. 1). Rather than traversing rigid phases, Agile teams release product pieces incrementally in brief cycles of development, known as sprints. This allows for rapid testing, continuous risk assessment, and greater insight into design problems.

Agile facilitates faster and more critical feedback from users and stakeholders, leading to products better meeting clinical and operational needs (Dingsøyr, Nerur, Balijepally, & Moe, 2012, pp. 1213–1215). By facilitating concurrent design and testing, Agile allows for a dynamic and responsive development process highly beneficial for medical devices that are required to be tailored or have evolving technology. It also complements ISO 14971's emphasis on lifecycle-oriented risk control by facilitating iterative identification and control of hazards.

Though Agile possesses these positives, it is not feasible in regulated environments where traceability, configuration control, and massive documentation are not possible. Agile's minimal documentation methodology is conflicted with regulatory audits unless complemented by tools and practices that enable traceability (Stålhane & Myklebust, 2014, p. 1133). One of the solutions is implementing Application Lifecycle Management (ALM) tools. They can automate compliance-ready document generation from Agile development (Granlund, 2016, p. 28) itself, thereby meeting the auditors' requirements without slowing the development.

Some firms use a hybrid style, combining Agile flexibility with Waterfall regulatory strength. A good example of a hybrid methodology is the Agile-Stage-Gate model in which Agile sprints are contained within a gated process and points of compliance are inserted at key milestones (Cooper & Sommer, 2016, p. 172). The model also facilitates concurrent engineering through the encouragement of collaboration among quality assurance, regulatory, and development teams throughout the life of the project.

Criteria	Agile	Waterfall
Flexibility	High	Low
Regulatory Fit	Requires adaptation	Naturally aligned
Risk Management	Iterative, continuous	Phase-end focused
Documentation Approach	Lightweight but traceable	Heavy, stage-gated
Stakeholder Feedback	Frequent	Infrequent

Table 1. Agile vs Waterfall Comparison

2.4 Risk Management in Medical Device Projects

Risk management is perhaps the most significant element in the development of medical devices, subject to stringent international regulation that prioritizes patient protection, risk minimization, and openness to regulatory requirements. The chief standard for risk management in this field is ISO 14971:2019, which sets out a lifecycle approach to identifying, assessing, and managing risks associated with medical products. To develop hardware with Agile, risk management processes must be included to not just meet but also enhance design responsiveness, flexibility, and reliability to safety problems. (ISO, 2019, p. 12.)

Risk is the association of the severity of injury and likelihood of such injury as ISO 14971 defines it. Its systematic lifecycle begins at the conceptual design stage and continues right through development, production, post-market monitoring, and potential product recalls. Key

steps involve risk identification, estimation and assessment, implementation of control measures, and residual risk evaluation. A distinguishing feature of ISO 14971 is the requirement that risk reviews be repeated iteratively, with manufacturers repeating their risk assessment as new information becomes available throughout the life of the product (ISO, 2019, p. 14). It does not sit as comfortably, however, with Agile's focus on ongoing improvement apart from adaptation to promote compliance alongside maintaining agility.

Traditional project management tends to synthesize risk analysis into one early-stage hazard report that ultimately becomes part of a closing Risk Management File (RMF). This fixed framework sits comfortably within Waterfall methodologies in which early product definitions are solidified. However, in Agile contexts, where product features are modified incrementally by running iterative cycles, risk management must also be similarly incremental and dynamic. The Agile teams must constantly update the risk documentation, trace evolving design changes to their respective risks, and have real-time traceability between the risk mitigations and corresponding verification and validation. (Plaza & Bongiovanni, 2021.)

One of the most widely used traditional risk analysis methodologies is Failure Mode and Effects Analysis (FMEA). FMEA requires identifying potential failure modes, assessing them for severity, probability, and detectability, and then ranking them by a Risk Priority Number (RPN). FMEA is not effective in high-velocity Agile environments. It relies on fixed product definitions, static scoring systems, and paper and spreadsheet documentation, which are counter to the dynamic, tool-based characteristics of Agile workflow. Furthermore, FMEA often drifts apart from actual development processes, failing to reflect the system in its current form and yielding scant value in rapidly evolving design contexts. (Stamatis, 2003.)

Faring better are numerous Agile-compatible risk management methods that have specific fixes for these shortcomings. One common practice is to integrate risk activity directly into product backlogs as "risk stories" so that they can be estimated, prioritized, and tracked similar to functional features. They comprise tools that graphically reflect the closure of open risks over time, providing real-time visibility among teams (Vähäniitty & Rautiainen, 2010). Traceability tools such as Jira, Helix ALM, and Polarion allow risk controls to be traced back to user stories, test cases, design components, and validation deliverables. This enables the production of "living" risk files that expand with the product, remaining audit-prepared but avoiding slowing down development (Granlund, 2016, pp. 13–15). Table 2, below summarizes and compares commonly used risk management tools in Agile-driven medical device projects, evaluating their purpose, compatibility, and stage of application.

Tool	Purpose	Agile Compatibility	Common Use Stage
FMEA	Identify failure modes and their effects	Moderate	Design & Development
Fault Tree Analysis	Analyse causes of system-level failures	Low	System Integration
Hazard Analysis	Assess hazards related to device use and environment	Moderate	Early Risk Assessment
Risk Register	Track risks, mitigation actions and status	High	Throughout Project
Risk Burndown Chart	Visualize risk reduction over time in Agile sprints	High	Sprint Reviews

Table 2. Risk Management Tools Comparison

Cross-functional team working is another secret to effective Agile risk management. Embedding regulatory, quality assurance, and clinical subject matter experts within Agile teams ensures that compliance is considered from the outset of the design process. Agile rituals such as sprint planning, reviews, and retrospectives serve as helpful checkpoints for identifying new risks, reviewing mitigation, and maintaining traceability through the development cycle (AAMI, 2016, p. 44). This approach discourages risk management from being a solo or back-end exercise and instead invites safety integration through the project.

