Kaunas University of Technology

School of Economics and Business

The Role of Open Innovation in Medical Device Development: Challenges of Navigating the European Regulatory Landscape

Master's Final Degree Project

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Innovation Management and Entrepreneurship (6211LX031)

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Summary

The innovation landscape for medical device manufacturers in the European Union has undergone significant changes since the introduction of the European Union Medical Device Regulation (EU MDR) in 2021. While open innovation practices offer strategic advantages in fostering technological advancement and agility, the need for compliance presents significant barriers to their practical implementation in small and medium-sized enterprises (SMEs). This study examines the interplay between open innovation and MDR compliance through a qualitative single-case study conducted at Spiegelberg GmbH, a Germany-based SME in the medical device industry. The firm specializes in developing and manufacturing neurosurgical devices, operating across more than 70 countries, and is representative of innovation-driven, internationally active SMEs navigating strict regulatory environments. The study's methodology employs semi-structured interviews across multiple functional departments and utilizes thematic analysis to interpret the data. As a result, five major themes emerged: *Regulatory burden and innovation constraints, Market access challenges and regulatory risks, Internal organizational adaptations, External collaboration barriers, and Strategic and ethical reflections.* Further subcode analysis revealed that documentation complexity, opportunity costs of compliance, and innovation fatigue are dominant internal barriers. At the same time, market access is hindered by regulatory misalignment across multiple markets and bottlenecks imposed by notified bodies. Internally, organizations face a steep learning curve in terms of regulations and fragile knowledge-sharing networks. Externally, selective openness and limited absorptive capacity hinder effective collaboration. Strategic reflections show contradictory insights on balancing innovation needs with regulatory expectations. The findings highlight a systemic misalignment between the iterative, rapid nature of open innovation and the methodological requirements of MDR compliance. SMEs are increasingly internalizing innovative activities to manage regulatory risks. However, structured frameworks that integrate external collaboration with robust compliance strategies can enable firms to retain agility while ensuring adherence to regulatory standards. This study contributes to the growing discourse on innovation management in regulated industries and offers practical recommendations for SME's seeking to harmonize open innovation practices with compliance obligations.

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Kaunas, 2025. 74.

Santrauka

Inovacijų aplinka medicinos prietaisų gamintojams Europos Sąjungoje iš esmės pasikeitė nuo 2021 m., kai buvo įvesta Europos Sąjungos Medicinos prietaisų reglamentas (EU MDR). Nors atvirosios inovacijos siūlo strateginių pranašumų skatinant technologinę pažangą ir lankstumą, reikalavimas laikytis reglamento kelia reikšmingų kliūčių jų praktiniam įgyvendinimui mažose ir vidutinėse įmonėse (MVĮ). Šiame tyrime nagrinėjamas atvirųjų inovacijų ir MDR atitikties tarpusavio ryšys, atliekant kokybinį vienos įmonės tyrimą, vykdytą „Spiegelberg GmbH“ Vokietijoje įsikūrusioje MVĮ, veikiančioje medicinos prietaisų srityje. Įmonė specializuojasi neurochirurginių prietaisų kūrime ir gamyboje bei veikia daugiau nei 70 šalių, todėl yra reprezentatyvi inovatyvioms, tarptautiniu mastu veikiančioms MVĮ, veikiančioms griežto reguliavimo sąlygomis. Tyrimo metodologija apima pusiau struktūruotus interviu su skirtingais įmonės padaliniais ir tematinį kodavimą analizei. Buvo išskirtos penkios pagrindinės temos: reguliacinė našta ir inovacijų apribojimai, prieigos prie rinkos iššūkiai ir reguliacinė rizika, vidinės organizacinės adaptacijos, išorinės bendradarbiavimo kliūtys ir strateginės bei etinės įžvalgos. Tolimesnė subkategorijų analizė atskleidė, kad pagrindinės vidinės kliūtys yra dokumentacijos sudėtingumas, atitikties sąnaudos ir inovacijų nuovargis. Tuo pačiu metu prieigą prie rinkos apsunkina reguliacinis nesuderinamumas tarp šalių ir akredituotų institucijų (notified bodies) trūkumas. Viduje organizacijos susiduria su stačia reguliacinio mokymosi kreive ir trapiomis žinių dalijimosi struktūromis. Išorėje efektyvų bendradarbiavimą apsunkina selektyvus atvirumas ir ribotas gebėjimas įsisavinti išorines žinias. Strateginės įžvalgos atskleidžia prieštaringus požiūrius, kaip subalansuoti inovacijų poreikius ir reguliacinius lūkesčius. Tyrimo išvados pabrėžia sisteminį neatitikimą tarp atvirųjų inovacijų spartaus, ciklinio pobūdžio ir MDR metodologinių reikalavimų. MVĮ vis dažniau internalizuoja inovacines veiklas, siekdamos suvaldyti reguliacinę riziką. Tačiau struktūrizuoti modeliai, apimantys išorinį bendradarbiavimą ir tvirtas atitikties strategijas, gali padėti išlaikyti įmonių lankstumą kartu užtikrinant reikalavimų laikymąsi. Šis tyrimas prisideda prie augančių diskusijų apie inovacijų valdymą reguliuojamose pramonės šakose ir pateikia praktines rekomendacijas MVĮ, siekiančioms suderinti atvirųjų inovacijų praktiką su reglamentų reikalavimais.

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Abbreviations:

AIMDD: Active Implantable Medical Devices Directives

CE: Conformité Européenne

CRO: Contract Research Organization

EUDAMED: European Database on Medical Devices

EU: European Union

GSPR: General Safety and Performance Requirements

IP: Intellectual Property

ISO: International Standard Organization

MDD: Medical Device Directive

MDR: Medical Device Regulation

MPDG: Medizinprodukterecht-Durchführungsgesetz

MPG: Medizinproduktegesetz

QMS: Quality Management System

R&D: Research and Development

SMEs: Small and Medium-sized Enterprises

UDI: Unique Device Identification

Introduction

Research Relevance:

Innovation drives economic growth, technological progress, and societal well-being. In fields such as healthcare, pharmaceuticals, aviation, energy, and financial services, it plays a vital role in addressing evolving user needs, global challenges, and competitive pressures. However, these industries often face stringent regulatory frameworks that emphasize safety, ethics, and accountability, thereby creating a delicate balance between innovation and compliance. The introduction of regulation into these sectors' innovative environments can lead to two significant consequences. First, compliance costs associated with regulations can function like taxation, diminishing the funds available for research and development. This often results in lower capital intensity and diminished innovation output, particularly in short-term cycles. Second, regulation alters the incentives for companies to invest in research and development. While some regulations, such as patent protection, may encourage innovation, others, like price controls or inflexible certification processes, can hinder it (Blind, Petersen, & Riillo, 2017).

With estimates of USD 800 billion by 2032, representing an impressive compound annual growth rate of 6.3%, these elements are particularly crucial in the medical device industry, valued at over USD 540 billion in 2024. (Fortune Business Insights, 2023). Over 90% of medical device firms in Europe are classified as small to medium-sized enterprises (SMEs), indicating that much of the sector's innovation originates from resource-constrained companies that rely heavily on agility, external collaboration, and open knowledge sharing (Yeung et al., 2021). Furthermore, medical devices typically have innovation cycles lasting just 18-24 months. Therefore, regulatory frameworks that are overly complex or misaligned with the pace of innovation can hinder progress rather than facilitate it (PwC, 2021).

Problem Analysis:

The case of the Passarola, an experimental airship invented by the Portuguese priest Bartolomeu Lourenço de Gusmão in the early 18th century, sheds light on historical perceptions of innovation, responsibility, and control. This groundbreaking invention illustrates the past mentality that placed the burden of risk solely on users, rather than on the technology itself. This perspective limited ethical assessments of technologies, emphasizing control over their social implications (Waltraud Zilch, 2022). In contrast, today’s society attributes the adverse effects of innovation to the inherent characteristics of the technology rather than to its users and operators. However, this shift has introduced new challenges, particularly the necessity to assess and mitigate the inherent risks associated with innovation. Current regulatory frameworks evaluate technology based on its intrinsic risks, which encompass safety, environmental effects, and societal and ethical implications, irrespective of who utilizes it. This change is evident in the regulatory evolution within the medical device sector from the established Medical Device Directive (MDD) to the Medical Device Regulation (MDR) (European Commission, 2021). The medical device field is recognized as one of the most complex and innovation-driven industries, operating in a high-stakes environment where innovation is crucial for competitiveness. Nonetheless, it is also subject to some of the world's strictest regulatory standards.

European Union Directive

Directives are legislative measures that establish objectives for all European Union member states to achieve. However, each country is responsible for defining and implementing its national laws to achieve these objectives (European Union, n.d.).

European Union Regulation

Unlike a directive, regulations are defined as binding legislative acts. Therefore, they are binding and do not require translation into national law. Regulations directly apply across the European Union (European Union, n.d).

The European Union (EU) Medical Device Regulation (MDR) embodies this shift, mandating rigorous safety, efficacy, and ethical standards to be practiced by manufacturers across the member states. Although these rules enhance public confidence, they also pose significant challenges for small and medium-sized enterprises (SMEs). Following the EU MDR, clinical assessments and certifications often require costly and stringent procedures. Startups or mid-sized businesses may find these expenses exorbitant, therefore limiting their capacity to launch fresh items onto the market. Long-standing regulatory procedures and technical paperwork impose an additional burden that delays new introductions, thereby impairing organizations' ability to respond to technical developments and consumer needs. The emphasis of regulatory systems on safety and efficiency may sometimes force businesses to take small steps toward radical innovations using their product lines. Regulatory uncertainty and the associated financial risks deter companies from investing in new concepts. Typically, larger companies have the resources to negotiate complex regulations, allocate funds for the approval process, and invest in comprehensive clinical studies, thereby consolidating innovation around a small number of powerful companies in the market (Ben-Menahem et al., 2025). Under these difficulties, SMEs explore alternative innovation approaches, including open innovation, to help offset Research and Development (R&D) expenses and expedite compliance initiatives. Moreover, this may be the beginning of a symbiotic relationship. Open innovation has advantages, but its integration in highly regulated contexts remains underinvestigated, mainly due to EU MDR compliance.

Research Gap:

Although the majority of the literature analyzes the implications of the EU MDR on innovation, much of it remains conceptual, policy-oriented, or focused on large companies or regulatory bodies. The key highlights remain on how MDR may hinder and encourage innovation. Nevertheless, they typically investigate these effects from a macro-level perspective, including the impact on the market, technological advancements, and regulatory changes. Concurrent with the growth in the literature on open innovation, which emphasizes its advantages in promoting external cooperation, information sharing, and agile development, the field has expanded significantly across various sectors. Studies that specifically combine the open innovation lens with MDR compliance procedures, particularly from the perspective of SMEs, which face unique challenges in balancing resource constraints, regulatory expectations, and the need to innovate, nevertheless reveal a gap. Furthermore, although theoretical models have examined the conflict between regulation and innovation, empirical studies documenting the actual experiences of medical device manufacturers under these limitations, primarily from a qualitative stakeholder perspective, remain scarce (Blind, Petersen, & Riillo, 2017).

Research Aim:
To explore the challenges small and medium-sized medical device enterprises face in implementing open innovation practices while operating under the Medical Device Regulation.

Research Object: The integration of open innovation practices within the MDR constraints

Research Objectives:

- To conduct a comprehensive problem analysis of the research necessity concerning the challenges faced by small and medium-sized enterprises in the medical device sector when engaging in open innovation under strict regulatory environments.

- To carry out a detailed literature review:
    - To understand the foundational principles of open innovation and its significance for small and medium-sized enterprises.
    - To investigate the theoretical conflicts between open innovation and MDR, particularly during the CE (Conformité Européenne) certification process.
    - To review cross-industry approaches to managing innovation under stringent regulations.

- To develop a conflict-mapping framework that theoretically connects open innovation attributes with MDR.

- To define and apply a qualitative case study methodology to examine stakeholder experiences across key functions (Research and Development, Regulatory Affairs, Production, Sales) within a selected small and medium-sized enterprise.

- Interpret the findings by considering the developed framework and offer recommendations that help start-ups and small and medium-sized enterprises in the medical device industry.

Structure & Methodology:
Figure 1 illustrates the visual representation of the research design employed in this thesis to investigate the challenges faced by SMEs in implementing open innovation under the EU MDR. This framework illustrates how the research aim guided the selection of literature, methodological choices, data collection techniques, and subsequent analysis. The first part of the thesis begins with a clearly defined research aim that sets the foundation for the entire inquiry, focused on exploring how SMEs manage the tensions between open innovation and MDR compliance. The next stage involves conducting a thorough literature review, understanding the concept of the traditional innovation process, also known as the closed innovation model, and further discussing its use case, benefits, and drawbacks. Later, the emphasis shifts to the attributes of open innovation and examples of value creation capabilities in companies that adopt open innovation. The literature also sheds light on the impact of regulatory rigidity on innovation in general scenarios. These thematic pillars provided the theoretical grounding for the study and the development of the conceptual framework. This framework mapped key phases of Conformité Européenne (CE) marking against open innovation attributes, serving as a guiding structure for data collection and analysis.

The study employs an in-depth, single-case qualitative approach, enabling the exploration of the real-world context of regulatory innovation. Empirical research methods employed included case sampling, interview selection, semi-structured interviews, and desk research to gain a comprehensive understanding of the internal challenges and departmental variations within the selected case company.

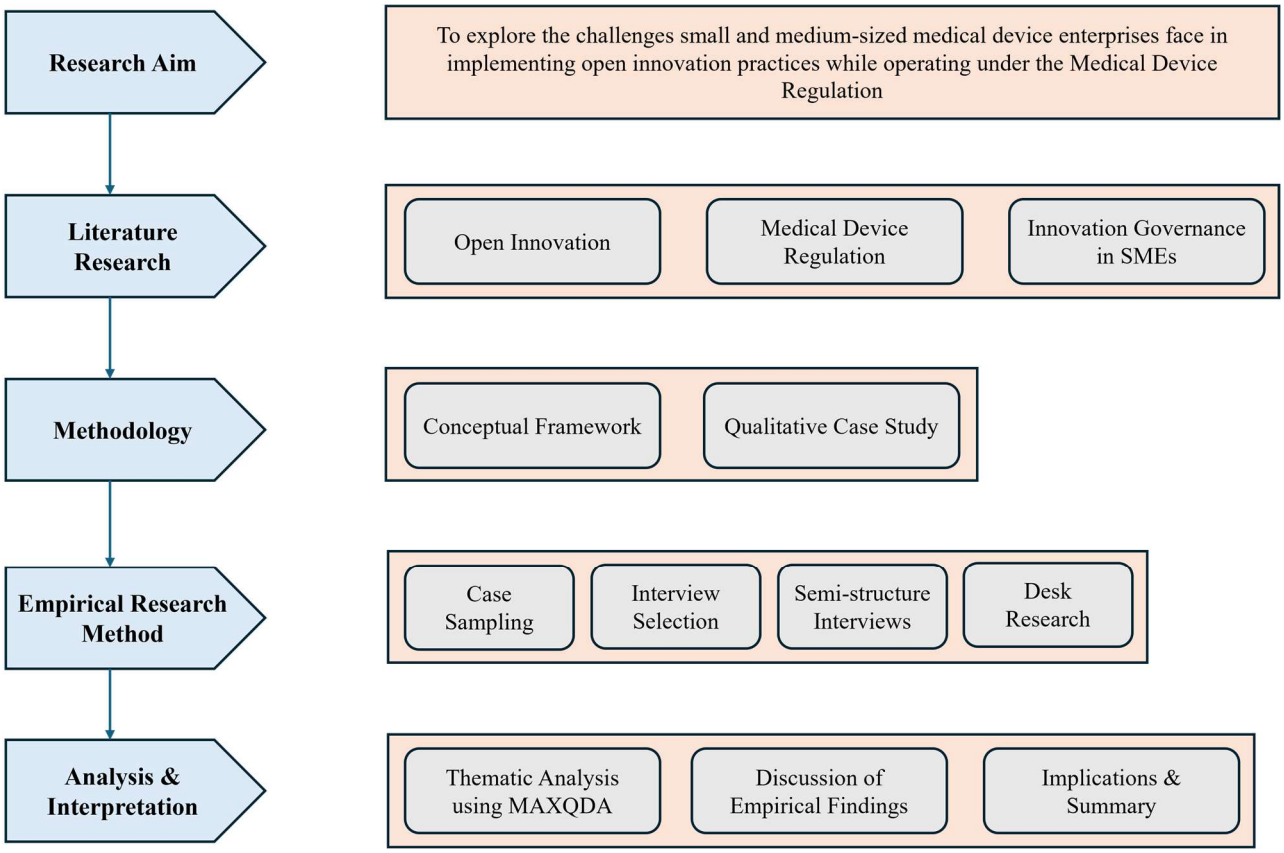

Figure 1 Research Design (Source: Own Illustration)

The study revealed five themes that emerged during the analysis, reflecting the critical challenges associated with integrating Open Innovation within the highly regulated medical device industry under the European Medical Device Regulation (MDR) framework. *Regulatory burden and innovation constraints, Market access challenges and regulatory risks, Internal organizational adaptations, External collaboration barriers, and Strategic and ethical reflections* are the key themes that explore the challenges caused by the complexity involved in documentation, opportunity cost of compliance, psychological effects of regulatory fatigue and understanding it's impact on collaboration and product portfolio management and also understanding its impact on go-to-market strategies and expectations management of different stakeholders. The study also highlights the fragmentation of perception of MDR-related challenges across different functional departments through a comparative analysis, identifying points of convergence and divergence across issues raised during the interviews. Furthermore, the study also explores the theoretical contributions made through the research and their implications for practical recommendations provided by the author.