One of the lesser-heard advantages of ISO 14971 is that it emphasizes post-market risk monitoring, something which easily fits into Agile's iterative mindset. Risk management after product launch does not stop but extends through post-market monitoring, based on information gathered from field performance, customer complaints, clinical experience, and adverse events. In Agile contexts, this is consistent with continuous delivery and improvement patterns, in which backlogs are revised based on real-world experience. Updates, patches, and design modifications can be placed into priority order and administrated within sprints, facilitating quick action to evolving risks and regulation alterations. (AAMI, 2016, p. 50.)

Comprehensive simulation and testing play a vital role in Agile practices as a risk mitigation strategy, particularly in hardware development projects such as CPR machines. Rigorous mechanical validation is essential to ensure reliability under stress and emergency conditions. For example, Salonen (2024) emphasizes the use of environmental stress testing, vibration and shock testing, and long-term wear simulations in the development of medical hardware. These testing procedures can be distributed across Agile sprints and embedded into continuous validation cycles, allowing for early fault detection and iterative design refinement (Roldán, 2015). In addition, advanced techniques such as Finite Element Analysis (FEA) and human factors modeling contribute to ensuring both structural integrity and usability in high-risk scenarios (Berve, 2023). This integrated approach minimizes the likelihood of costly rework and aligns with medical device standards like ISO 14971 and IEC 62366-1.

Hardware-oriented Agile development also possesses challenges beyond those that are encountered in software environments. Risks arise due to component sourcing, mechanical tolerance, firmware interaction, and physical design constraints. In devices like CPR machines, electrical, mechanical, and embedded software hazards must be handled concurrently by engineers. Multidisciplinary sprint planning and design walkthroughs are required here, wherein potential safety issues are found and tackled

early on with the help of regulatory experts (Salonen, 2024). Embedding risk awareness within cross-disciplinary activity makes safety a natural aspect at every level of design.

From a compliance perspective, Agile teams must ensure that risk management activities are traceable, reproducible, and version-controlled. Regulators anticipate that such documentation as risk plans, hazard analyses, and residual risk justifications should be readily available. In Agile projects, they must be iteratively developed and well-maintained with good tooling to reflect the current design status. From an early stage, setting up documentation protocols and then aligning these with the Agile change management process maintains flexibility without breaching the compliance rules (FDA, 2020). Standards such as IEC 62304 or AAMI TIR45 highlight that including a risk and safety thinking attitude in the development stage is highly relevant, rather than including it as an add-on step at the end of the stage.

Effectively maintaining the balance between innovation and safety compliance is a defining challenge in Agile medical device hardware development. Agile methodologies enable development teams to rapidly incorporate feedback, explore novel ideas, and iteratively refine product designs. However, without structured governance and regulatory integration, such agility may introduce unforeseen vulnerabilities (Roldán, 2015). Organizations that successfully integrate ISO-conformant risk management, such as those outlined in ISO 13485 and ISO 14971 within Agile workflows are more likely to deliver innovative yet safe medical devices (Salonen, 2024). Achieving this alignment requires not only procedural changes but also cultural transformation that prioritizes teamwork, discipline, and a collective commitment to patient safety.

In the broader context of Agile transformation, the organizational and cultural shifts necessary for robust risk management are frequently overlooked. A safety-first culture must be cultivated across all roles, including engineers, developers, project managers, and quality assurance

teams. As noted by Berve (2023), psychological safety where team members feel empowered to raise safety concerns is fundamental to early risk detection. Agile ceremonies such as sprint reviews and retrospectives should be deliberately structured to include discussions focused on risks and safety learnings, which can inform continuous improvement strategies.

Equally important is aligning training and internal procedures with both Agile values and regulatory expectations. Teams unfamiliar with ISO standards may struggle to distinguish compliance obligations from Agile best practices, while Agile-focused practitioners may view documentation as a burden. Cross-functional training is therefore critical: engineers need an understanding of regulatory traceability, and regulatory professionals must appreciate the iterative logic of Agile delivery (Roldán, 2015). Standard Operating Procedures (SOPs) must be tailored to support hybrid workflows that permit incremental risk documentation, iterative verification, and version-controlled updates to safety files (Salonen, 2024).

Additionally, vendor and supply chain risks are becoming increasingly significant in Agile-driven hardware projects. Given that many hardware components are sourced internationally, Agile teams must address part availability, supplier compliance, and manufacturing variability. Including supplier assessments, quality checkpoints, and inspection data in the Agile backlog ensures that these risks are actively managed throughout the development process (Salonen, 2024). This is particularly important during rapid prototyping cycles or high-frequency design iterations, where material substitutions or design changes can affect biocompatibility, safety validation, and regulatory certification.

Finally, the expanding role of software and connectivity in hardware products demands that Agile risk management extend beyond traditional mechanical and electrical domains. Devices now often include

Bluetooth modules, wireless communication, or embedded AI algorithms, which introduce new vulnerabilities such as cybersecurity threats, software bugs, and ethical concerns. These emerging risks must be evaluated alongside functional features during Agile sprints, and their mitigation, such as security patches must be incorporated into the release cycle to ensure continuous compliance and product integrity (Berve, 2023).

2.5 Mechanical Development of CPR Devices

Cardiopulmonary resuscitation (CPR) remains a necessary lifesaving intervention, but providing consistent, high-quality compressions during emergency circumstances is a well-documented global issue. Human factors such as responder fatigue, variable skill level, and changes in posture tend to result in inconsistencies in the depth, rate, and recoil of compressions. These inconsistencies are critical because they have direct effects on coronary and cerebral perfusion during cardiac arrest (Rubertsson et al., 2014, p. 24). The challenges are even greater in prehospital environments where manual CPR is often interrupted by motion of transport, rough terrain, or equipment deployment.

To address these constraints, mechanical CPR devices arose that deliver automated compressions more reliably and with less interruption. Earlier devices like the Thumper™ and CPR-Ezy™ used pneumatic or mechanical drive and typically consisted of cumbersome apparatus and external gas sources. These devices, while functionally useful, were heavy and loud to use. More modern technologies, such as the LUCAS™ and AutoPulse™, are battery-powered and designed for rapid deployment in active emergency situations. The LUCAS™ delivers vertically aligned compressions through a piston driver, while the AutoPulse™ delivers circumferential pressure through a load-distributing band (Ong et al., 2006).

Although there remains controversy regarding the long-term advantage of survival with mechanical CPR, subsequent studies provide some clarity regarding its performance advantages. The LINC trial concluded that mechanical CPR allowed for a shorter defibrillation interruption time and less "hands-off" time on transport (Rubertsson et al., 2014). Concurrently, the PARAMEDIC trial assessed out-of-hospital cardiac arrest patients and found improvements in continuity of compression but no statistically significant improvement in survival (Perkins et al., 2015). Li et al. (2016) in a meta-analysis concluded that mechanical CPR devices could improve return of spontaneous circulation (ROSC) and admission survival but neurological outcomes were generally as good as with manual CPR.

The effectiveness of mechanical CPR devices is not only dependent on their mechanics but also on human action in emergency cases. Operators are typically not able to position the device correctly or initiate the compression process under stress conditions. These problems are very common in unorganized or noisy environments (Wang & Brooks, 2018, p. 6). To avoid such problems, producers are adopting human factors engineering requirements, for example, IEC 62366-1, to improve usability and reduce cognitive load on rescuers. Gear must be provided with clear guidelines, consistent feedback, and fast attachment systems to prevent delay or malalignment. (Zhou et al., 2019.)

Despite their benefits, mechanical CPR devices pose some inherent risks. Perhaps the most deplorable is the potential for severe injury, including rib fractures and damage to internal organs. Clinical presentations have reported cases of liver lacerations, hemoperitoneum, and other related complications with overuse or inappropriately applied compressions (Lardi et al., 2015). Sharma and Hernandez-Caballero (2020) reported a lethal hepatic injury from excessively deep mechanical compressions in a case report. These dangers indicate the necessity for rigorous training, proper patient selection, and the use of safety features such as pressure modulation and depth sensors.

There are also mechanical CPR devices, which are subject to rigorous regulatory oversight. Products must comply with international standards such as ISO 13485 for medical device quality management systems, IEC 60601 for safety of electrical medical equipment, and IEC 62304 for software development processes in the context of embedded devices (IEC, 2015). Premarket testing includes extensive bench trials to measure compression rate, depth accuracy, durability, and environmental stress resistance. Simulated emergency scenarios are typically used to test device performance in real environments and identify latent failure modes.

The use of Agile methodology for hardware development has also enabled innovation in CPR technology. Although hardware development cycles are generally slower than software iterations, Agile methods allow for modular sprint planning and iterative problem-solving. Compression modules, firmware, and casing designs can be developed in parallel, and emergency experts' input can be inserted into every process. Usability issues, such as alignment issues or delayed deployment, are monitored as backlog items and fixed in upcoming sprints. This way, the end product reflects real use cases and clinical needs.

Feedback led by clinicians is increasingly in the limelight when it comes to device optimization. In a recent study, Mattila (2023, p. 22) indicated that the involvement of clinical staff during device development reduced deployment time by a significant amount and improved emergency readiness. Simulated environments were utilized for testing initial prototypes, uncovering battery limitations, and refining user interfaces before hitting the production level. The feedback process ensures design updates that improve usability as well as safety, all while keeping pace with regulatory compliances.

2.6 Regulation Frameworks Supporting Agile Projects

The medical device industry operates under one of the most stringent regulatory environments in the world. In this context, the application of Agile project approaches must neatly integrate into expressed standards that govern safety, quality, risk management, and software lifecycle processes. While Agile is designed to add faster feedback loops, enhanced collaboration, and iterative planning, all of these benefits must be reinforced with strict documentation, traceability, and validation requirements. This balance is possible by a thoughtful interpretation of influential worldwide standards such as ISO 13485, ISO 14971, and IEC 62304, and pragmatic guidance from guidelines such as AAMI TIR45.

ISO 13485 is the foundation quality management system (QMS) standard for manufacturers of medical devices. It offers extensive requirements for processes for design, development, and manufacturing, and post-market activity. Whereas Agile tends to prioritize flexibility and little bureaucracy, ISO 13485 demands repeatable procedures and documentation throughout the device life cycle (International Organization for Standardization, 2016). Agile teams will therefore need to adapt their workflows to fit ISO's organizational structure. For example, sprint planning can be converted to design and development planning (Clause 7.3.2), sprint reviews to incremental deliveries of design (Clause 7.3.4), and verification to be carried out embedded within sprints in order to meet requirements under Clause 7.3.5. Such incremental compliance approach allows Agile teams to take care of regulatory requirements without breaking their iterative development process.