1. Problem Analysis of Challenges Faced by the European Medical Device Regulatory Landscape

This chapter aims to establish the relevance of the study by examining the significance of the current European medical device regulatory landscape and exploring the challenges faced by medical device manufacturers in Germany. Furthermore, it also examines the intricate relationship between regulatory compliance and innovation, focusing on the barriers that impede open innovation practices in the development of medical devices in SMEs.

1.1. Medical Device Landscape in Germany

Europe holds a strong global position in the medical technology sector, with a 26.4% share of the world market, following the United States (MedTech Europe, 2023). Germany is the largest medical device market in the European Union, projected to generate over $36 billion in revenue by 2025 (Statista, n.d.). Additionally, Germany boasts an outstanding healthcare system, particularly in its hospitals, healthcare professionals, and infrastructure. The nation also employs the most significant number of individuals in the medical technology sector, which contributes approximately 12% to Germany‘s GDP (Germany - Healthcare and Medical Technology, 2023). This sector is characterized by its high research and development intensity, rapid product life cycles, and significant dependence on regulatory approvals. This dynamic, innovation-focused atmosphere consistently advances medical technology. However, it also introduces greater complexity, particularly as companies work to comply with changing regulatory standards. In this environment, medical technologies encompass a range of products, services, and solutions designed to diagnose, monitor, treat, and enhance patient quality of life. These technologies are crucial throughout all stages of care, from prevention and early diagnosis to chronic disease management and rehabilitation. A key feature of the medical device industry is that SMEs primarily drive innovation, not large corporations. Historically, these smaller firms have been instrumental in driving significant technological progress and product development within the sector. For example, in the Czech Republic, research indicates that small and medium-sized enterprises, rather than larger companies, lead most innovative efforts in medical devices (Peter et al., 2020). This trend is evident throughout Europe, including Germany, where a robust ecosystem of medical technology start-ups and small to medium-sized enterprises (SMEs) plays a crucial role in the healthcare technology landscape. It is crucial to acknowledge that the medical device sector is economically important for healthcare delivery. Regulation changes can influence business operations and might impact patient access to cutting-edge medical technologies. Balancing patient safety through regulation while promoting innovation presents a complex challenge for both policymakers and industry stakeholders (Maresova et al., 2021).

1.2. Understanding Medical Device Regulation (MDR) and its Significance

There has been a significant need for medical device companies to reassess their innovation strategies over the past few years, in response to market demands and increasingly stringent regulations. This transformation has been driven by the adaptation of the European Union Medical Device Regulations (MDR), which replace the Medical Devices Directive (MDD). The EU MDR was introduced to standardize the regulatory framework and approval processes for medical devices across the European Union (Yeung et al., 2021). Furthermore, it introduces additional updates and new requirements compared to the previous directives, leading to significant changes for all stakeholders.

The Medical Device Regulation (EU) 2017/745, also known as the MDR, is a legislative framework established by the European Union to ensure the safety, performance, and quality of medical devices marketed within the European Union. It was officially adopted on April 5th, 2017, and became applicable on May 26th, 2021, replacing the former Medical Device Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). According to Article 2(1) of the MDR, a medical device is defined as:
"Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes (European Union, 2017):

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of diseases,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement, or modification of the anatomy of a physiological or pathological process or state,
- Providing information using in vitro examination of specimens derived from the human body, including organs, blood, and tissue donations,
- Devices for the control or support of conception,
- Products specifically intended for the cleaning, disinfection, or sterilisation of devices".

Unlike its predecessors, the Medical Device Regulation (MDR, 2017/745/EU) functions as a regulation rather than a directive (European Union, 2017). This distinction is significant because the regulations are immediately binding and directly applicable in all EU member states without requiring transposition into national law (Germany - Healthcare and Medical Technology, 2023). The definition broadens the scope from the previous directive by explicitly including software, aesthetic devices, and products without an intended medical purpose but with similar risk profiles. These profiles are classified by risk level, as shown in Table 1:

Table 1 MDR Device Classification Table (European Union, 2017) (Source: Own Illustration)

Device Category	**Risk Profile**
Class I	Low risk
Class ls	Low risk - sterile
Class lm	Low risk – with measuring function
Class lr	Low risk – reusable surgical
Class IIa	Moderate risk
Class IIb	Medium to high risk
Class III	High risk
Custom-Made Devices	Special category – risk depends on intended use.

In Germany, the MDR is complemented by the Medizinprodukterecht-Durchführungsgesetz (MPDG), which replaces the old Medizinproduktegesetz (MPG). This national law introduces specific requirements for Germany and clarifies implementation aspects in addition to the main guidelines of the MDR. It is crucial for medical device manufacturers in the German market to grasp both the EU-wide regulations and the German-specific details (Ladd, 2023). The MDR is significant for its aim to enhance patient safety, improve regulatory oversight, and increase the transparency and traceability of medical devices within the EU market.

Key motivations for this regulatory shift include:

- Strengthening patient safety: The major driver for MDR was the strengthening of patient safety through enhanced pre-market and post-market criteria, as well as improved device traceability (Peter et al., 2020).

- Addressing gaps revealed by scandals: High-profile events like the Poly Implant Prosthese (PIP) breast implant controversy highlighted MDD flaws, therefore stressing the need for a more strict and open system (Donawa & Gray, 2012).

- Improved clinical evaluation: MDR emphasizes the importance of clinical data, particularly for higher-risk devices, which necessitate more reliable and ongoing clinical studies (Kearney & McDermott, 2023).

- More explicit classification rules: MDR has proposed more precise classification criteria, such as software, nanomaterials, and implantables, resulting in a reduced uncertainty in MDD (Peter et al., 2020).

- Enhanced Transparency: The new European Database on Medical Devices (EUDAMED) aims to provide greater openness and public access to data related to medical devices (European Union, 2017).

- Lifecycle approach to regulation: The MDR supports a product lifetime view, comprising design and development as well as post-market surveillance, thereby ensuring continuous safety monitoring (Kearney & McDermott, 2023).

- Better alignment across the EU: The MDR is a regulation (not a directive), thereby guaranteeing consistent application across all EU member states and reducing national interpretation variances (Maresova et al., 2021).

- Inadequate oversight of notified bodies under MDD: Under MDD, insufficient control of notified entities results in vastly different quality and breadth of assessments as MDR refines Notified Body designation and control (Peter et al., 2020).

- Digitalization and technological advancements: The earlier MDD framework lacked sufficient attention to new and emerging technologies, such as artificial intelligence software and nanotechnology (Maresova et al., 2021; European Union, 2017).

- Rebuilding public trust: Rebuilding the public confidence in the regulatory system, which has suffered from MDD discrepancies and shortcomings; however, MDR seeks to restore faith in the EU medical device control (Ladd, 2023).

Figure 2 illustrates the transition from the MDD framework to the MDR represents a crucial period for the European Union and its member states. On May 26th, 2017, the beginning of a planned four-year transition period was initiated. However, the original implementation date for MDR was postponed due to the COVID-19 pandemic. After a one-year delay, MDR was established on May 26th, 2021, replacing MDD and AIMDD. Furthermore, the full functionality of the EUDAMED database will be available in 2026.

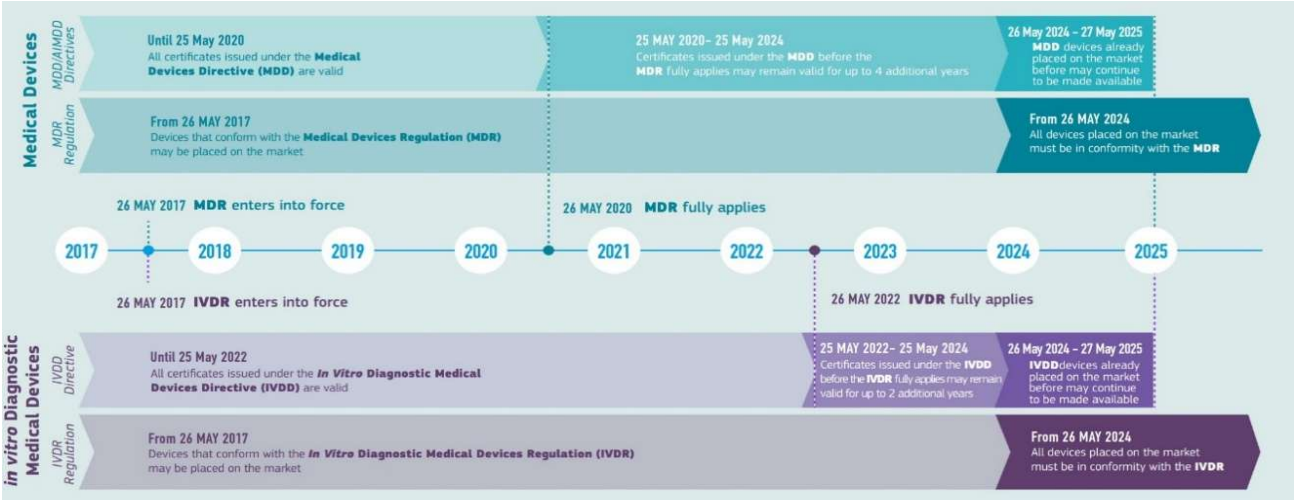

Figure 2 Transition Timelines from MDD to MDR (Source: European Commission, 2020)

The change from MDD to MDR represents a fundamental shift in the European regulatory framework governing medical devices. It is essential to note that this change was driven by the need for enhanced patient safety, increased transparency, and harmonized practices across EU member states. The MDR introduces more stringent and comprehensive requirements across various aspects of device regulation, including clinical evaluation, post-market surveillance, classification rules, and the role of notified bodies (Ladd, 2023). Table 2 highlights the key differences between the MDD and MDR, illustrating how the regulatory landscape has evolved to address the complexities of modern medical technologies and societal expectations.

Table 2 Difference between MDD & MDR based on Council Directive 93/42/EEC, 1993 and Council Directive 93/42/EEC, 1993 (Source: Own Illustration)

Aspect	**MDD**	**MDR**
Legal framework	The directive requires transposition into national laws	Regulation is directly applicable across all EU member states
Scope	Limited to medical devices and accessories	Expanded scope, including specific aesthetic devices and reprocessed single-use devices
Clinical evidence	Less stringent requirements: existing clinical data is sufficient	Stricter clinical evidence requirements: existing clinical data might not be sufficient
Post-market surveillance	Basic post-market surveillance requirements	Enhanced post-market surveillance, including mandatory reporting and vigilance systems

Aspect	MDD	MDR
Classification rules	Based on risk categories, fewer specific rules	More detailed classification rules, with stricter criteria
Notified bodies	Larger number of Notified Bodies	Reduced number of Notified Bodies and stricter designation criteria
CE marking	CE Marking required	CE Marking is required, but with additional scrutiny
EUDAMED database	No centralized database	Need for a centralised database for transparency and traceability
Unique Device Identification (UDI)	Not required	Mandatory UDI system for all devices

1.3. Challenges Faced by SMEs Under the EU Medical Device Regulation (MDR)

In the past, breakthroughs in medical innovation have often come from talented engineers tackling critical, unmet health needs. This was due to clinical validation occurring late, just before products entered the market. Moreover, market-focused advisory boards, rather than unbiased experts, often guided decisions at this stage. This approach allowed potential hazards to go unnoticed, leading to product delays and added costs. The original EU directives prioritized manufacturers' Quality Management Systems (QMS) over device safety, with evaluations often conducted by International Organization for Standardization (ISO) quality auditors rather than clinical specialists (Ben-Menahem et al., 2025). These regulatory changes have posed considerable hurdles for start-ups and SMEs, especially those developing entirely new medical devices or in vitro diagnostics, which were previously subject to lighter regulations.

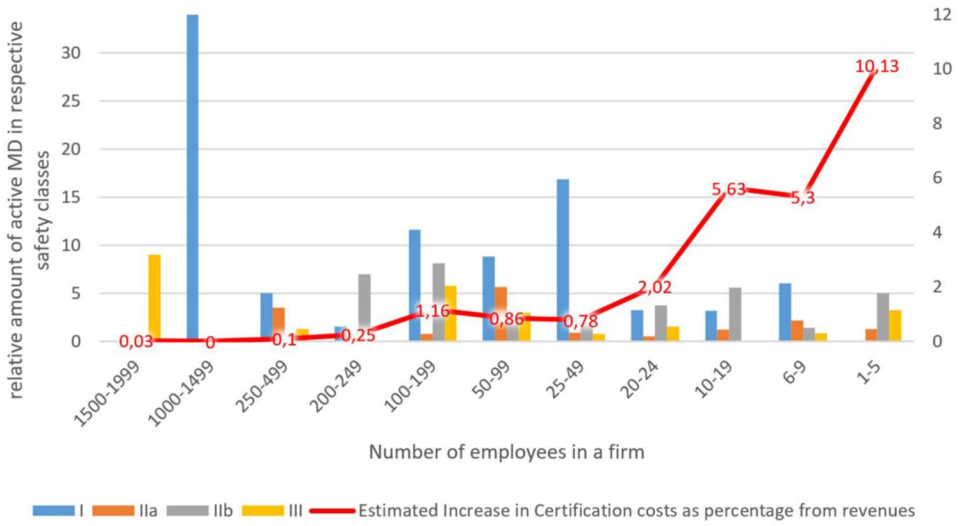

Figure 3 Overall Certification Costs (Source: Maresova et al., 2021)

These companies now face significantly larger investment requirements for conducting thorough clinical trials, usability studies, and laboratory validations, in addition to covering increasing certification costs and fees associated with notified body assessments, as illustrated in Figure 3.

Consequently, many SMEs find it challenging to comply with the Medical Devices Regulation (MDR). This issue is particularly severe in Germany, where SMEs dominate the industry, accounting for about 60-70% of market revenue, with 93% of these companies employing fewer than 250 individuals (Carl & Hochmann, 2023). The financial strain of compliance falls heavily on these smaller firms, often forcing them to divert resources away from innovation to focus on regulatory documentation and clinical evaluations, which stifles innovation and leads to a Reduction in their product offerings (Yeung et al., 2021). The EU MDR has imposed stricter demands for clinical evaluation, post-market surveillance, and documentation to enhance patient safety and traceability. However, the industry is experiencing delays in implementation, leading to widespread repercussions. By 2022, over 85% of legacy devices were still pending their MDR certification, and many SMEs reported interruptions in their product pipelines due to difficulties in accessing notified bodies and confusing guidance (MedTech Europe, 2022). This detrimental effect is apparent in the past, where regulatory requirements have hindered hospitals from adopting CT scans, resulting in them being more frequently requested by independent physicians' offices instead. Other sectors, such as the pharmaceutical industry, have experienced a significant decline in the introduction of new drugs to the market, accompanied by a decrease in affordability (Maresova et al., 2021). These issues are increasingly pressing for SMEs, who often lack dedicated regulatory teams and the necessary resources to quickly adapt to evolving regulations. Moreover, while the MDR has raised compliance standards, it has also sparked vital questions regarding its impact on innovation, particularly on agile product development, external collaboration, and knowledge exchange. In contrast to frameworks like the U.S. FDA's Breakthrough Devices Program, which supports accelerated innovation through flexible review processes (FDA, 2022), the MDR currently lacks mechanisms that strike a balance between compliance and innovation. This has resulted in unintended obstacles to market access, particularly for SMEs with limited resources and a strong focus on innovation, as illustrated in Figure 4.