The major headache in ISO 13485 is traceability and document control. Agile projects need user stories, acceptance criteria, test logs, and design decisions to be versioned and linked to product requirements. Agile-friendly tools such as Jira, Polarion, and Helix ALM are often used for traceability matrix management, design history files (DHF), and device

master records (DMR). These tools generate structured metadata, enabling teams to satisfy auditor needs and maintain Agile velocity. Without such systems being established, Agile projects can flounder under regulatory inspections or internal quality audits.

ISO 14971, on the other hand, is specifically concerned with risk management across the entire product life cycle. It lays down systematic methods for hazard identification, risk quantification, controls application, and residual risk determination (International Organization for Standardization, 2019). Though conventionally employed within Waterfall models, Agile methodologies can easily incorporate ISO 14971 concepts. For instance, risk can be traced as separate "stories of risk" in the backlog, and prioritized along with technical work. Specific mitigation activities for risk can be added to each sprint, for instance, testing of controls or user testing. End-of-sprint retrospectives are a great moment to refresh and examine the risk management file (RMF) so that risk-informed decisions become part of the day-to-day workflow and not an isolated process.

IEC 62304 addresses software lifecycle processes for medical device software specifically, classifying systems into risk categories (Class A, B, and C) and specifying requirements for development, testing, maintenance, and configuration control (International Electrotechnical Commission, 2006). While Agile software teams often implement user stories and continuous integration pipelines, traceability from each requirement through implementation and verification is guaranteed. Traceability is never optional in regulated spaces. Tools such as Git and test automation tools can generate the necessary documentation e.g., test reports, code coverage reports, and change logs that serve as documentation of compliance with IEC 62304.

For example, build pipelines can be automated to produce version-controlled release notes and software validation summaries. Through appropriate metadata tagging, teams can show that each user story has

been implemented, tested, and released according to pre-specified acceptance criteria. This type of structured compliance engineering enables Agile teams to maintain both innovation speed and traceability discipline.

Another useful resource for implementing Agile under IEC 62304 is AAMI TIR45. Although not a regulation, this guide document stipulates working methods for mapping Agile processes onto medical device software requirements (Association for the Advancement of Medical Instrumentation, 2012). It promotes a mixed model whereby Agile sprints are supplemented by in-built compliance checkpoints such that regulatory documentation and decision logs are generated at set frequencies. TIR45 also emphasizes placing emphasis on the importance of early involvement of quality and regulatory specialists in Agile teams to impart mutual understanding of both compliance needs and engineering goals.

Several authors have explored how Agile methodologies can be adapted to meet the strict regulatory requirements of medical device development. Roldán (2015) describes the integration of a "compliance layer" into Agile workflows, where each sprint incorporates formal activities such as documentation, risk evaluation, and design review. In such models, sprint reviews may include structured checklists to verify risk controls, ensure documentation of design outputs, and confirm that verification activities are completed. This approach embeds compliance into the Agile cadence, improving traceability and audit preparedness.

Salonen (2024) emphasizes the importance of role clarity in aligning Agile processes with regulatory structures. The mapping of Agile roles such as Product Owner and Scrum Master to regulated positions like Design Authority or Quality Representative enhances visibility into accountability. This alignment facilitates regulatory inspections, where clear identification of those responsible for decision-making, risk ownership, and release approval is required.

Audit readiness is also addressed in existing research. According to Berve (2023), Agile teams that track user stories, tasks, and compliance activities within centralized tools can generate audit trails that include training records, change logs, and defect histories. This traceability enables teams to demonstrate ongoing compliance and explain design decisions when required. Internal sprint-level audits have also been noted as effective in detecting nonconformities early and enabling timely corrective action.

Roldán (2015) further highlights how Agile can align with established standards when implemented with discipline. Standards such as ISO 13485 for quality management, ISO 14971 for risk management, and IEC 62304 for software development provide the structural backbone for compliant product development. Additionally, the AAMI TIR45 guidance supports the incorporation of these standards into iterative Agile processes. Aligning Agile tools, documentation methods, and team structures with regulatory expectations allows for innovation and compliance to coexist within the demanding context of medical device hardware development.

2.7 Best Practices and Agile Adoption Strategy

Effectively inserting Agile practices into regulated medical device development is not an issue of how to implement new software tools and work management within sprint cycles. It requires a more existential mind change, organizational transformation, and alignment with regulations.

Cross-functional team formation is among the most critical success enablers of Agile. In traditional medical device development, departmental tasks are segregated into quality assurance, regulatory affairs, clinical validation, and risk management. Fragmentation can create communication breakdowns and delays. However, Agile environments benefit by explicitly including these roles within the Agile team. This provides

timely and continuous consideration of regulatory and safety matters and reduces the likelihood of rework at a high expense while improving design quality (Campanelli & Parreiras, 2015, p. 87). Cross-functional communication ensures that every iteration is constructed based on feedback from every important domain, sharing a uniform understanding of constraints and trade-offs during the development process.

Yet another important strategy is the use of the Agile–Stage-Gate hybrid strategy, which merges the iterative process of Agile with the formalized structure of experienced stage-gate systems. In this system, Agile sprints are performed within each gate-defined phase, and compliance checkpoints and documentation review at the end of each stage. This method incorporates the agility of Agile with discipline for validation and traceability (Cooper & Sommer, 2016, p. 24). The hybrid method performs well in healthcare settings where design control and regulatory submission milestones are crucial and cannot be avoided or delayed. Gate reviews are anchoring points when the reviewers, auditors, or internal quality groups examine the completeness and adherence of work done within previous sprints.

Agile documentation practices also must be modified cautiously. One common pitfall for regulated teams targeting Agile is either abandoning documentation to keep pace or reverting to rigid, linear-style document templates that sully Agile principles. A balanced solution is to treat documentation as a sprint deliverable with thoroughly documented outputs for compliance. For instance, Agile teams can create user stories explaining the application of verification processes or changes to risk management reports. These can then be tracked, executed, and documented utilizing tools like Jira or Confluence that facilitate automatic tracing report creation and audit logs (Barlow, 2015, p. 517). This approach keeps compliance in sight and ongoing without interfering with the pace of iteration.

The use of Agile frameworks to the precise requirements of a medical device and the degree of maturity of an organization is imperative. While Scrum is largely promoted as a default Agile methodology, it is not compatible with all product types, especially where hardware is predominant. Scrum's emphasis on strict definitions of sprints and frequent releases can clash with prototyping limitation reality, test validation timelines, and physical integration dependencies. In such cases, alternative frameworks like Kanban or larger Agile systems like SAFe can offer a closer match with more accommodated workflow and varying iteration time (Campanelli & Parreiras, 2015, p. 94). Tailoring also means synchronizing team capability with regulatory deliverables having sprint goals encompass not just technical progress, but also verification, validation, and documentation milestones as well.

Risk-based backlog prioritization is one of the rising top practices in Agile medical device development. It means assigning backlog items their respective risk levels derived from the potential impact of failure or use error and positioning higher-risk features earlier in the development life cycle. Such a method is nicely aligned with the requirements of ISO 14971, wherein risk identification, mitigation, and residual risk analysis are carried out all along the product's life cycle (International Organization for Standardization, 2019, Clause 4.4). By incorporating visibility into the risks within the backlog management itself, the Agile team can be demonstrated to manage risks proactively and ensure safety-critical modules authenticated as soon as possible. It also enables auditors to audit treatment of risk activity as regular sprint review reports without requiring additional documentation efforts.

Training and cultural alignment is also a major success factor in implementing Agile. Agile comes with roles, responsibilities, and workflows that differ significantly from the conventional development paradigms. Developers must learn to enjoy the fact that their work ends up in artifacts like the Design History File (DHF), Device Master Record (DMR), and Risk Management File (RMF). Likewise, regulatory staff members

must understand how Agile artifacts map to evidence for compliance. Without education at every level team members, managers, and compliance officers misalignment can occur, leading to inconsistent execution or audit failure (International Organization for Standardization, 2016, Clause 6.2). Best practice dictates formal onboarding efforts, routine role-based Agile training, and cross-functional workshops to create common language and expectations.

Tooling infrastructure is a critical enabler to sustain Agile momentum and manage regulatory compliance. Modern Agile clinical teams increasingly rely on integrated development environments (IDEs) combining issue tracking, version control, test management, and documentation generation. Tools such as Polarion, Jira (with regulatory plug-ins), and Helix ALM allow teams to automate test evidence, accommodate audit trails, and generate traceability matrices compliant with the requirements of IEC 62304 (International Electrotechnical Commission, 2006, Clause 5.5). The tools also accommodate role-based access, electronic signatures, and validation workflows for all mandated in ISO 13485-compliant systems (International Organization for Standardization, 2016, Clause 4.2.5). Automation reduces overhead of manual reporting and improves audit readiness confidence.

Another place where Agile is stronger is in stakeholder input and in medical product development, "stakeholder" is more than customers. Clinicians, nurses, biomedical engineers, and even regulators can provide valuable input into usability, design constraints, and safety considerations. Best practice mandates frequent feedback gathering via design demos, simulation testing, and early clinical review cycles. Engaging these voices helps ensure the product not only meets compliance needs but also offers genuine clinical utility and user satisfaction (AAMI, 2016, pp. 13–14). Preliminary contacts with notified bodies or consultive regulatory experts are also undertaken by some companies to provide interpretation of ISO clauses and validation of assumptions of software categorization before formal submission stages.

By adopting these practices hybrid workflows, cross-functional teams, frameworks tailored to the organization, risk-prioritized backlogs, team training, tooling integration, and stakeholder collaboration organizations can map Agile practices against published standards such as ISO 13485 (International Organization for Standardization, 2016), ISO 14971 (International Organization for Standardization, 2019), and IEC 62304 (International Electrotechnical Commission, 2006). Agile is not only a method for rapid development, but a competitive value proposition for the delivery of safe, innovative, and user-focused medical devices, if executed with care.

Figure 3. Agile-Stage-Gate Hybrid Model

3 RESEARCH METHODOLOGY

This chapter outlines the methodology used to analyse how Agile practices can be integrated into risk mitigation activities during medical device hardware design. Since research is intended to come up with conceptual concepts and not hypotheses testing, a qualitative design was used. Specifically, the study relies on a systematic literature review to draw relevant data from academic and industrial sources, with ultimate thematic analysis for the identification of patterns and themes that recur within selected materials.

3.1 Data Collection Methods: Systematic Literature Review

This research applied the systematic literature review (SLR) as a major means of data collection to investigate the extent to which Agile methods can be applied to medical device hardware development in compliance frameworks. The objective was to find academic knowledge, methodological blueprints, and useful practice that captures the fusion of Agile, compliance standards such as ISO 13485 and ISO 14971, and hardware project management. A systematic approach was used to render the data collection process explicit, reproducible, and scholarly credible.