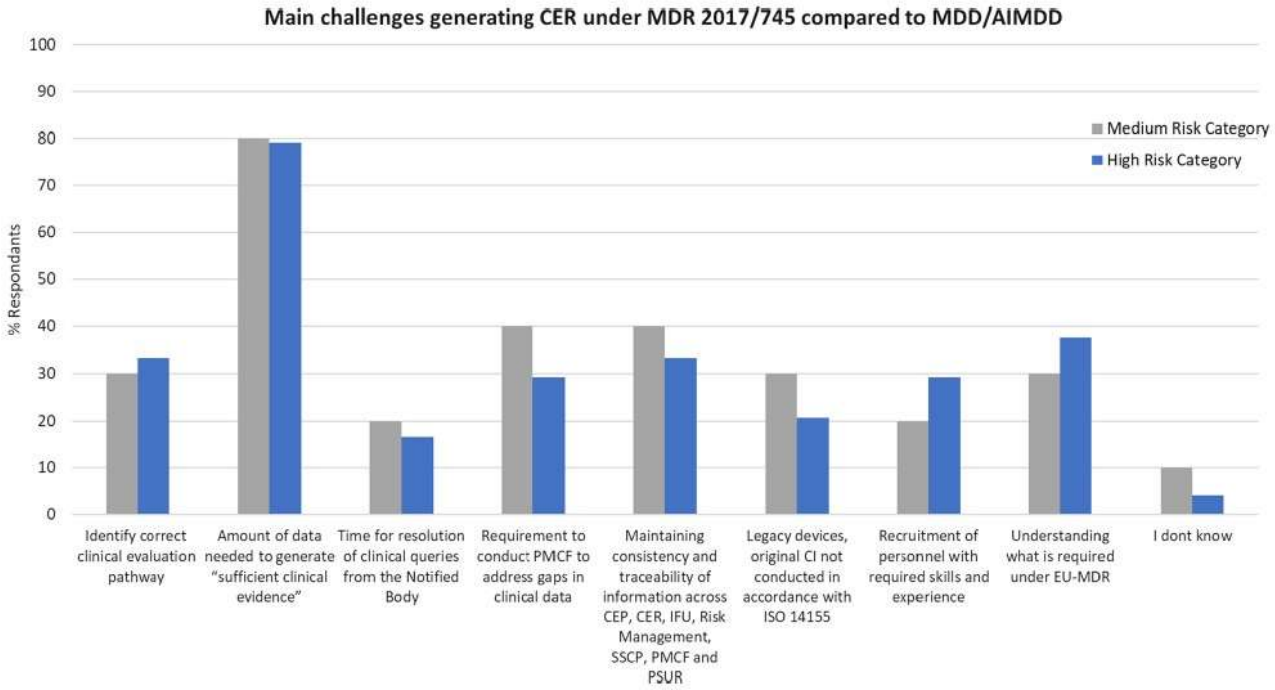

Figure 4 Challenges Faced by SMEs under MDR (Source: Kearney & McDermott, 2023)

1.4. The Impact of Regulatory Rigidity on Innovation

Innovation at its core thrives on flexibility, experimentation, and the freedom to test novel ideas in dynamic environments. Regulation, on the other hand, is inherently structured, cautious, and designed to ensure safety, fairness, accountability, and public welfare. While regulation plays a vital role in safeguarding consumers and markets, its interaction with innovation is complex and, in many instances, inhibitory, particularly when misaligned with the pace and nature of technological change. It is essential to note that different forms of regulations impact innovation, which can be particularly relevant to the type of innovation input the firm considers and the resulting outcome. Furthermore, it is important to comprehend the nature of these various types of regulations. For instance, the type of regulations solely focused on promoting innovative activities in the industry, such as intellectual property (IP) rights, and so on. Other regulations focus on achieving objectives such as public health, environmental protection, and market entry. A good example is the EU MDR, which is primarily aimed at achieving specific objectives but does not promote innovation independently. However, it is crucial to distinguish between regulations that hinder innovation and those that enable it. Not all regulation is restrictive. Smart, adaptive regulation can serve as a framework for responsible innovation, particularly in sectors with high public stakes. Additionally, factors affecting a firm's innovation capability include sector-specificities such as highly regulated sectors, the size of the companies, and the degree of flexibility in implementing regulations, which strongly influence companies' innovation output. While regulation is essential for safeguarding societal interests, it must also evolve in response to innovation. When rigid, ambiguous, or overly burdensome regulation becomes a bottleneck to creativity, deterring entry, delaying development, and diverting resources away from core innovation activities. Especially in SMEs and emerging sectors, regulatory design must strike a careful balance by protecting without paralysis, and guidance without gatekeeping (Blind, Petersen, & Riillo, 2017).

In the wake of global health challenges such as the COVID-19 pandemic and the accelerating pace of digital health innovation, the demand for fast, safe, and scalable medical technologies is higher than ever. However, the rigidity of the MDR and the risk of administrative burden may stall the development of urgently needed devices and inadvertently discourage breakthrough innovations, particularly from resource-constrained innovators. Moreover, with the transitional deadlines under MDR now entirely in effect, the industry faces significant consequences, including the withdrawal of legacy devices, delays in product approvals, and reduced access to niche technologies. Given the vital role SMEs play in driving innovation and addressing unmet clinical needs, it is essential to understand the challenges faced by small and medium-sized enterprises under the MDR and explore how innovation can thrive in a highly regulated environment.

In summary, the problem analysis section addresses the first research objective by providing a comprehensive examination of the challenges faced by SMEs in the medical device sector when adopting open innovation practices under the EU MDR. Firstly, the section emphasizes the German medical device market and its potential for future growth. It later explains the significance of the MDR and the transition from the MDD, highlighting key differences between the two regulatory frameworks. The section also discusses the impact of regulatory rigidity on innovation in general terms.

2. Theoretical Solutions for Bridging the Gap between Open Innovation and Regulatory Compliance

2.1. Closed Innovation Model: Foundations, Evolution, and Critique

The closed innovation model refers to a traditional approach to innovation management wherein the entire idea generation, development, and commercialization process is conducted internally within a single firm. This innovation governance is coined in contrast to the more recent open innovation paradigm. However, closed innovation dominated the industrial landscape through much of the 20th century. This reflects a vertically integrated innovation system where in companies control every aspect of the value chain, from basic research and development to product marketing and customer service. The emergence of this model was a response to the knowledge environment of the early 1900s. However, most scientific advancements remained isolated within academic circles during this period, while the infrastructure for disseminating knowledge and collaborating across organizational boundaries was largely underdeveloped. Consequently, companies seeking technological leadership had little choice but to build extensive internal research laboratories and retain control over all innovation-related activities. This resulted in incumbents epitomizing this model by establishing world-class research and development centres staffed with top scientists and engineers, shielded from external influence. The fundamental belief underpinning the closed innovation model is that innovation depends on firm-specific capabilities and proprietary knowledge. This led companies to regard external ideas skeptically, a phenomenon known as "Not Invented Here" (NIH) syndrome. This self-reliant innovation model emphasized secrecy, internal development, and control over intellectual property as mechanisms to sustain competitive advantage (Chesbrough, 2003).

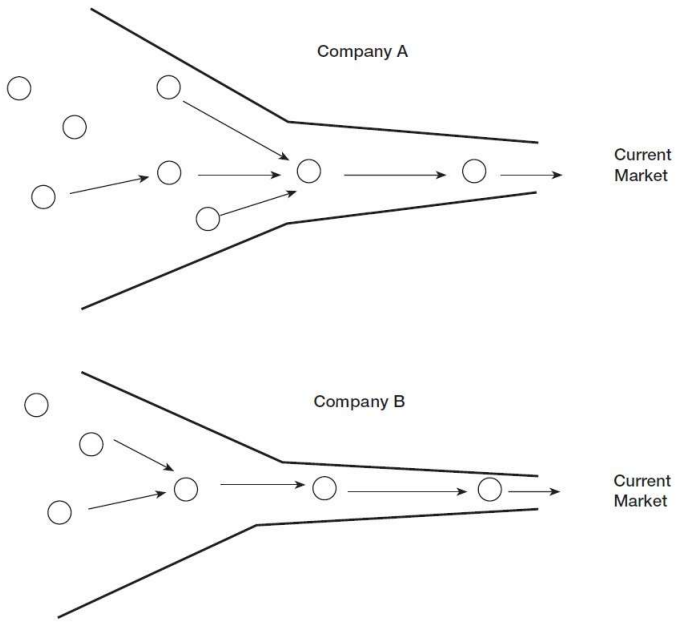

Figure 5 Closed Innovation Model (Source: Chesbrough, 2003)

In the closed innovation paradigm, as shown in Figure 5, innovation follows a linear trajectory that starts with basic research, proceeds through development and design, and culminates in commercialization. This end-to-end process occurs behind organizational boundaries, with firms aiming to generate, protect, and monetize their intellectual property.

The logic follows a pipeline model, where novel ideas are entered, screened, and filtered through internal review mechanisms, and ultimately deliver market-ready products. This suggests that innovation projects can only initiate the innovation process at the very beginning, are developed using internal resources and capabilities, and can only exit the process by being commercialized through corporate channels. The fear of losing intellectual property to other companies will thus prevent many great ideas and technologies from being utilized; most companies lack the knowledge to capitalize on every new research result or possess all the necessary tools to implement those prospects (Philipp Herzog, 2011).

Despite the eventual shift toward more open and networked models of innovation, the closed innovation paradigm has historically played a crucial role in shaping modern industrial research and development, driving some of the most significant technological advances of the 20th century. Its inherent strengths contributed to long-lasting competitive advantages for major corporations and helped establish foundational processes for managing innovation systematically within firms. One of the defining features of closed innovation is the centralization and internal protection of intellectual property. By keeping research and development activities strictly within the organizational boundaries, companies could guard their innovations from competitors, maintain secrecy, and secure exclusive rights to commercial exploitation. This control enabled them to fully capitalize on their inventions without the risk of knowledge leakage or imitation. The strategic use of patents, trade secrets, and proprietary technologies helped maintain market leadership and created significant entry barriers for new firms. For example, IBM‘s tightly integrated hardware and software systems were protected through layers of internally developed and legally secured innovations, which competitors found difficult to replicate (Kuan, 2020). In the closed innovation model, firms oversee the entire product lifecycle from research and development to manufacturing, marketing, and post-sale service. This end-to-end ownership enabled high integration across functions, allowing for rigorous quality control, seamless product compatibility, and a unified customer experience. Since products were developed with in-house components and systems, companies could guarantee the quality of the products being sold. Xerox, for instance, focused on maintaining high-performance standards in its copiers by manufacturing its own toner, paper, and image-processing systems. This vertical integration ensured consistent quality, allowing the firm to deliver sophisticated, highly reliable copying solutions to its institutional customers. While the closed innovation model dominated the 20th century and underpinned various technological successes, it began to show severe limitations toward the end of the century. Internal inefficiencies and external environmental changes revealed that a strictly inward-focused research and development approach could hinder innovation, prolong time-to-market, and result in significant missed opportunities. Several interrelated factors have contributed to the underutilization of the Closed Innovation model, transforming the global innovation landscape and compelling firms, specifically SMEs and startups (Chesbrough, 2003).

The rising mobility of highly skilled employees, particularly scientists, engineers, and research and development managers, acts as the key disruptor of the closed innovation paradigm. In earlier decades, companies could retain top talent by offering lifetime employment, internal career advancement, and exclusive access to cutting-edge research facilities. However, by the 1980s and 1990s, the professional landscape had shifted toward more fluid labor markets, with employees moving across companies, industries, and even countries more frequently.

This increased mobility due to digitalization and globalization made it difficult for companies to monopolize knowledge. As a result, former employees took with them tacit knowledge, expertise, and even ideas that are needed in development. The diffusion of intellectual capital diluted the competitive advantages once secured through internal research and development, and challenged the assumption that innovation could be contained within organizational boundaries. Furthermore, the rise of venture capital in the early 1990s also provided a powerful alternative to the corporate research and development model. In the closed innovation model, firms typically place ideas that do not fit existing business lines and are awaiting future use. However, the availability of venture capitalist funding allowed external startups to pick up and accelerate the development of these shelved ideas. This shift undermined a key premise of closed innovation, that a firm must develop and commercialize all valuable ideas internally. However, external innovation agents proved more effective at identifying, adapting, and monetizing nascent technologies, rendering internal monopolization of research and development less viable. As globalization and the digital revolution progressed, access to scientific knowledge became more democratized. Universities, research institutions, independent labs, and even users began contributing meaningfully to the innovation ecosystem. This expanded the knowledge landscape well beyond the confines of corporate research and development (R&D) departments. Furthermore, digital technologies, the internet, and collaborative platforms enabled the rapid dissemination of knowledge across organizational and national boundaries. Companies could no longer rely solely on internal sources of innovation, as many helpful ideas were now emerging externally, often from unexpected or peripheral domains, such as user-driven innovation, university spin-offs, and international consortia. This shift challenged the core assumption of the closed innovation model, which posits that the best and most valuable knowledge resides within the firm. The closed innovation model often led to longer development cycles and higher costs, as all phases of the innovation process, including idea generation, R&D, prototyping, testing, and commercialization, were conducted internally. Large companies built extensive research infrastructures and bureaucratic review processes to manage risk, but these systems also slowed decision-making and increased overhead. Despite their potential value, promising ideas that fell outside the firm's immediate strategic focus were frequently abandoned or shelved. This rigidity and inability to experiment with alternative paths to the market resulted in opportunity costs and diminished innovation returns. In contrast, the emergence of external markets for ideas, such as licensing, partnerships, and intellectual property trading, demonstrated that innovation could be faster and more cost-effective through collaboration and openness. The closed innovation model often led to longer development cycles and higher costs, as all phases of the innovation process, from ideation to research and development, prototyping, testing, and commercialization, were conducted internally. It is essential to note that large companies have established extensive research infrastructures and implemented rigorous bureaucratic review processes to manage risk. However, these systems also slowed down decision-making and increased overhead. Additionally, promising ideas that fell outside the firm's strategic focus were frequently abandoned, despite their potential value. This rigidity and inability to experiment with alternative paths to the market resulted in opportunity costs and diminished innovation returns. In contrast, the emergence of external markets for ideas, such as licensing, partnerships, and intellectual property trading, has showcased that innovation can be faster and more cost-effective through collaboration and openness (Kuan, 2020). Table 3 examines the contrast between closed and Open Innovation practices.

Table 3 Differences between Closed & Open Innovation Principles based on Chesbrough, 2003 (source: Own illustration)

Aspect	**Closed Innovation**	**Open Innovation**
Core philosophy	The smart people in our company will solve our problems	Not all smart people work for us. We need to collaborate.
Knowledge flow	Linear and internal (idea generation to commercialization within the firm).	Multi-directional, involving inflows and outflows of knowledge across organizational boundaries.
IP strategy	IP is tightly controlled, used for protection and exclusivity	IP is a strategic tool; it can be licensed out or in, traded, or co-developed for mutual benefit
R&D responsibility	Conducted solely within the company's labs and teams	Sourced from both internal teams and external partners
Commercialization	Internal development and go-to-market are preferred	Ideas may be commercialized internally or externally
Role of external actors	Limited or no involvement	Encourages collaboration with external actors
Flexibility and agility	Low and rigid structures, longer development timelines, and high sunk costs	Highly adaptive to market changes, faster time-to-market through partnerships
Risk management	The firm bears the full cost and risk of R&D	Risk and cost are shared among collaborators in a diversified innovation portfolio.
Employee mobility impact	High risk of knowledge loss when employees leave	Often benefits from employee mobility; brings in new ideas and external expertise.
Knowledge utilization	Only ideas that align with current business models are pursued.	Valued ideas may be repurposed, sold, or externalized, even if they are not internally usable.
Market responsiveness	Slow to adapt to external changes and emerging technologies	More responsive and dynamic; frequently interacts with market trends

Aspect	Closed Innovation	Open Innovation
Best suited for	Stable, capital-intensive industries with long product life cycles and high regulatory control	Fast-paced, knowledge-driven sectors where innovation ecosystems and collaboration are key

2.2. Understanding Open Innovation in the SME Context

The concept of open innovation, as introduced by Henry Chesbrough (2003), represents a fundamental shift in how organizations have evolved to manage innovation processes. Unlike the traditional closed innovation model, which relies solely on internal research and development capabilities, open innovation emphasizes the deliberate and strategic use of both external and internal knowledge to accelerate innovation, reduce costs, and create and capture value more effectively, as seen in Figure 6. According to Chesbrough, open innovation is a model whereby companies can and should utilize ideas generated both inside and outside, as well as explore internal and external routes to market, thereby advancing their technology. This viewpoint recognizes the need to push the company's boundaries to engage all stakeholders. Although large companies have employed open innovation over the years, the challenges small and medium-sized businesses face in implementing open innovation still require further research, regardless of the sector in which they operate.

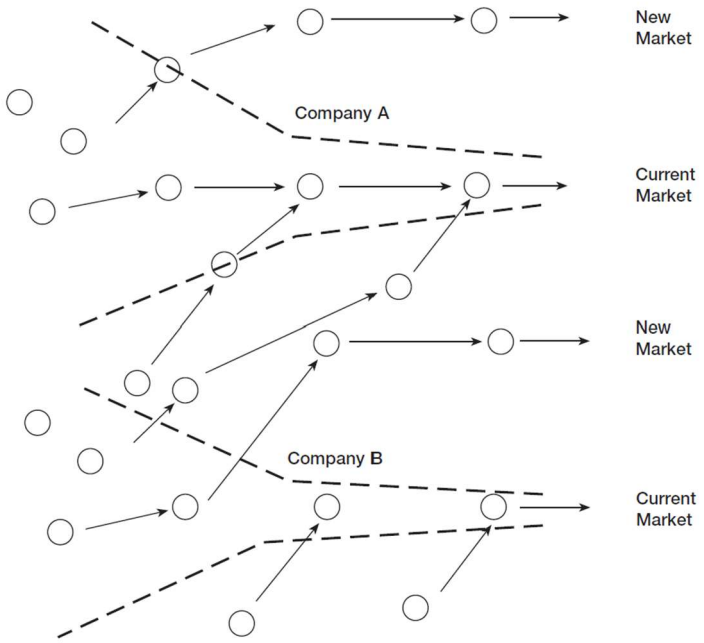

Figure 6 Open Innovation model (Source: Chesbrough, 2003)

Open innovation is grounded in several theoretical ideologies that serve as the foundational framework for companies to adopt. *Knowledge-based view* of the firm encompasses the perspective of firms as repositories and processors of knowledge; however, knowledge is increasingly distributed across networks and institutions.

This also states that a firm‘s primary source of competitive advantage lies in its ability to create, store, apply, and integrate knowledge. According to this approach, firms are not just producers of goods or services, but are also repositories of specialized knowledge.

Absorptive capacity is the capacity of a company to identify the value of fresh knowledge, absorb it, and use it for business interests. Especially in settings rich in external information, it is a significant factor influencing a company's innovation performance. By determining whether outside information is helpful and how to absorb and adapt it to fit internal settings, companies can develop a strong absorptive capacity. Moreover, it can be leveraged by utilizing fresh business strategies, tools, or products. Absorptive ability is also path-dependent, meaning it develops over time through past relevant knowledge and investments in research and development.

The *Resource-Based View* identifies a firm‘s unique resources and capabilities that are central to achieving and sustaining a competitive advantage. These resources may include tangible assets, intellectual property, technical expertise, reputation, and organizational culture. The alignment of Open Innovation with the resource-based view enables leveraging external capabilities without necessarily possessing them, which is particularly prominent for startups and SMEs with limited internal assets.

Transaction Cost Economics focuses on the costs of exchanging goods or services, including search, negotiation, contracting, monitoring, and enforcement. Typically, in traditional firms, high transaction costs were a key reason for vertical integration, which involves keeping innovation in-house. However, Open Innovation challenges this assumption by arguing that digital technologies, legal frameworks, and innovation platforms have significantly reduced the transaction costs of collaboration. By working with external partners through licensing, alliances, or joint ventures, firms can share the cost and risk of research and development, reduce sunk investments in fixed infrastructure or talent, and increase flexibility by outsourcing non-core innovation activities. Furthermore, this also gives rise to coordination and control challenges, which must be managed through contracts, governance mechanisms, and trust.

According to Chesbrough (2006), *Open Innovation* can be defined as “purposeful inflows and outflows of knowledge to accelerate innovation internally while also expanding the markets for the external use of innovation”. This inflow and outflow of knowledge is processed as inbound and outbound open innovation. A company that decides to in-license a technology developed outside the firm for its technological solution, rather than seeking to develop it in-house, is said to be practicing *inbound open innovation*. Furthermore, companies that decide to out-license their technology to other firms, enabling further product development for distribution, could be considered to be engaging in *out-bound innovation*. *The coupled innovation process* combines the inbound and outbound dimensions of the innovation process, in which firms come together to co-create and co-develop. This could mean a potential scope for joint ventures, collaborations, forming alliances, or crowdsourcing (Brant & Lohse, 2014). Open innovation frameworks are generally a continuum of openness rather than a stark choice between open and closed. The essence of open innovation lies in its flexibility and its adaptability to the firm’s current processes.

Technology sourcing method	Typical Duration	Advantages	Disadvantages
Internal R&D	Long term	▪ Build absorptive capacity ▪ Exclusiveness of technology and knowledge exploitation	▪ May not always be sufficient to keep pace with speed and complexity of technological developments in high-technology industries ▪ High commitment ▪ Low to medium reversibility
Licensing	Fixed term	▪ Fast technology access ▪ Lower development cost ▪ Less technology and market risks ▪ Low commitment and high reversibility	▪ Loss of control over decision-making due to contract constraints ▪ Competitive advantage may depend on exclusive licence
Joint R&D agreements	Medium to long term	▪ Explore emerging technologies ▪ Define and establish standards ▪ Access to public funding ▪ Reduced risk ▪ Exploit established technologies ▪ Develop system solutions	▪ Potentially limited flow of technological knowledge ▪ Knowledge leakage ▪ Opportunism risk
Innovation challenge	Short term	▪ Crowdsourcing broadens base of potential collaborators ▪ Cost-effective ▪ Reduced risk due to arms-length affiliation	▪ In-house, follow-on R&D may enhance control over technology developed ▪ IP management may be more complex with many contributors
Corporate venture capital	Flexible	▪ Window on technology ▪ Option to defer high commitment of resources ▪ High reversibility	▪ Information asymmetries between new venture and investing firm ▪ Modest control over development of technology
Joint ventures	Long term	▪ Technology convergence ▪ Define, establish standards ▪ Smoother information flows ▪ Coordination and control ▪ Exclusivity of technology ownership	▪ Organizational risk ▪ High commitment ▪ Low to medium reversibility
Acquisitions	Long term	▪ Hierarchical control over new technology, know-how ▪ Short-cut to new technologies	▪ Highest degree of commitment ▪ Low reversibility

Figure 7 Forms of Technology Sourcing (Source: Brant & Lohse, 2014)

In-licensing, out-licensing, cross-licensing, collaborative R&D partnerships, corporate venture capital, joint ventures, and inorganic expansion via acquisition are just a few of the several methods open innovation provides for the development and market introduction of a concept. For example, Procter & Gamble has opened its creative process through its "Connect & Develop" initiative while keeping control over the sale of the produced items. The corporation maintains control over its marketing, even when it receives ideas from outside sources. Leading pharmaceutical corporations have substantial R&D budgets—equivalent to 15–20% of their sales revenues—but they are increasingly relying on outside research and incorporating niche players into their pipelines (Bhattacharya & Guriev, 2005). The evolving external context for innovation has prompted creators to adopt open innovation models. These approaches may be particularly relevant in light of globalization, which necessitates the worldwide integration of economic activity, thereby reducing barriers to cooperation, facilitating the free movement of skilled labor, and promoting the dissemination of information, as illustrated in Figure 7. Even multinational companies (MNCs) cannot afford to perform everything in-house, given the rapid growth of digitalization, the rapid changes in market demands, and the growing complexity of products. This is also a result of businesses outsourcing the creation of auxiliary features, therefore emphasizing their core expertise. Still another element, though, is the phenomenon of industry convergence, which is the blurring of

technical and regulatory lines separating the various economic sectors. For instance, the convergence of the food and pharmaceutical sectors has given rise to a new category of nutraceutical and functional foods. Open innovation models are prevalent in fields marked by technology fusion, globalization, and high technological intensity, including biotechnology (Brant & Lohse, 2014), according to empirical data.

2.3. Value Creation through Open Innovation

Acceleration of time to market and minimization of costs and risks: Collaborative R&D significantly reduces the time and cost associated with bringing a medical device to market. This could be partnerships with Contract Research Organizations (CROs) and other virtual research platforms that enable SMEs to conduct clinical trials more efficiently (von Schomberg, 2013), leveraging the infrastructure and regulatory expertise can be used to streamline processes for extensive documentation and validation for MDR components such as Annex IX (Conformity Assessment) and Annex XIV (Clinical Evaluation). For instance, Johnson & Johnson's partnership with multiple external research institutes has accelerated its R&D pipeline, resulting in a reduction of the average time-to-market for new devices (Johnson & Johnson, 2023)**.**

Fostering long-term innovations: Open innovation is a state of continuous integration that combines diverse perspectives, expertise, and technologies from external stakeholders. The increased compliance costs associated with MDR regulations can hinder innovation, but through collaboration, companies can focus on incremental and novel innovations without being constrained by resource limitations. This is seen in Medtronic's innovation strategy. This medical device company has set prominence with academic institutions and startups, enabling it to develop novel medical devices through a sustained collaborative ecosystem that follows MDR's General Safety and Performance Requirements (GSPR) that mandates iterative product improvements (A Healthy Life. A Healthy Planet. For Everyone. FY24 Impact Report 2, n.d.).

Enhancing product and service quality: Incorporating valuable feedback from diverse stakeholders, including healthcare professionals, patients, and regulatory experts, can be an optimal way to improve product quality, as this is critical under MDR, where compliance with Annex I (GSPR) demands rigorous safety and performance standards. Siemens Healthineers collaborates with hospitals and research centers to co-develop imaging technologies, ensuring the final products meet clinical and patient safety requirements. Hence, such partnerships enable companies to integrate real-world insights into their R&D processes, enhancing device quality and reliability (How We Innovate, n.d.).

Unlocking new market opportunities: The open innovation model enables companies to identify and capitalize on new opportunities by leveraging external networks and knowledge. This means accessing previously untapped markets that were previously inaccessible due to resource limitations. Partnerships with multiple stakeholders, especially external stakeholders such as an extensive global network of distributors, can help SMEs comply with regional regulatory nuances while expanding their market presence. Philip's strategy includes collaboration with local healthcare providers in emerging markets, enabling the development of region-specific devices that meet local regulatory requirements and global MDR standards (Driving Innovation in Health Care through Strategic Partnerships, n.d.). Another prominent source of information to explore unmet needs and emerging trends is the MDR's post-market surveillance requirements (Article 83).

Increasing organizational flexibility in regulatory environments: Companies quickly adapt to changing regulatory requirements and market demands through open innovation practices. In the context of MDR, flexibility is crucial given the frequent updates to compliance standards and the need for iterative product improvements. Further collaboration with external partners, such as regulatory consultants or innovation hubs, enables companies to pivot their strategies without the delays associated with internal restructuring. For instance, Boston Scientific's partnerships with multiple regulatory experts across different regions allow it to navigate MDR requirements more efficiently, ensuring timely compliance and market entry (PURPOSE HUMANITY SCIENCE, n.d.).

Building absorptive capacity for better innovation process: In terms of absorptive capacity, or the ability to recognize, assimilate, and apply external knowledge, is a critical factor in leveraging open innovation. MDR's requirements for extensive clinical evaluations and risk management (Annexes IX and X) necessitate a high degree of technical and regulatory expertise. Hence, collaborating with academic institutions and research consortia enhances a company's ability to integrate external innovations into its R&D processes. For example, GE Healthcare collaborates with leading universities to co-develop imaging technologies, enabling it to integrate cutting-edge research into its product development cycles rapidly. This improves compliance efficiency while fostering innovation (University of California San Francisco and GE HealthCare Launch a Joint Research Program to Drive Innovations in Imaging, Brain Health and Precision Oncology | GE HealthCare, 2025).

Creating and monetizing spillovers through collaborative ventures: It is evident that collaboration through open innovation can create monetizable spillovers, such as intellectual property (IP) licensing, joint ventures, or spin-offs. These spillovers generate additional revenue and foster a culture of innovation within the company. In the context of MDR, companies can license out technologies developed for compliance purposes, such as advanced risk management tools or clinical trial software, to other organizations. An example is Roche's collaboration with digital health startups, which resulted in the commercialization of software solutions initially developed in-house. MDR's emphasis on documentation and transparency (Annexes II and III) provides a foundation for creating IP assets that can be monetized (*Roche | New Ways to Bring Digital Innovation to Patients Faster*, n.d.).

2.4. Barriers to Open Innovation

There has been a fundamental shift in the innovation paradigm in industries like pharmaceuticals, information technology, and, more recently, medical technology. As large corporations have led the adoption of open innovation, the emergence of start-ups and SMEs as key innovation actors has introduced new opportunities and unique challenges, especially in the MedTech sector, where regulation, complexity, and speed are intricately intertwined. For example, data from the U.S. National Science Foundation (NSF) show that R&D spending by small firms grew 40-fold from 1981 to 2005, outpacing the growth of larger corporations (Chesbrough, 2010). Moreover, this market trend acknowledges the shift where SMEs are recognized as the innovation engines in sectors that rely on agility, specialization, and customer-centric solutions. For the Medical device industry, this holds importance as many breakthrough ideas originate from clinical needs identified by small innovators or start-ups, and digitalization has lowered the barrier to prototyping, testing, and collaboration. Large firms often acquire innovations from small and medium-sized enterprises to enrich their pipeline. Furthermore, the main challenges encountered by the MedTech SMEs are due to structural, financial, and institutional constraints. For instance, SMEs often lack dedicated resources to identify and

internalize external knowledge systematically. When practical knowledge is sourced, SMEs may lack the technical depth required or the infrastructure to adapt and apply it for commercial purposes, resulting in limited absorptive capacity, as discussed earlier. Furthermore, academic institutions and large firms have preferences in terms of partnerships with established corporations or opt to spin off their startups, leaving existing SMEs with fewer options for collaboration. Additionally, inconsistent internal innovation processes make it difficult for SMEs to engage in structured, long-term partnerships, which in turn makes them less attractive as innovation partners. Hence, this results in struggles for MedTech SMEs in enforcing Intellectual Property rights due to high legal costs and their dependence on large customers or distributors. This inability to protect or profit from externally sourced intellectual property reduces their incentive to engage in open innovation.

2.5. The EU Medical Device Regulation (MDR) and CE Certification

After the EU was established in the early 90s, the MDD was introduced to unify regulations across The states of Europe should eliminate trade barriers within the internal market. These directives allowed medical device manufacturers to access the entire EU market once their products received the 'Conformité Européenne (CE) marking.' This mark signified that the device met EU standards for safety, health, and environmental protection, as well as the guidelines set by ISO. The procedural steps that need to be followed to obtain the CE marking have been classified into the following phases:

1. Classification, 2. Development, 3. Assessment, 4. Certification, 5. Market Entry, 6. Compliance Maintenance.

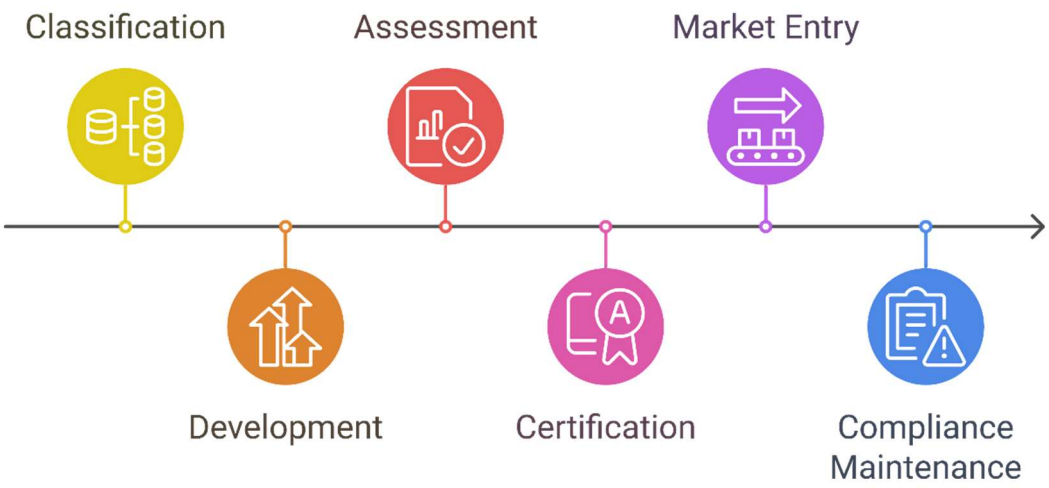

Figure 8 CE Marking Phases (Source: Own Illustration based on (EMA, 2024))