Scholarly databases such as IEEE Xplore, PubMed, ScienceDirect, SpringerLink, and Google Scholar were used for literature searching. Keywords and search terms employed were "Agile in medical device development," "Agile hardware development and ISO 13485," "Risk management in Agile medical projects," and "Medical device standards ISO 14971." The search was limited to peer-reviewed journal articles, master's theses, conference proceedings, and industry white papers from 2015 to 2024. The rationale for choosing this time frame was to ensure the research remained current while simultaneously capturing foundational information from earlier Agile and regulatory integration work.

The selection was grounded in literature that had addressed Agile adoption in areas of regulation, made specific reference to risk management and compliance needs, or involved hardware-software integration in the medical device context. Full-text articles published in English were chosen. Studies based on non-regulated contexts, were unclear in methodology, or included exclusive theoretical discussions without systematic results were excluded. Out of the initial pool of more than 120 documents, 58 were shortlisted to be reviewed in full from title and abstract. During full-text screening, 36 were deemed appropriate for inclusion in the analysis since they were most relevant to the research objective. Additional references were added through backward citation tracking to total more than 60 sources used in the research.

A systematic literature review was selected for three primary reasons. First, it provided methodologically sound groundwork upon which to research a multidisciplinary topic involving project management, regulatory science, and Agile hardware development. Second, it provided a practical route by which to examine how Agile has been utilized within the same fields and identify best practices and areas for research. Third, this process was very well-suited to the application of thematic analysis based on rich, contextually rich literature to obtain significant themes and patterns.

Given the nature of this research, qualitative was the most appropriate approach. Rather than seeking numerical generalization, this research was interested in exploring how Agile frameworks interact with medical regulatory processes and how project teams might integrate within these limitations. A qualitative approach allowed the researcher to explore existing literature in depth and identify the most significant thematic outcomes across the data, which underpins the next section of the methodology.

3.2 Data Analysis: Thematic Analysis

In the data analysis of data collected through systematic literature review, this study employed a qualitative approach referred to as thematic analysis. Thematic analysis is best recognized for its flexibility and versatility in the identification of, analysis of, and reporting of patterns of qualitative datasets. Given the context of this study investigating where Agile practices intersect regulatory frameworks in the development of medical device hardware, it was particularly well-suited. It allowed for the determination of themes and concepts that recurred across a broad variety of academic and industry sources, which in turn informed the development of a conceptual model of best practice within this field.

Analysis adopted the six-step thematic analysis process outlined by (Naeem et al., 2023, p. 39) to be especially relevant in facilitating conceptual model development within qualitative research. This model was used because it was transparent, methodologically rigorous, and most appropriate for studies looking to draw practical recommendations from literature rather than interviews. The process began with a familiarization that involved multiple readings of the selected articles for purposes of acquainting oneself with the background, key findings, and terms used throughout the literature. In this process, reflective notes were taken for the purposes of beginning to observe patterns and comments that would later develop into formal codes.

The second step involved identification of keywords and phrases that were highly associated with root ideas of the research, which were "iterative development," "risk control," "regulatory alignment," "traceability," and "Agile adaptation." Keywords were manually identified and placed under initial categories based on their contextual similarity. In step three, open coding was applied, keeping the "6Rs" guidelines of (Naeem et al., 2023, p. 39) in mind, that emphasize strength, relevance, recurrence, resonance, richness, and relationship. The code for each was

a unique practice, observation, or challenge that was referenced over and over across the sources.

Once the original codes were generated, developing themes was the fourth step, and this consisted of coding the codes into broader thematic categories. Not only did these need to be logical within themselves, but they also needed to be meaningfully distinct from one another. The process employed the "4Rs" of theme development (recognizable, representative, responsive, and reliable) in a bid to provide conceptual clarity. The developing themes were iterative validation within regulatory limits, Agile–ISO integration strategies, risk-driven design thinking, and adaptive documentation processes.

In the fifth step, further conceptual meaning was drawn from themes. In this step, the emerging themes were matched against the research goals and against established theoretical structures, such as ISO 13485's principles of quality management and ISO 14971's risk management process. This was done with the idea of observing the way in which the developed practices support or contradict current regulatory expectations for medical device hardware development. The review guaranteed that the majority of Agile concepts such as incremental releases, customer collaboration, and flexible planning were able to comply with regulatory standards when adapted accordingly.

The final stage was to integrate the findings into a conceptual model illustrating the implementation of Agile methods within a regulated medical device development environment. The model does not prescribe a one-size-fits-all approach but rather delineates a group of adaptable principles and methodologies that can be used by developers based on project size, risk level, and maturity of the organization. The model forms the foundation for follow-on research and applied work in regulated product development.

Throughout thematic analysis, integrity was tried to be preserved in the results. Credibility was enhanced via triangulation of findings from a

broad range of peer-reviewed research. Transferability was enhanced via rooting themes in actual standards and issues that are broadly transferable across the medical device industry. Dependability and confirmability were assured via meticulous documentation of the coding process and an open rationale behind each analytical decision. Since the study did not involve human subjects or confidential data, official ethical approval was not required.

4 FINDINGS AND DISCUSSION

This chapter presents the most critical results drawn out of thematic analysis of the literature in regard to Agile adoption within regulated medical device development environments. From impressions gleaned through systematic literature review, the chapter untangles recurring themes that symbolize prevalent practices, challenges, and fixes related to the adoption of Agile methods in hardware-driven, compliance-focused environments. This chapter attempts to bridge the gap from theory to practice through a combination of thematic analysis and real-world application.