Figure 8 illustrates the procedural steps that also serve as the roadmap for obtaining the CE Mark for the commercialization of medical devices in EU Member States. During the *classification phase*, medical devices are classified based on their intended use, duration of contact, and invasiveness into Class I, Class IIa, Class IIb, and Class III categories, as outlined in MDR Annex VIII (European Parliament and Council, 2017), refer to Table 1. A common challenge firms encounter in this stage includes ambiguity in classifying novel or innovative devices that may not fit into predetermined categories (Yeung et al., 2021). In the *Development Phase,* firms gather design requirements ensuring compliance with General Safety and Performance Requirements (GSPR) Outlined in Annex I

(European Parliament and Council, 2017), another key task is to develop technical documentation (Annex II) covering device description and specifications, risk management plan, clinical evaluation plan, also implementing a Quality Management System (QMS) compliant with ISO 13485 (Yeung et al., 2021). This phase involves challenges related to high costs for tests such as biocompatibility testing, performance evaluations, and risk management implementation. SMEs often lack in-house expertise in regulatory affairs and engineering. Another resource-intensive task would be compiling technical files and maintaining version control for the documentation (Ben-Menahem et al., 2025). In the *Assessment Phase,* firms conduct clinical evaluations (Annex XIV) to demonstrate the safety and performance of their products, as supported by literature reviews, pre-clinical studies, and clinical investigations. Carrying out risk assessments to identify and mitigate potential hazards and engaging a notified body for conformity assessment (Annex IX), which includes QMS audit and technical documentation review. Challenges in this stage include the limited availability of MDR-designated Notified Bodies, which can cause delays. According to a survey report by MedTech Europe, at least 15% and up to 30% of small and medium-sized enterprises (SMEs) still lack access to a Medical Device Regulation (MDR)- designated notified body. As a result, the average time for certification by notified bodies has doubled, from 13 to 26 months (MedTech Europe, 2022). In the *Certification Phase,* firms must prepare the EU Declaration of Conformity (Annex IV) to affirm compliance with MDR requirements, ensuring correct placement of the CE Mark on the device, packaging, and instructions for use, if needed, firms must compile the Summary of Safety and Clinical Performance (SSCP) for class IIa and higher devices. Key challenges include high costs concerning certification fees and audits, SMEs often lack the personnel or tools needed to meet strict deadlines, and generating and maintaining accurate documentation is labor-intensive, which also results in slow progress to certification, around 14% of all certificates (QMS and Technical File) have been issued so far (MedTech Europe, 2022). In the next phase, known as the Market Entry Phase, key activities include establishing a post-market surveillance (PMS) system (Article 83) and developing a post-market surveillance report (PMSR) or Periodic Safety Update Report (PSUR). Furthermore, a vigilance system (Article 87) must be established to report serious incidents and field safety corrective actions (FSCAs), and it must comply with Market Surveillance (Article 89) (European Parliament and Council, 2017). Challenges in this phase include an increased workload for continuous monitoring, reporting, and documentation, which often require dedicated teams. Implementing robust systems for data collection and analysis can be expensive. Additionally, non-compliance with reporting obligations can result in penalty risks or product recalls (Carl & Hochmann, 2023). In the final phase, *Compliance Maintenance,* firms must maintain technical documentation and carry out necessary updates (Article 10), undergo periodic surveillance audits by notified bodies (Annex VII), and retain records for a specified duration (Article 103). Furthermore, firms must also update their Quality Management System to align with changes in regulations or technology. The key hurdles in this stage include SMEs' lack of dedicated teams to handle ongoing audits and documentation updates, which require audits to be substantially prepared and disrupt daily operations (Carl & Hochmann, 2023).

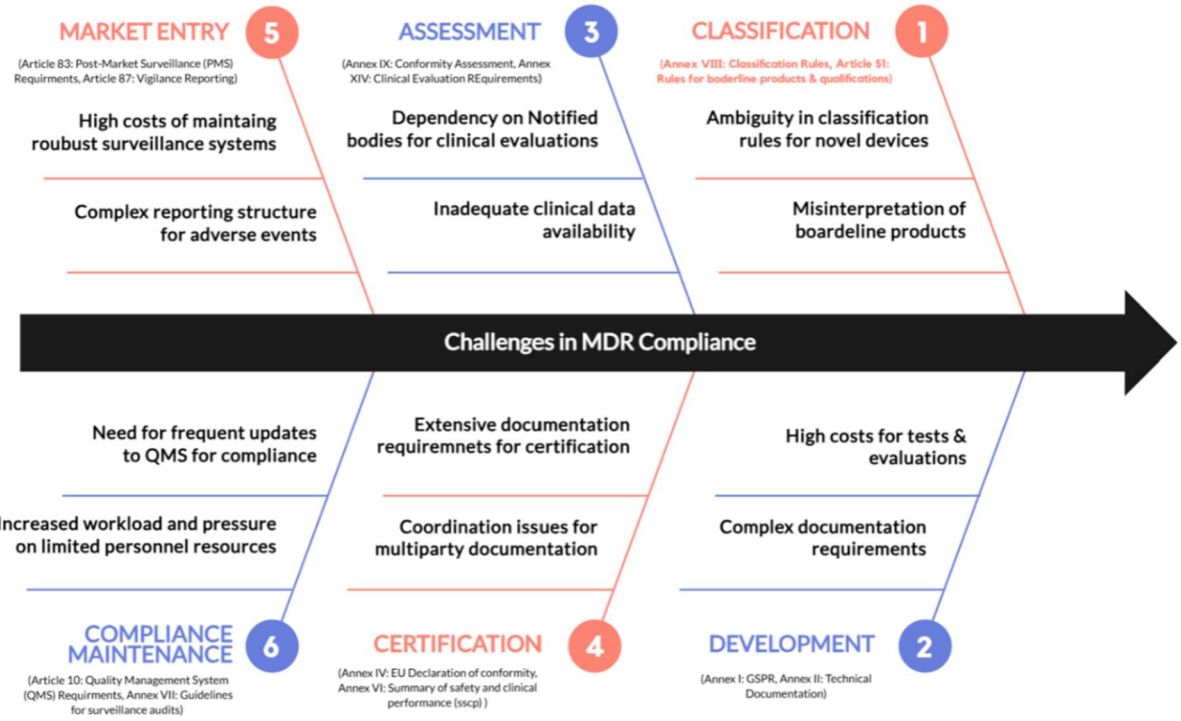

Figure 9 Conflicts with MDR Compliance and Open Innovation Incorporation (Source: Own illustration)

Figure 9 presents the conceptual framework designed to identify challenges in CE certification, map the relevant MDR components for each phase, and analyze their current conflicts with open innovation attributes. In the initial phase of the accreditation, *Classification*, the MDR components that hold relevance are Annex VIII (classification rules) and Article 51 (Rules for borderline products & qualification) due to the need to classify the medical devices correctly, challenges in this phase include difficulty in classifying novel technologies as they do not fit in predefined classification rules, which leads to misclassification, rework, delays, and resource strain. There is also ambiguity in classifying emerging technologies, which discourages collaboration with external partners due to increased regulatory uncertainty (Carl & Hochmann, 2023). In the *Development Phase*, Annex I (General Safety and Performance Requirements – GSPR), Annex II (Technical Documentation, Annex III (Post-Market Surveillance) holds relevance due to the need to ensure compliance with safety and performance standards requires extensive internal testing, which results in reduced willingness to share sensitive data with the external partners due to Intelectual Property (IP) concerns, there is also complexity in aligning external innovations with detailed technical documentation requirements, which causes delay in integrating external technologies which slows down product development (Ben-Menahem et al., 2025). Additionally, there is a requirement for robust risk management and surveillance plans, which leads to increased costs; furthermore, this restricts their ability to engage in open collaboration effectively (Maresova, 2022). In the *Assessment phase,* Annexes IX (Conformity Assessment), XIV (Clinical Evaluation), and X (Risk Management) are relevant. The conflicts in this phase include dependence on external partners for clinical trial data, which increases the risk of non-compliance. Misalignment with clinical evidence among collaborators leads to regulatory delays. Fragmented collaboration makes it challenging to establish consistent risk management frameworks, which in turn affects the trust between SMEs and their partners, thereby stifling knowledge exchange (Schuhmacher et al., 2016). In the *Certification Phase,*

Annex IV (EU Declaration of Conformity), and Annex VI (Summary of Safety and Clinical Performance – SSCP), which create hurdles in terms of multiple entities contributing to conformity documentation create inconsistencies, which results in an extended timeline for final documentation, delay in certification and market entry. Moreover, external innovations must also meet stringent MDR conformity standards; as a result, firms often hesitate to adopt external innovations, fearing non-compliance. In the *Market Entry Phase,* Article 83 (Post-Market Surveillance) and Article 87 (Vigilance Reporting) hold importance. Collaboration increases complexity in monitoring safety and performance data, and failure to align vigilance reporting with external partners risks regulatory penalties (von Schomberg, 2013). Additionally, variability in compliance practices among global partners complicates the collection of data. However, it reduces the scalability of Open Innovation models for SMEs. In the last phase, *Compliance & Maintenance,* Article 10 (Quality Management System – QMS), Annex VII (Audits), Article 103 (Record Retention Periods) holds significance, and the challenges include frequent audits and updates, requirements of consistent quality management across collaboration, as a result, increased administrative burden reduces SME's ability to focus on innovation. Auditing joint ventures or partnerships exposes operational inefficiencies, which results in reduced trust in external collaborations, limiting the scope of OI (Nnamseh et al., 2020). There are also requirements for long-term data retention that discourage short-term collaborations; this means that potential collaborations are also rejected due to misaligned data governance policies.

2.6. The broader Impact of Regulation on Innovation

Regulations have the capability to serve as both constraints and catalysts in the innovation process. However, they are designed to ensure safety, ethics, and fair competition; they can impose compliance burdens, particularly in rapidly evolving sectors such as medical technology (MedTech). According to Blind (2012), there are two aspects impacted by the regulation. Firstly, in the short term, it can inhibit innovation due to high compliance costs and uncertainties. Secondly, in the long term, it can stimulate innovation by setting performance standards that encourage companies to develop better solutions.

Economic regulations
Competition enhancing and securing regulation
Antitrust regulation
Merger & acquisitions
Market entry regulation
Price regulation
Regulation of natural monopolies and public enterprises
Social regulations
Environmental protection
Workers health and safety protection
Product and consumer safety
Institutional regulations
Liability law
Employment protection legislation
Immigration laws
Bankruptcy laws
Intellectual property rights

Figure 10 Types of Regulations (Source: Blind, Petersen, & Riillo, 2017)

It is essential to recognize that various types of regulations impact innovation differently. Figure 10 depicts the different types of regulations. For instance, economic regulations may foster or hinder innovation depending on their design. Social regulations, particularly those that are technology-neutral, often encourage firms to adopt cleaner and safer innovations. Regulations, such as Intellectual Property (IP) laws, influence risk-taking behavior and the broader innovation culture. When considering the pharmaceutical and biotechnological industry, it is evident that these industries face rigorous regulatory scrutiny. However, frameworks such as orphan drug regulations and fast-track approvals demonstrate that regulation can stimulate targeted innovation. Studies indicate that reduced approval times can lead to increased investment in R&D. In the automotive sector, Environmental mandates, such as emissions standards, have historically led to innovations like catalytic converters and hybrid vehicles. Performance-based rules generally encourage more radical innovation than rigid prescriptive regulations. Furthermore, deregulation and flexible pricing mechanisms have led to infrastructure innovation and diversification of services in the telecommunications industry. Regulatory models that reduce entry barriers while maintaining oversight tend to foster innovation driven by competition. In the energy and environment industry, Market-based instruments such as carbon trading and eco-labeling have spurred innovation in clean technologies. The Porter Hypothesis suggests that stringent, well-designed environmental regulation can enhance sustainability and competitiveness (Blind, Petersen, & Riillo, 2017). The MedTech sector operates under increasingly complex regulatory frameworks such as the EU's Medical Device Regulation (MDR). These frameworks aim to improve safety but impose heavy documentation, high certification costs, and slower market access.

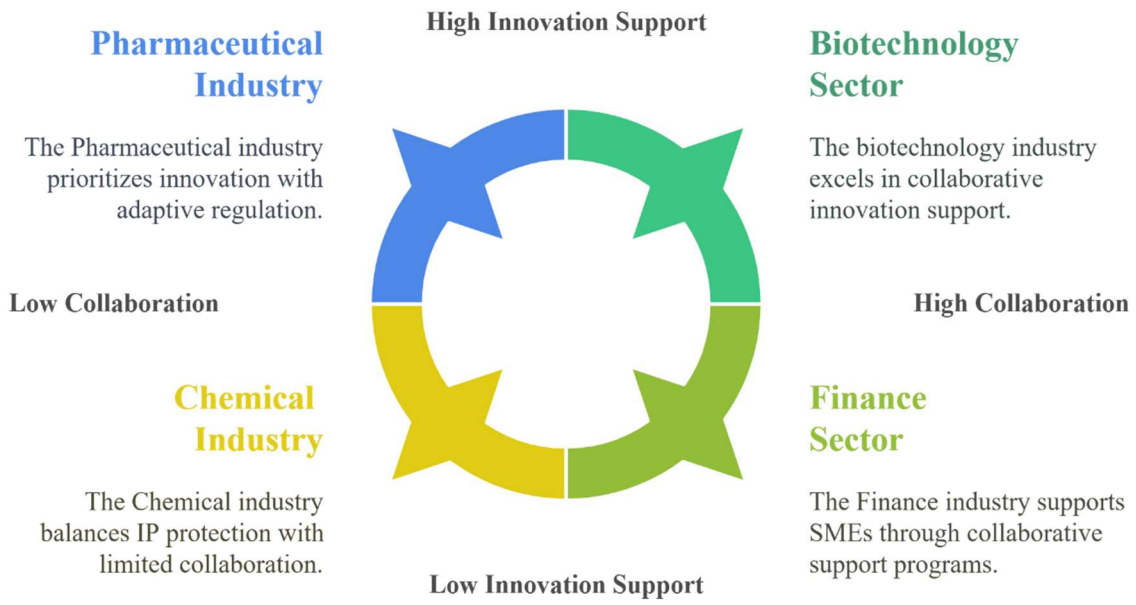

Figure 11 Strategies in Highly Regulated Industries based on (Schuhmacher et al., 2016), (Blind, Petersen, & Riillo, 2017), (Brant & Lohse, 2014), and (Nnamesh et al., 2020) (Source: Own illustration)

However, as illustrated in Figure 11, key learnings from other highly regulated industries include:

Adaptive and performance-oriented regulation: This is exemplified in the pharmaceutical industry, which is highly regulated and has leveraged adaptive regulatory pathways, such as accelerated approval, orphan drug designation, and priority-based review, for high-risk, high-reward innovations as these pathways offer a model for regulatory bodies to prioritize breakthrough innovations without compromising safety (Schuhmacher et al., 2016).

Co-creation and collaborative environments: This is adapted in the biotechnology sector, which has fostered co-creation environments that enable regulators, industry experts, and researchers to collaborate and align product development with compliance requirements. This ensures stakeholder management and prevents innovation from being stifled by regulatory uncertainty (Blind, Petersen, & Riillo, 2017).

Balanced intellectual property (IP) frameworks: Industries such as the chemical industry have benefited from balanced IP regulations that focus on protecting innovations while allowing for knowledge diffusion, which enables innovators to protect their technologies without creating monopolies that could potentially hinder market entry (Brant & Lohse, 2014).

Support systems for SMEs: The finance sector has introduced targeted support programs that recognize the unique challenges faced by SMEs, including capacity-building initiatives and regulatory sandboxes. Furthermore, these support mechanisms reduce the compliance burden on smaller firms while maintaining market integrity (Nnamesh et al., 2020).

Clear and transparent guidelines: The energy sector has adopted clear and transparent regulatory guidelines that minimize compliance ambiguity by providing well-defined standards and flexible compliance options, thereby fostering sustained innovation in this industry and helping firms adopt new practices.

The shift from the MDD to the MDR marks a turning point in the European medical devices industry, with a significant impact on patient safety measures, innovation strategies, and market access. As much as it is supposed to drive public health and openness, MDR has disproportionately fallen on SMEs, which are the backbone of the MedTech community in countries such as Germany (Stewart, 2021). With over 85% of medical devices still to be recertified (MedTech Europe, 2022), the threat of innovation paralysis and market withdrawal hangs ever larger. Protracted delays, insufficient notified bodies, and rising compliance costs for most SMEs lead some to opt for the European market instead of pursuing faster, less burdensome regulatory paths elsewhere. This research exists within the broader vision of enhancing regulatory systems without strangling innovation. It offers hands-on guidance on how to integrate Open Innovation practices in a regulated environment, with MDR being a prime case. Although the current framework identifies counterproductive tensions between OI and MDR components, such as clinical evaluation, technical documentation, and conformity assessment, it also aims to empower SMEs with scalable models that are both agile and compliant. Secondly, the MDR constantly evolves or is replaced by something else, so the relevance of this research remains. The key concern of coping with innovation in a regulated environment transcends this specific policy.

These examples underscore the broader applicability of this study's findings and reinforce the relevance of the proposed framework beyond the MDR context. Ultimately, the study contributes to the emerging discourse on how SMEs can remain innovative and agile even as regulatory environments shift and evolve.

In summary, the theoretical section addresses the second and third research objectives by conducting a detailed literature review to understand the foundational principles of open innovation and their relevance to SMEs. The section, firstly, explains the traditional innovation model, termed closed innovation, and its current adoption in R&D-intensive firms, as well as its drawbacks. Furthermore, it highlights various aspects of value creation through the open innovation model, emphasizing its advantages for SMEs. It also discusses the barriers that firms face when adopting open innovation practices in general, and specifically, the conflicts between open innovation attributes and components of MDR, through a conflict-mapping framework that bridges the gap between innovation practices and regulatory obligations. Furthermore, cross-industry perspectives on managing innovation under regulatory constraints, along with key learnings, are provided.

3. Methodology of empirical research for exploring conflicts between open innovation and MDR regulatory compliance

3.1. Research Design

With the research gap identified and acknowledging the lack of work involving open innovation in the EU MDR landscape, as noted in the Introduction section, the author conducts in-depth literature research to provide a detailed outline of the crucial topics related to the study area. This research includes two parts, the first being a systematic review of existing literature, including journals, reports from industry reports, books, and other online databases such as Google Scholar, Research Gate, etc, The search criteria was developed in accordance to the research object and the gap identified emphasizing on understanding aspects of the EU MDR landscape, Medical device market in Germany, impact of these regulations on innovation and understanding principles and charateristics of Open Innovation and how SMEs find it challenging to adopt in their firms and understand the reasons behind it and their implications. Only writings relevant to the thesis were further reviewed, and patterns were identified. All sources used in this report are cited using the APA 7th edition method of citation.

The next part of the research includes conducting an empirical study to validate the literary findings. The chosen research method is qualitative. This research method was determined mainly based on criteria such as 1. To explore and understand the impact of MDR on different aspects of innovation, which are complex, dynamic, and not fully measurable through quantitative means 2. There is a need to understand the diverse perspectives, experiences, and nuances of professionals. 3. Flexibility to explore emerging themes in the relatively under-researched area.

3.2. Case Description and Participants Sampling

The research employed a single-case study method, with Spiegelberg GmbH being the focus, a German small and medium-sized enterprise in the medical devices sector. The company was established in 1986 in Hamburg and has since endeavored to design, manufacture, and distribute neurosurgical medical devices. The company has expanded and now sells its products to customers worldwide, operating in nearly 70 countries. Spiegelberg is a medium-sized company with in-house manufacturing and different departments, including technology, Research & Development, Quality Management, Regulatory Affairs, and Sales and Marketing. According to Yin (2018), a case study is an approach of preference when:

- The researcher is trying to explore "how" and "why" questions,
- The researcher has little control over events in behavior.

  The research examines a contemporary phenomenon within its real-life context.

The case study methodology also allowed for the use of secondary data through desk research, while primary data were gathered through semi-structured interviews. Multiple interviews were evaluated simultaneously to enhance the richness and power of the findings and maximize the likelihood of attaining thematic saturation, as recommended in qualitative case study studies (Yin, 2018). Furthermore, Spiegelberg's context enabled the examination of nested units of analysis, such as cross-functional departments encompassing Research & Development, Regulatory Affairs, Quality Management, Production, and Sales & Marketing, thereby increasing the richness of the case and

supporting cross-unit comparisons. Thus, combining qualitative interviewing with a detailed case study enabled the exploration of both individual perspectives and organizational processes over a broad range, creating findings that are both particular to Spiegelberg and also applicable to broader issues in SMEs within the medical device industry. To investigate the intersection between open innovation practices and regulatory compliance issues, according to the EU MDR, Spiegelberg GmbH & Co. KG was identified as the most suitable case study object.

The case company was chosen due to several compelling reasons. Firstly, being a European medical device company, Spiegelberg is required to follow the MDR regulation, and hence it is an apt setting in which to place the effects of regulation on innovation practices. In addition, as an SME, in comparison to large multinational corporations with extensive regulatory departments, it is disproportionately affected when it must comply with new regulatory environments, thus offering a rich and influential case for analysis. Spiegelberg engages heavily in external partnerships, such as suppliers, research centers, and hospitals, hence making it very apt for analyzing the limitations of open innovation under regulatory strain. Additionally, the company was accessible to the researcher, and its organizational context was sufficiently understood to enable a more nuanced comprehension of internal and external innovation processes. The selection of the case is in line with the notion that single-case studies are particularly valuable when the study object displays elements that are theoretically congruent with the research objectives (Gaya & Smith, 2016). Identifying the case firm, purposeful sampling was also employed in choosing the participants to be interviewed. The aim was to gather cross-functional opinions from various departments that were impacted by innovation and regulatory activities. The sampling criteria for interviewees were defined as follows:

Table 4 Interviewee Sampling Criteria (Source: Own Creation)

Must-have Sampling Criteria	**Could-have Sampling Criteria**
Must be a current employee of Spiegelberg GmbH	Could have cross-departmental experiences
Must be involved in activities related to product development, regulatory compliance, or innovation	Could hold leadership or strategic planning roles within the company
Must have knowledge and practical experience regarding MDR implementation	Could be directly involved in external partnerships or innovation projects.

The sampling criteria were structured around both must-have and could-have attributes to maintain alignment with the research objectives discussed, as shown in Table 4. Interviewees were required to be current employees of Spiegelberg and actively engaged in product management activities. Additionally, they needed substantial knowledge or practical experience concerning MDR implementation. Preference was given to individuals holding cross-functional roles, leadership positions, or involvement in external partnerships to capture a diverse range of perspectives. Based on these criteria, 9 participants were identified and interviewed. They represented various functional departments critical to innovation and compliance processes, as shown in Table 5.

Table 5 Overview of Interviewees

Position	**Department**	**Focus Area**	**Duration of Interview**
Innovation Manager	R&D	Innovation management, early-stage development	45 mins
Regulatory Affairs Specialist 1	Regulatory Affairs	MDR implementation, compliance strategy	45 mins
Regulatory Affairs Specialist 2	Regulatory Affairs	Clinical evaluation, document control	45 mins
Quality Manager	Quality Assurance	Post-market surveillance, quality processes	45 mins
Validation Engineer	Production	Process validation, production scalability	45 mins
Head of Production	Production	Production & operations, Supply chain management	45 mins
Head of Sales and Marketing	Sales	Market feedback, distributor engagement	45 mins
Head of Research & Development	R&D	Strategic development leadership	45 mins
Development Engineer	R&D	Product innovation and technical design	45 mins

3.3. Methods for Qualitative Data Collection

To gather empirical data for this study, semi-structured qualitative interviews were conducted with key employees, as seen in Table 6, at Spiegelberg GmbH & Co. KG. The interviews were scheduled and conducted between April 3rd and April 11th, 2024. Participants were selected based on purposeful sampling criteria as discussed earlier (Table 5) to ensure coverage of key departments involved in innovation, compliance, and market access.

Before contacting the interviewees, a prewritten standard message was prepared, outlining the aim of the research, the expected scope of the interview, and the ethical standards that would be followed. This message assured the participants of the confidentiality and anonymity of their responses, explicitly stating that company-specific details and team names would not be disclosed outside the research context. The consent procedure was integrated into the interview guide created for each department. At the start of each interview, the interviewer verbally read the consent information and sought explicit verbal consent from the interviewees before proceeding. Upon agreement, the interviews were recorded to facilitate later transcription and analysis.

The interview guides were tailored individually for each functional department to ensure relevance to the interviewee‘s expertise and functional responsibilities. However, the core structure was based on the insights from the preliminary literature review and research objectives. The interview questions were slightly adjusted based on the flow of the conversation and the interviewee‘s domain-specific knowledge. High-priority questions were consistently addressed, while lower-priority follow-up questions were asked when time allowed. The feedback from initial interviews was used iteratively to refine subsequent interviews, thereby enhancing the interview experience and enriching the collected data.

English was the comfortable and preferred language used in all the interviews, as both the interviewer and the candidates spoke it. Depending on the intensity of the conversation and the time constraints of the interviewers, each of the approximately 45-minute interviews was conducted online, primarily via Microsoft Teams. Information saturation—the point at which no fresh relevant data or themes surface from further interviews—determined the number of interviews (Guest, Bunce, and Johnson, 2006). Following every interview, a preliminary review was conducted to determine whether any new ideas or material had surfaced. Parallel interviews and analysis continued until no notable fresh insights were found, therefore suggesting that saturation had been reached. After nine interviews, saturation was achieved, thereby capturing a thorough understanding of the dynamics between MDR compliance within the organization and open innovation approaches.

The use of MAXQDA provided further assistance with data management, transcription, and systematic analysis, a qualitative analysis software that was utilized throughout the research process. The interviews were transcribed verbatim within MAXQDA, ensuring consistency and preserving the richness of the original data. The software‘s integrated features enabled the structured coding of interview transcripts based on deductive codes derived from the conceptual framework and literature, as well as inductive codes emerging from the interview data. This facilitated a transparent and traceable coding process, enhancing the reliability and rigor of the thematic analysis. Moreover, MAXQDA ‘s visualization and memo functions supported the development of thematic structures and helped in identifying patterns across the different functional departments.

3.4. Data Analysis Procedure

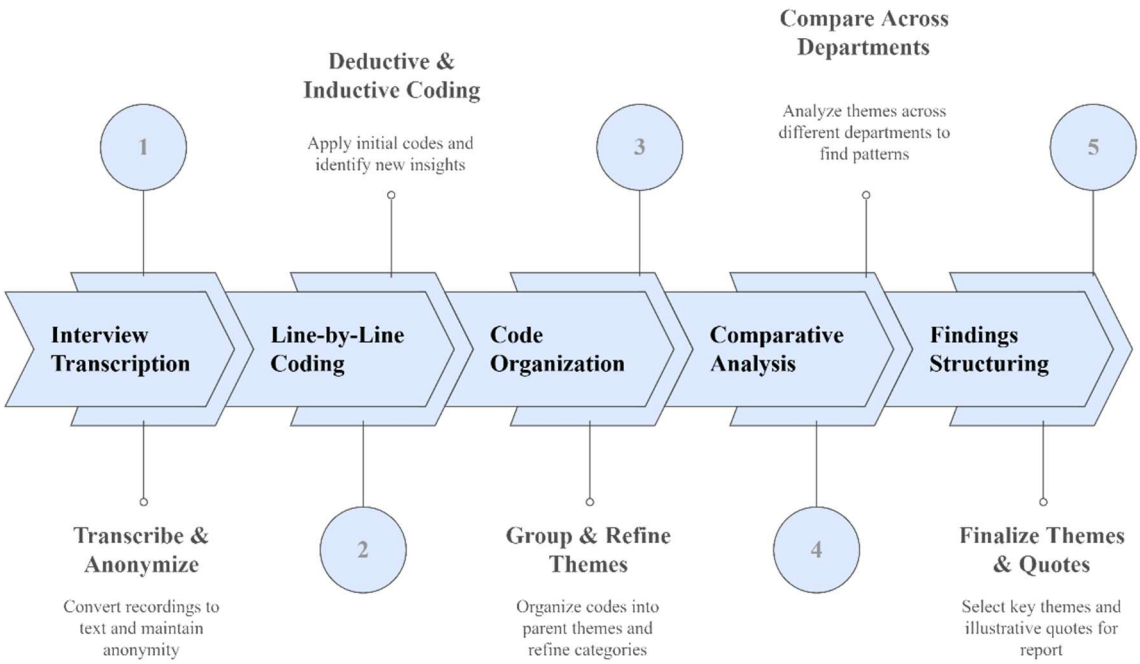

Figure 12 Data Analysis Procedure (Source: Own Illustration)

The analysis of the interview data was conducted systematically in four significant steps, as shown in Figure 12:

- At first, each interview recording was transcribed using functionality within MAXQDA, and the resulting transcripts were carefully reviewed and corrected manually by the researcher to ensure accuracy. Anonymization was performed to protect the identity of the participants and maintain ethical research standards.

- Secondly, line-by-line coding was undertaken in line with qualitative research traditions, particularly the view that coding is not a mechanical process but a relational journey between comprehension and interpretation (Locke, Feldman, and Golden-Biddle, 2022). Initial codes were derived deductively from the conceptual framework developed during the literature review. However, additional inductive codes were also created during the analysis to capture unexpected emergent insights.

- Once the initial coding was complete, the codes were organized into broader thematic categories. Later, the deductively generated codes and the newly emerged codes were clustered under parent themes aligned with the research focus: *Regulatory Burden and Innovation Constraints, Market Access Challenges, Internal Organizational Adaptations, External Collaboration Barriers, and Strategic and Ethical Reflections*. Furthermore, iterative re-evaluation of the code's meaning and relational significance was carried out to ensure conceptual coherence within each theme.

- Finally, a comparative thematic analysis was conducted across different functional areas and participant perspectives. This allowed the researcher to identify key patterns, similarities, and contradictions regarding the interplay between innovation activities and regulatory compliance. MAXQDA software was used throughout the analysis process to ensure systematic coding, transparent data management, and comprehensive traceability of analytical decisions. The findings from the interview analysis are discussed in detail in Chapter 4.

In summary, the methodological section addresses the fourth research objective by defining and applying a qualitative case study methodology. This methodology is conducted through semi-structured interviews across multiple functional departments, including R&D, Regulatory Affairs, Quality Assurance, Production, and Sales & Marketing, gathering diverse perspectives on the intersection of open innovation and MDR compliance. Furthermore, the research design, sampling criteria, data collection procedures, and thematic analysis, using MAXQDA as a qualitative analysis tool, are systematically explained, ensuring methodological rigor.

4. Empirical Research Findings

This chapter presents the empirical research findings regarding integrating open innovation practices within medical device SMEs operating under the European Union Medical Device Regulation (EU MDR) regulatory framework. The findings are derived from the qualitative analysis of interviews conducted with the key stakeholders across different functional departments at Spiegelberg GmbH & Co. KG. Firstly, the chapter introduces the overarching themes that emerged as the overall result of the thematic analysis, aimed at illustrating the main patterns identified in the data and their significance for the research objectives. Furthermore, the code creation process is described, highlighting the combination of deductive codes derived from the conceptual framework and literature review and inductive codes developed through emergent insights captured during the interviews.