4.1 Key Findings regarding Agile Implementation

Thematic analysis of the literature revealed some key findings related to the adoption of Agile methodologies in regulated medical device development, particularly to hardware projects. One of the most prevalent among the themes found was regulatory compliance without compromising agility. Contrary to conditions dedicated to software creation, medical hardware development is guided by stringent standards such as ISO 13485 and ISO 14971, which emphasize traceability, documentation, and risk control. Agile's flexible and iterative approach is likely to conflict with these requirements. However, various studies exemplify that Agile can be successfully applied to regulated environments with the support of a formal quality management system as well as an openly defined "definition of done" including the consideration of compliance.

Another vital trend is rising use of hybrid models of development. Rather than applying Agile principles in their purest form, organizations are increasingly putting together Agile with traditional plan-driven methodologies, particularly in certain areas like design verification, risk analysis, and documentation. For example, iterative sprints can be used for design and prototyping, but to regulate compliance and formal review

gates, and checklists for compliance. This hybrid approach allows teams to preserve the responsiveness and flexibility of Agile while complying with regulatory demands.

A third thread is the importance of collaborative, cross-functional teams in Agile implementation. The literature emphasizes that successful Agile implementation in regulated systems requires defined roles, open communication, and unambiguous alignment among engineering, regulatory, and quality assurance teams. Retrospectives and daily stand-ups, typical ceremonies in agile, came in handy not only for tracking progress but also in identifying compliance issues at the outset. Participation by stakeholders, such as end-users and regulatory experts, in sprint review and planning also helps ensure that what is being developed is technically correct and regulatory compliant.

The report also identifies incremental risk management as an impetus for Agile processes in hardware design. Incremental risk management processes generally utilize big, up-front analysis. This contrasts with the risk analyses that change continually in Agile environments, consonant with each sprint or development iteration. Evidence shows that risk documentation and controls, when refreshed frequently rather than solely at defined points in the project, can be more responsive to design changes and customer feedback.

Finally, the literature stresses adaptive documentation practices. Arguably the most controversial aspect in regulated Agile projects is finding the balance between total documentation and Agile's emphasis on working product rather than formal paperwork. The research indicates that while total documentation remains essential, Agile teams are moving toward just-enough documentation that is versioned, modular, and constantly updated throughout the development life cycle. Software such as automated traceability matrices and compliance tracking built into Agile platforms (e.g., Jira with plugins of medical-grade) is increasingly

used to automate documentation while satisfying audit and certification requirements.

These results collectively demonstrate that while Agile adoption within medical device hardware development projects presents unique challenges, it is not merely possible but also successful when adapted with care. The next section discusses how the resulting findings have practical ramifications for teams working in regulated development environments.

Figure 4. Agile Feedback Loop

4.2 Implications for Medical Device Hardware Projects

The outcomes of the thematic analysis have a number of key implications for real-world use of Agile methodologies for medical device hardware projects. Foremost among these is that Agile cannot be applied as

is from software development to regulated hardware fields without modification. While Agile supports flexibility, emergency, and responsiveness to the customer, the design process for hardware, particularly in the health care industry, is subject to regulatory requirements that necessitate rigorous documentation, risk management, and regulation of design. Therefore, teams must enable Agile practices within the limitations of standards like ISO 13485 and ISO 14971, rather than attempting to bypass them.

One of the most important implications is the need for intentional and coordinated compliance planning in Agile processes. The compliance activities must be integrated into the Agile process and not as an addition or an after-the-fact procedure. For example, compliance functions such as traceability, design verification, and risk analysis must be included in the product backlog and be given priority along with the functional functionalities. The Agile "definition of done" concept can be used for compliance deliverables to ensure that each iteration or sprint produces not just working but also review-complete, from the regulatory point of view, deliverables.

Another implication is the growing need for toolchain support to handle increased complexity of documentation and traceability in hardware development. As opposed to conventional software development, hardware development entails the use of mechanical, electronic, and embedded software components whose documentation, testing, and verification need to be performed as per regulation requirements. Agile teams can take advantage of platforms allowing for automated document generation, version control, and tracing mapping in real-time, hence minimizing complexities without sacrificing efficiency. The integration of Agile tools like Jira or Azure DevOps with regulatory tracking systems has proven to be a successful solution in the majority of reported cases.

Additionally, according to the study, cross-functional collaboration and shared ownership are main success drivers in regulated Agile hardware

development. Medical device projects include not only engineers and designers but also quality assurance personnel, regulatory affairs personnel, and clinical specialists. Agile's emphasis on communication and ongoing feedback has the ability to cause these stakeholders to better align with one another, provided roles and responsibilities are clearly defined. Periodic sprint reviews, risk workshops, and documentation retrospectives will help ensure all voices are heard, and compliance issues addressed proactively and not as after-the-fact responses.

Incremental risk management is also demonstrated in the literature as being feasible and even a superior methodology for medical hardware projects. Rather than a single, upfront, fixed risk analysis at the project start, Agile teams are able to perform ongoing assessments during the product development life cycle. This enables teams to respond in real time to design changes or new interpretations of the regulations, improving the overall integrity and safety of the device. This has to be done with careful planning, however, so that modifications are properly documented and the overall risk profile is maintained within proper limits.

Finally, the application of Agile methods in medical device hardware development offers strategic benefits to firms like faster time to market, improved product quality, and improved ability to adjust to changing requirements. All these can only be realized, however, when Agile is used within the regulatory environment. In order to realize this, investment in the training of employees should be done, internal processes should be updated, and the culture must be one that supports innovation and compliance. As the medical device market evolves further especially with increases in connected health technologies and software-based diagnoses the requirement to implement Agile principles in a controlled and compliant manner will increasingly become a necessity.