4.1. Overview of Themes and Coding Process

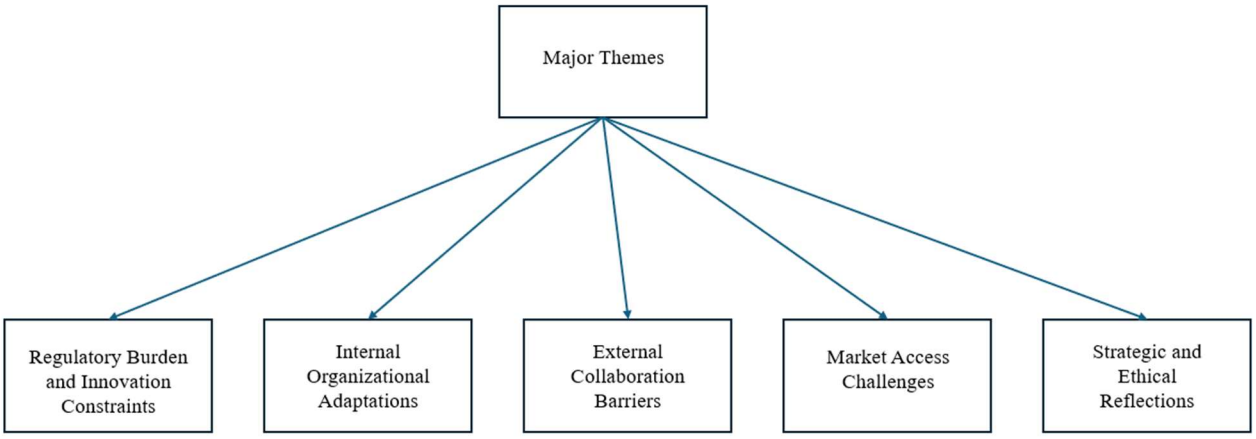

Figure 13 Overview of Themes

Figure 13 illustrates the five major themes that emerged from the thematic analysis. These themes reflect the key areas where open innovation practices intersect with regulatory challenges under the European Union Medical Device Regulation (EU MDR). The deductive and inductive codes were clustered thematically based on content similarity and organizational relevance. The first theme, *Regulatory Burden and Innovation Constraints,* addresses the hindrances faced by SMEs regarding document complexity and new documentation processes resulting from the transition from MDD to MDR. Difficulties with clinical data availability and misalignment also play a significant role in the progress of companies. It also presents the tendencies for teams to innovate informally or delay collaborations to bypass compliance checks under the pretense of shadow innovation. It also highlights the challenges teams face in maintaining regulatory standards for new products while engaging in creative ways to innovate truly. The opportunity cost of compliance due to resource limitations is also revealed. The theme also explores the continuous regulatory hurdles and their impact on team motivation to engage in innovative activities. There are also highlights of incidents that resulted in the evaporation of many opportunities that the company encountered due to the regulatory burden. The next theme, *Internal Organizational Adaptations,* highlights the inadequacies in internal cross-functional processes and outsourcing practices due to a knowledge gap. Moreover, it acknowledges the tendency for teams to make decisions based explicitly on compliance. However,

there was evidence of mature compliance integration, where compliance processes are now better integrated into daily operations, with cross-functional teams proactively managing regulatory tasks. The theme also oversees the involvement of regulatory affairs only at later stages of innovation, creating risks of network or product non-compliance. This can also be observed in effective cross-functional communication, as well as maintaining regular design reviews and discussions with project teams; however, early-stage regulatory involvement remains variable. This resulted in a steep learning curve for teams to understand fully and operationalize expectations. The next theme is *External Collaboration and Openness Barriers.* This theme suggests that intellectual property (IP) protection is not perceived as a significant constraint on innovation, yet external partnerships are approached with caution. There are also limitations regarding organizations' ability to effectively absorb external knowledge, collaborate, and engage in innovation-related activities under the regulatory workload. This also caused firms to showcase selective openness regarding partnership, prioritizing low-risk and tightly managed partnerships. Further hesitations exist regarding the building and sustaining of strong external partnerships under regulatory constraints. The next theme, *Market Access Challenges and Regulatory Delays,* addresses the perception of innovation among distributors, who often view MDR-compliant upgrades as minor or non-innovative updates, resulting in brand perception and sales challenges. Different regulatory requirements between Europe and other regions complicate international expansion and strategy. Regulatory bottlenecks are often caused by the limited capacity and overloaded certification processes of notified bodies, which delay certification and hinder timely product launches. Moreover, such MDR timelines and requirements restrictions create friction when entering new markets or onboarding new distributors. Oftentimes, long compliance timelines squeeze the available window for product registration, market launches, and distributor engagements. The theme also highlights the lack of clarity regarding when CE certification under MDR will be achieved, which delays market entry and sales planning, causing frustration among stakeholders. Finally, *the Strategic and Ethical Reflections theme* addresses mixed or conflicting views on innovation priorities, compliance needs, and market strategy, which are underrepresented in the existing literature research. There are also profound concerns regarding classification rules for medical devices, which can sometimes be ambiguous, making early-stage innovation decisions riskier and slower. This theme also highlights the pressure firms face in managing customers' and distributors' expectations regarding slow, visible progress during regulatory transitions.

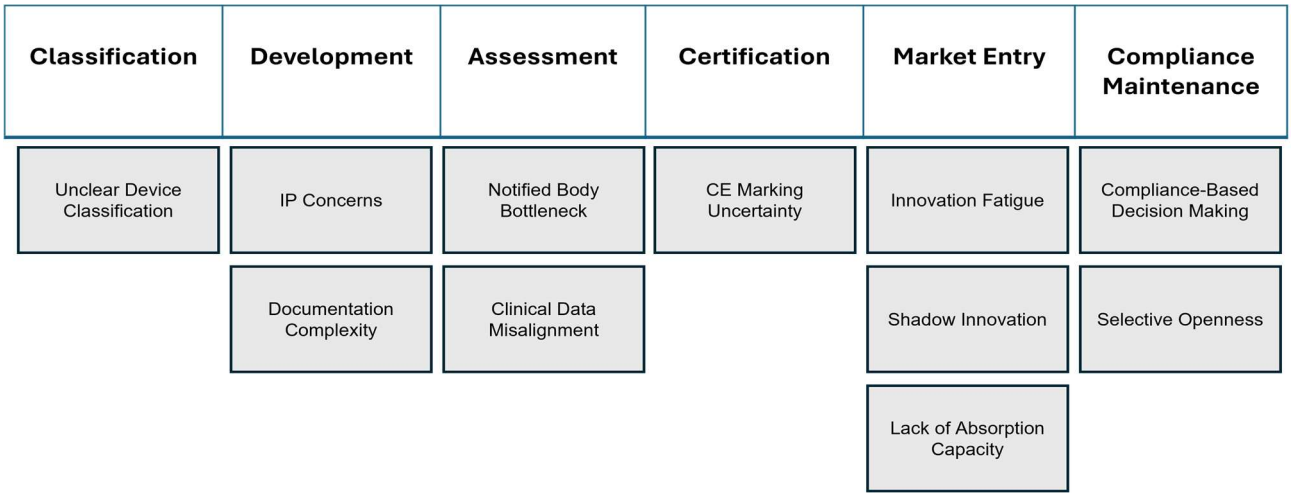

Figure 14 Predefined Thematic Codes Derived from Literature and Conceptual Framework (Deductive Codes) (Source: Own Illustration)

However, the theme reveals that after completing documentation regarding MDR transition, companies' strategic moves progress towards innovation planning, balancing optimization with market-driven needs. Figure 14 illustrates the predefined coding framework developed from the literature and the conceptual model. These codes have provided a guiding structure for the initial rounds of data analysis and are based on scholarly sources on open innovation, MDR compliance, and SME innovation management. Moreover, these codes are aligned with critical phases of the CE certification process, such as classification, development, assessment, certification, market entry, and compliance maintenance, to understand the specific conflicts with open innovation attributes. Furthermore, during the coding phase, the interview transcripts were systematically reviewed, and segments of text relevant to the predefined codes were extracted, which enabled the identification of the structure of the data around anticipated challenges in the innovation-regulation interface.

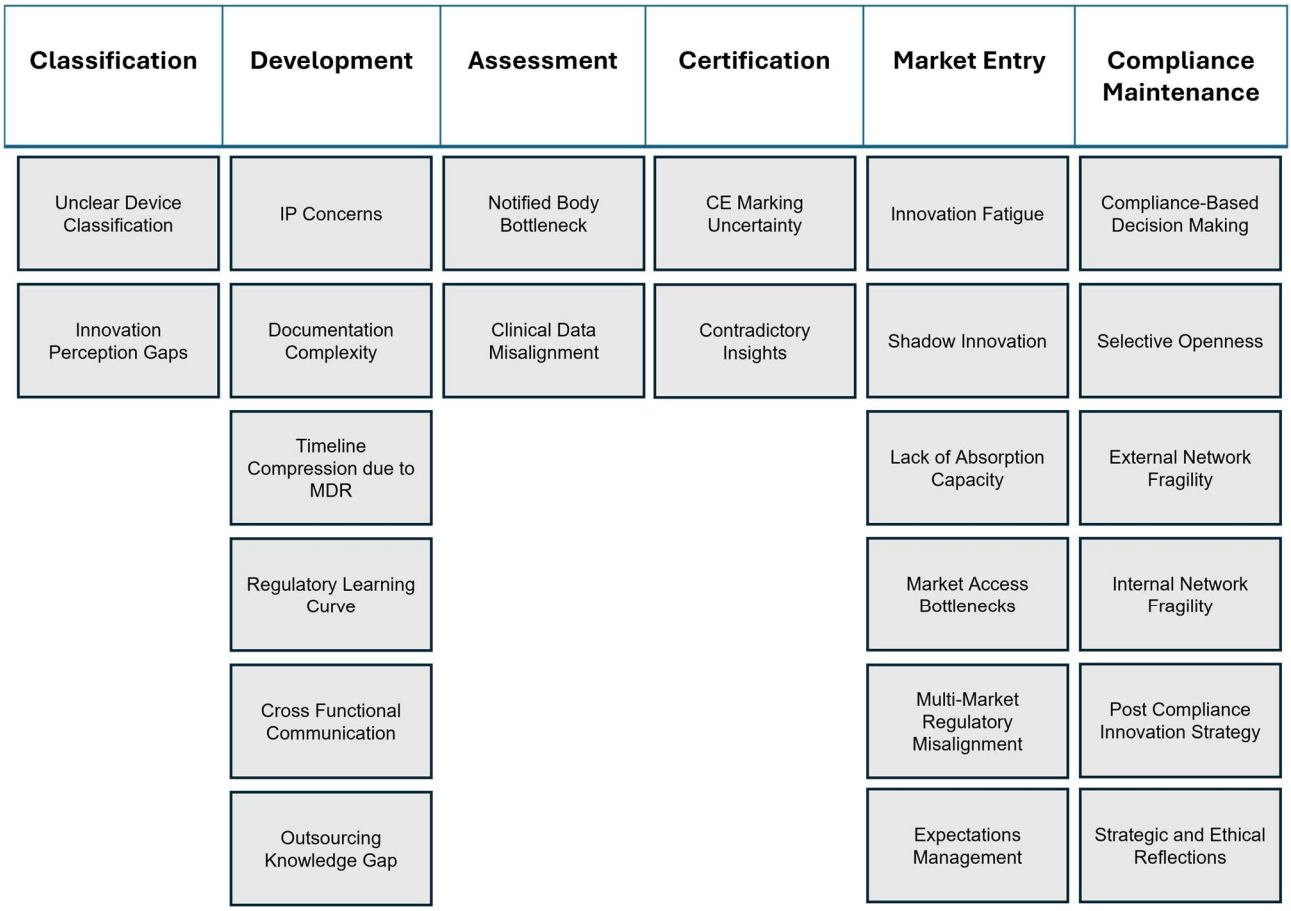

Figure 15 Emergent Codes Derived from Empirical Data (Inductive Codes) (Source: Own Illustration)

However, not all relevant insights could be captured within the predefined structure; hence, emergent codes were identified during the coding process to account for recurring patterns and perspectives that fell outside the predefined framework. Figure 15 illustrates the inductive codes derived from the actual language used by the interviewees and were grounded in the data rather than theory. This iterative process ensures that the analysis remains open to new insights while looking for predefined codes established through the literature. There were also instances where data segments were often coded with multiple overlapping codes, highlighting the complex and interconnected nature of regulatory, organizational, and innovation-related challenges. Finally, a comprehensive coding framework was developed by integrating deductive and inductive approaches, comprising five main overarching themes and multiple subcodes. The final structure preserved the CE certification phase

logic for deductive codes, while inductive codes were mapped under these phases based on their relevance and timing within the innovation process.

4.2. Theme 1: Regulatory Burden and Innovation Constraints

Implementing the European Union Medical Device Regulation (EU MDR) has fundamentally reconfigured the innovation landscape for small and medium-sized enterprises in the medical device industry. The intention to enhance patient safety and product transparency is the focus under MDR. However, documentation requirements have imposed a substantial regulatory burden. This theme encapsulates how compliance with MDR hinders innovation, manifested through insufficient resources and psychological fatigue across organizational levels.

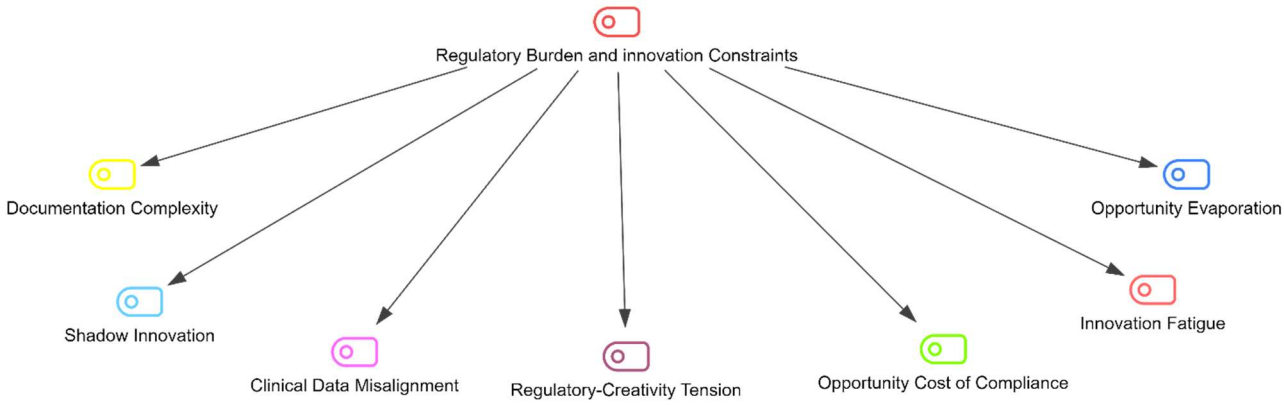

Figure 16 Theme 1: Regulatory Burden and Innovation Constraints

Figure 16 illustrates seven subcodes that explain the overall regulatory burden faced by SMEs and constraints to innovation. *Documentation Complexity* reflects the excessive workload of generating, updating, and validating technical documentation to MDR standards. As depicted, it is one of the earliest and most pervasive stress points, affecting all subsequent innovation activity. There is also an indication that documentation tasks are not only voluminous but also recursive, especially when development is outsourced or when legacy products are adapted, which results in the absorption of innovation bandwidth. The phenomenon of *shadow innovation* is characterized by minor product modifications that are incorporated into mandatory compliance tasks. This highlights a strategic adaptation to regulatory rigidity, encouraging companies to introduce incremental changes that would otherwise not justify standalone investment without contributing to radical innovation. There is a core friction point where new product features or design updates cannot leverage historical clinical data, which prompts organizations to generate new data, often at a high cost and with uncertain value. *Clinical data misalignment reveals* how this requirement not only delays development cycles but also undermines cumulative innovation by severing links with previous regulatory and clinical efforts. *Regulatory-Creativity Tension* highlights the early involvement of regulatory requirements, designed to ensure compliance from the ideation stage onward. However, it hurts creativity, suppressing it. This tension exists at the conceptual level of innovation planning, discouraging companies from engaging in free ideation and exploration due to concerns about anticipated regulatory constraints. *Opportunity Cost of Compliance* explains the trade-offs that firms face in maintaining compliance. It also emphasizes the resource reallocation that accompanies regulatory overhaul. Resources like human, financial, and temporal capital are redirected from exploratory or collaborative innovation projects toward compliance activities. This trade-off directly affects the central burden, diminishing

firms' capacity to engage in transformative innovation or pursue strategic partnerships. The cumulative impact of the subcodes mentioned above, *Innovation Fatigue*, sets in as a psychological and organizational burnout resulting from prolonged regulatory focus and stagnated product development. This captures the hesitance and inexperience in venturing into new innovative product development. Ultimately, all this together results in Opportunity Evaporation, which refers to the decay of potential innovation initiatives or collaborations due to chronic resource scarcity and a misalignment of focus. It completes the thematic circuit by illustrating how the initial regulatory burden ultimately leads to missed market opportunities and a lost strategic advantage.

Table 6 Coded Interview Excerpts Demonstrating Regulatory Burden and Innovation Constraints (Source: Own Creation)

Code	**Code Segment**	**Meaning Unit**	**Theme**
Documentation Complexity	*"So, we do a lot of outsourcing. I think we could. (...) At some points, of course, you could do more. But it's always also a bit of a problem if you outsource, like the development parts. Because then we only must do the whole documentation again, and it's like, you know, the fun parts for the engineers are outsourced."*	Excessive MDR documentation discourages outsourcing.	Regulatory Burden and Innovation Constraints
Shadow Innovation	*"With product X, doctors indicated the Y component was too short, causing drainage bags to hang awkwardly. Since MDR required comprehensive documentation and new prototyping anyway, we took the opportunity to incorporate these minor improvements, though the product essentially remained unchanged."*	Minor improvements were made opportunistically during MDR tasks.	
Clinical Data Misalignment	*"Maybe not. Regarding the risks, but regarding clinical data, because every time you do something new and can't rely on old data, you must produce your new clinical data or do more testing, more functionality testing, to prove it. Like the new design, the new functionalities are working."*	Challenges in gathering MDR-required clinical evidence for new features.	
Regulatory-Creativity Tension	*"So, I think it's beneficial to start later with the regulatory input for getting a bit more creative and innovative, because it just keeps people from being free and open-minded during the idea finding process."*	Early regulatory input restricts creative idea generation.	
Opportunity Cost of Compliance	*"Anyway, to do something we may not have done in the normal life cycle. But on the other hand, of course, the MDR transition bound all our resources. So. (..) Doing things like new products and putting time into actual*	MDR compliance consumes resources, hindering genuine innovation.	