5 CONCLUSION

This final chapter presents the main findings resulting from the research study, as informed by the outcome of the thematic analysis and literature review. It condenses the main insights into how Agile practices can be customized to meet the specific requirements of medical device hardware development in controlled environments. The chapter also presents recommendations for future research and offers final thoughts on the usefulness and relevance of Agile in this tightly controlled industry sector.

5.1 Literature Analysis Findings Summary

This study purposed to examine how Agile methodologies can effectively be utilized in the creation of regulated medical device hardware, with particular emphasis on risk mitigation and conformity to standards such as ISO 13485 and ISO 14971. Using a systematic literature review as the primary source of information and thematic analysis as the methodology, the research extracted a collection of recurring themes that represent current practices, challenges, and strategic changes within the industry.

One of the strongest conclusions was that there is increased emphasis on compliance without sacrificing agility. Most organizations developing medical hardware no longer consider Agile and compliance to be two opposing worlds. Instead, as suggested by literature, Agile principles particularly those based around iteration, feedback, and continuous delivery can be adopted to meet regulatory needs with systematic documentation and traceability tools.

The study also revealed that hybrid development models were used extensively. Rather than attempting to use Agile in its pure form, the majority of medical device developers blend Agile practices with their traditional, plan-based methods. This is able to ease the flexibility needed

for innovation without losing the controls necessary for certification and quality control.

The second dominant theme was incremental risk management versus static initial risk estimation characteristic of waterfall processes. The literature highlights how Agile teams can integrate continuous risk assessment into their development to see that changes and risks are dynamically assessed and not after the fact.

Furthermore, the study confirmed the growing need for adaptive documentation practices. Traditional documentation paradigms are considered to be slow and cumbersome within Agile projects. However, evidence shows that teams can have compliant, audit-ready documentation that is in sync with the product using the appropriate tools and mindset without slowing down the development process.

Lastly, cross-functional collaboration was the central enabler of Agile success in compliant environments. The inclusion of regulatory experts, quality experts, engineers, and customer stakeholders into Agile ceremonies like sprint reviews and backlog refinement sessions helps ensure that technical and compliance goals are achieved side by side.

Collectively, these findings indicate that Agile, when properly tailored, offers an efficient path for advancing medical device hardware innovation without compromising safety or regulatory rigor. These findings form the basis on which additional research can be explored, including more application-case-specific deployments and empirical validation in subsequent studies.

5.2 Recommendations for Future Research

While this study provides a formalized understanding of how Agile practices may be applied in regulated medical device hardware development, there are a few areas that need to be explored in subsequent research.

One of the key suggestions is empirical validation of emergent themes using real case studies. Follow-up studies would involve direct interviews with regulatory professionals, engineers, and project managers who have used Agile frameworks on hardware-based medical device projects. This would provide us with a clearer idea of how Agile functions in practice, the issues encountered, and the specific steps that are implemented to facilitate compliance.

Another promising field for further research is comparison between small and big organizations in adopting Agile practices. Small firms may be more agile but less equipped to ensure compliance, while big corporations may be under more strict frameworks but have also established quality systems already. Understanding how the size of the organization, organizational culture, and maturity level affect Agile adoption within compliance environments could be very practically insightful.

Lastly, an extension of research could be the integration of Agile with specific regulatory schemes beyond ISO 13485 and ISO 14971, such as the U.S. FDA Quality System Regulation (QSR) or the EU Medical Device Regulation (MDR). Having knowledge of how Agile processes can be scaled to these local regulatory needs would bring world applicability.

Finally, additional research is encouraged on integrating digital tools, such as how project management software (e.g., Jira, Polarion) may be optimized best to enhance both Agile workflow effectiveness and traceability against compliance. With evolving regulatory expectations and with the advancement of digital health technologies, these kinds of software will become more of a central part in allowing Agile practices in the medical product development environment.

5.3 Final Thoughts

This study has explored the potential for the application of Agile methodologies to the development of medical device hardware, a field traditionally dominated by rigorous regulatory demands and risk-averse cultures. Through a systematic review of the literature, the study has shown that Agile does not necessarily have to be ruled out in regulated environments. Instead, it can serve as a helpful blueprint for enhancing innovation, collaboration, and responsiveness after it is thoughtfully adapted to meet the needs of quality and compliance.

Agile's inherent benefits of iterative development, early feedback, and team empowerment can contribute to safer, more efficient medical device design when paired with practices bringing regulatory conformance. Achievement with this synthesis does not depend on an either-or decision of Agile or compliance, but on integrating them in a formal, hybrid approach that respects the demands of both.

As the medtech industry evolves alongside technological innovation, the necessity for development models that can maintain pace without compromising patient safety grows. Agile opens a pathway to address this challenge. While the findings of this study are literature-derived, they provide an input to additional applied research and a pragmatic way forward for development teams operating at the difficult intersection of innovation and regulation.

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APPENDICES

Appendix 1: Summary of ISO Standards Referenced

Standard	Description	Purpose in Study
ISO 13485:2016	Quality Management Systems for medical devices	Demonstrates QMS integration in Agile environments
ISO 14971:2019	Application of risk management to medical devices	Core framework for Agile risk compliance
IEC 62304	Software lifecycle processes for medical device software	Addresses embedded systems and compliance
IEC 62366-1	Usability engineering for medical devices	Supports human-factor analysis in CPR design