Code	Code Segment	Meaning Unit	Theme
	innovation. That was, of course, yeah, due to the MDR. not possible."		
Innovation Fatigue	*"We haven't had any innovative projects in recent years because we only transformed from MDD to MDR with our existing products."*	Exhaustion from prolonged MDR transition stifles innovation.	
Opportunity Evaporation	*"You know, it starts when you have contact with someone, you have a few emails going back and forth, and it's like, oh, we could, we could do something. But oh yeah, right now we don't have resources. But let's talk again, like, you know, in a few months, and then it just, yeah, vanishes somewhere. And it's not happening because you have other things on your mind. So, I think that's one of the main problems, and many times, it's not that you have something concrete."*	Potential collaborations fade due to MDR-driven resource constraints.	

Table 6 presents selected coded segments and meaning units illustrating how the MDR implementation process disrupts innovation dynamics across multiple fronts. Each quote has been systematically analysed to extract a "meaning unit," offering insight into the practical and psychological ramifications of compliance for SMEs in the medical device industry. The first code, *Documentation Complexity*, highlights a critical operational bottleneck: the intensification of technical documentation requirements under MDR. The code segment also reveals how increased documentation load not only discourages external collaboration but also redirects internal resources away from core innovation tasks. There is also a revelation of potentially diminishing intrinsic motivation and job satisfaction among technical staff due to prolonged documentation and less research work. The approach to including minor product modifications opportunistically into mandatory regulatory updates reflects a form of creative adaptation. However, it also signifies a strategic compromise, where teams halt the dedication of resources to breakthrough innovations, as companies defer to incremental changes that are often less resource-intensive and more likely to gain regulatory approval swiftly. This suggests a pattern of compliance-driven innovation, which lacks the strategic foresight of market- or user-driven innovation and may lead to stagnation in product differentiation. *Clinical Data Misalignment* underscores the regulatory friction by drawing attention to the high evidentiary standards that MDR imposes, which result in significant financial and logistical costs, as well as delays in the time-to-market of new products. Moreover, it undermines the ability to build upon prior innovations, especially for SMEs with limited access to clinical trial infrastructure. This results in a fragmented innovation process in which even minor modifications can trigger disproportionate regulatory hurdles. Furthermore, compliance-driven thinking also infiltrates the ideation stage, constraining exploratory thinking and reducing the scope for radical innovation. It also suggests that innovation suffers not only from logistical constraints but also from cultural risk aversion cultivated by regulatory oversight. The psychological toll of this shift is captured in *the Innovation Fatigue* code, where interviewees acknowledge that this transition is not only a pipeline delay but also a source of organizational burnout. This is the cumulative result of unrealized potential,

prolonged focus on legacy products, and constant regulatory adaptation. The last code segment encapsulates how these constraints materialize in lost external collaborations.

Table 7 Comparative Reflections on Regulatory Burden and Innovation Constraints (Source: Own Creation)

Functional Team	Convergence Point	Divergence Point
Regulatory Affairs	Strong consensus on MDR-induced documentation burden, rising costs, and unclear clinical data expectations impeding innovation.	Emphasize ambiguity in equivalence claims and varying perspectives on whether clinical studies or documentation is the bigger hurdle.
Research & Development	Aligns with Regulatory Affairs' assertion that documentation and clinical expectations constrain new product development and have caused a shift toward incremental or shadow innovation.	Some view MDR as a long-term opportunity to streamline documentation and innovate through user-driven prototyping, while others express profound innovation fatigue.
Quality Assurance	Agrees with RA and R&D on excessive documentation and historical gaps creating MDR compliance challenges.	This highlights the unique burden of a lack of historical documentation, leading to rework that is not equally evident in other departments.
Sales & Marketing	Confirms that MDR hinders the pipeline of new innovations and frustrates market expectations.	Observes external disappointment from partners and missed sales due to delayed launches, which are not always acknowledged in RA or R&D narratives.

Table 7 provides a comparative overview of functional departments in terms of regulatory burden and Innovation Constraints. There is a notable agreement in identifying the MDR as a significant source of innovation constraints, particularly due to documentation demands, resource depletion, and lost opportunities. Regulatory Affairs, R&D, and Quality Assurance consistently recognized the complexity of documentation as a significant challenge, underscoring that compliance-related workloads are generally burdensome and often appear redundant. Additionally, both Regulatory Affairs and R&D acknowledged the disconnect between clinical data requirements and iterative development, viewing the inability to reuse legacy data as a barrier to effective innovation. Moreover, the fatigue of innovation and the opportunity cost associated with compliance were widely recognized, with participants expressing frustration at having to redirect time and resources from proactive innovation to reactive compliance. This highlights a common struggle within the organization to sustain innovation momentum amidst regulatory transitions.

However, subtle differences emerged in how various departments interpret and internalize these constraints. For example, while Regulatory Affairs focused on the ambiguity surrounding equivalence claims and documentation expectations, R&D sometimes viewed MDR as a long-term opportunity to enhance product traceability and improve development practices. On the other hand, Sales and Marketing expressed greater concern about external factors, emphasizing lost commercial opportunities and partner frustrations, as well as less apparent issues in upstream departments. These

variations suggest that although the fundamental regulatory burden is experienced uniformly across the organization, its perceived effects differ based on departmental roles and proximity to market outcomes. This highlights the need for a more integrated regulatory-strategic alignment to reduce fragmentation and promote a cohesive innovation path within MDR constraints.

4.3. Theme 2: Market Access Challenges and Regulatory Delays

The crucial implications of MDR implementation for medical device SMEs are their substantial impact on market access efficiency and ability to navigate the regulatory landscape. The theme, *"Market Access Challenges and Regulatory Delays,"* emerges as a synthesis of organizational experiences surrounding delayed product approvals, fragmented international regulations, and reduced strategic responsiveness.

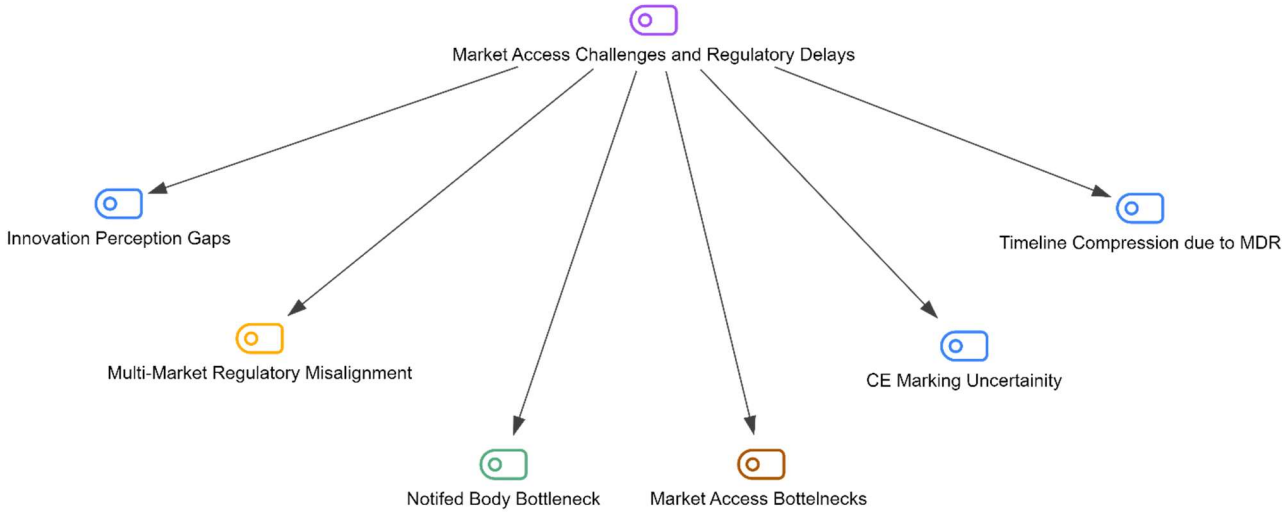

Figure 17 Theme 2: Market Access Challenges and Regulatory Delays

Figure 17 illustrates six interrelated subcodes that converge around the central theme of examining how MDR-driven delays, combined with system-level regulatory ambiguity, distort time-to-market strategies and erode competitive positioning for firms operating across multiple jurisdictions or relying on early-mover advantages. The code, *Innovation Perception Gaps,* highlights the differences between how firms view product innovations and how regulators and distributors interpret them. This misalignment complicates firms' ability to frame their innovation narratives and strategies. *Multi-market regulatory misalignment refers to* the fragmentation within the regulatory landscape. Firms working across multiple countries found it difficult to develop a cohesive market strategy due to country-specific interpretations and rollouts of MDR. This misalignment led to resource duplication, making coordinated regional launches nearly impossible and undermining economies of scale, thereby eroding strategic clarity. *Notified Body Bottlenecks* refer to the systemic delays caused by the limited capacity of notified bodies under the MDR. This is due to the low number of MDR-designated notified bodies and prolonged waiting periods faced by SMEs for product evaluation. Due to firms' preference for incremental innovation, market access, competitiveness, and distributor satisfaction, as well as overall market dynamics, the challenges are considerable. There are also concerns regarding the process of achieving the CE mark. This perceived uncertainty stems from the inconsistent interpretations of documentation and classification standards by notified bodies, leading to strategic hesitation. In such an uncertain environment, firms are reluctant to invest in product

development or regulatory submissions due to the fear of unforeseen non-compliance risks. Furthermore, due to the unpredictability and infrequency of notified body availability, companies often experience last-minute accelerations in product development cycles—this timeline compression results in rushed validations, condensed testing periods, and internal strain across departments.

Table 8 Coded Interview Excerpts Demonstrating Market Access Challenges and Regulatory Delays (Source: Own creation)

Code	**Code Segment**	**Meaning Unit**	**Theme**
Innovation Perception Gaps	*"This isn't real innovation—it's merely a product upgrade. Distributors, particularly in Europe, expect more substantial innovations, yet after six years of MDR efforts, our products remain 99% unchanged."*	Products are considered upgrades, not genuine innovations, leading to unmet distributor expectations.	Market Access Challenges
Multi-Market Regulatory Misalignment	*"For instance, in the FDA, we have a database where I can go and, based on my summary, find the predicate device on which I can base my submission. But, in this scenario, we don't have anything as such. Even if there are documents you can refer to from competitors, it's a very, very grey area."*	MDR lacks accessible reference systems, making cross-market submissions unclear.	
Notified Body Bottleneck	*"What was confusing in the past was our communication with the notified body. We expected clear guidance, but they were unprepared, and we didn't know what to do either. The issue wasn't with the MDR itself, but with how it was being applied."*	Lack of preparedness from notified bodies caused confusion during the MDR application.	
Market Access Bottlenecks	*"Now, expanding into new markets and onboarding distributors has become much slower than in previous years. It's a challenging period, and we're actively discussing entering some markets earlier to overcome these delays."*	MDR has slowed distributor onboarding and market expansion efforts.	
CE Marking Uncertainty	*"What all distributors need for registration is the CE mark under MDR, which is essential. Fortunately, we have strong, trust-based relationships with them, and they understand we're a smaller company, not a global giant."*	Distributors rely on the CE mark, but delays affect smaller firms with limited resources.	
Timeline Compression Due to MDR	*"For example, one of our key international distributors is waiting to launch a new product line until we*	Extended MDR timelines are pushing product	

Code	Code Segment	Meaning Unit	Theme
	complete MDR certification. Since registration in that market takes up to two years and we don't yet have the certificate, they may only begin by the end of 2025, meaning the product won't be available until late 2027. This transition from MDD to MDR significantly impacts our long-term development and market entry plans."	launches years into the future, affecting strategy.	

The coded segments in Table 8 illustrate how the external regulatory structure creates significant downstream obstacles to market access, expansion, and product launch strategies. The primary focus of this theme is to identify external barriers that limit the timely commercialization and strategic responsiveness of medical device firms. *Innovation Perception Gaps* highlights a growing disconnect between internal innovation efforts and external stakeholder expectations. The meaning unit reveals a dual-layered tension, firstly, to demonstrate innovation externally, and secondly, the stifling effect of MDR on transformative product development. When internal efforts fail to translate into perceived novelty, they weaken commercial traction and undermine distributor confidence. The *Multi-Market Regulatory Misalignment* code illustrates the lack of harmonized regulatory infrastructure across geographies and its complications on companies' global strategies. There is a need for a reference system that provides clear, well-defined device pathways to prevent challenges when benchmarking submissions based on competitors' documentation. This regulatory opacity introduces uncertainty, forcing firms to overcompensate in their documentation and testing strategies, which often delays global submissions and fragments product development roadmaps. A lack of procedural clarity further compounds *the Notified Body Bottlenecks*. The operational gap between regulation and implementation is unclear, and expectations from designated bodies delay progress and contribute to strategic paralysis. When distributor onboarding and expansions are postponed due to market access issues, firms attempt to reassess their business strategy, which forces them to reevaluate traditional sequencing and prioritization of market entry efforts. The CE Mark is crucial for firms seeking to sell their products internationally, as uncertainty and delays can create barriers to market access. This highlights the structural imbalance whereby MDR imposes uniform certification expectations across companies of vastly different sizes and capacities. Finally, timeline compression concerns arise due to disruptions in long-term planning introduced by protracted certification processes. The code segment of *Timeline Compression Due to MDR* highlights that timeline compression distorts not only product availability but also entire development cycles, partnership milestones, and strategic investments. It underscores how compliance-driven scheduling reverberates far beyond regulatory affairs, reshaping the firm's competitive positioning and market relevance over multiple years. These coded excerpts reveal a regulatory environment where the absence of clarity, uneven institutional capacity, and inflexible certification timelines culminate in strategic delay and reputational risk.

Table 9 Comparative Reflections on Market Access Challenges and Regulatory Delays (Source: Own Creation)

Functional Team	Convergence Point	Divergence Point
Regulatory Affairs	Recognize that CE certification delays can increase registration complexity across global markets.	Express concern over the limited structural support for managing multi-country compliance and communication gaps with notified bodies
Research & Development	Acknowledge regulatory bottlenecks and the increasing burden of documentation.	Stress on how regulatory demands disproportionately hinder innovative and niche product development
Quality Assurance	Align with Regulatory Affairs on the impact of MDR on timelines and global market access.	Emphasize the importance of early-stage planning for compliance and highlight mismatches in market-specific requirements.
Sales & Marketing	Highlight how distributors, both new and existing, wait for MDR certification, resulting in unpredictable sales forecasts and delayed market entry.	Note increasing frustration among distributors about delayed innovations and unmet market expectations.

Table 9 presents a comparative analysis of the theme of *Market Access Challenges and Regulatory Delays*. Across departments, there is an apparent convergence in recognizing the obstructive role of MDR in delaying product certifications and complicating market access strategies. Regulatory Affairs, R&D, and Quality Assurance collectively acknowledge that CE certification delays and the growing complexity of registration across global markets have become central barriers to commercialization. However, these bottlenecks, particularly those tied to notified body limitations and documentation overload, are seen as shared organizational pain points with all teams experiencing their downstream effects. Sales and Marketing similarly confirms this impact from a customer-facing perspective, noting how unavailable MDR certificates stall distributor onboarding and disrupt new market launch timelines. However, divergence emerges in how these challenges are interpreted and prioritized across functional units. For instance, Regulatory Affairs, while aligned on the existence of certification delays, focuses on the structural shortcomings, such as weak institutional support for multi-country compliance and ineffective communication with notified bodies, which exacerbate the issue. In contrast, R&D voices concern over how these delays disproportionately suppress innovation in niche and exploratory product segments, revealing a creative tension not equally emphasized by other departments. Meanwhile, Quality Assurance draws attention to market-specific regulatory mismatches and stresses the need for early-stage compliance integration. The Sales and Marketing department, situated at the interface between the company and its commercial partners, offers a unique perspective. Although there is alignment regarding the implications of certification delays, their emphasis lies in addressing distributor frustration and maintaining market expectations amid delayed product launches. Moreover, they distinctly underscore the gap in the perception of innovation, wherein updates constrained by the Medical Device Regulation (MDR) are no longer regarded as genuine innovations by the market, consequently undermining brand credibility.

4.4. Theme 3: Internal Organizational Adaptations and Challenges

The theme *Internal Organizational Adaptations and Challenges* captures how firms have evolved structurally and behaviourally over time in response to the complexities introduced by MDR. Rather than viewing compliance as an isolated regulatory task, organizations have been forced to adapt internally by reshaping processes, roles, and communication pathways.

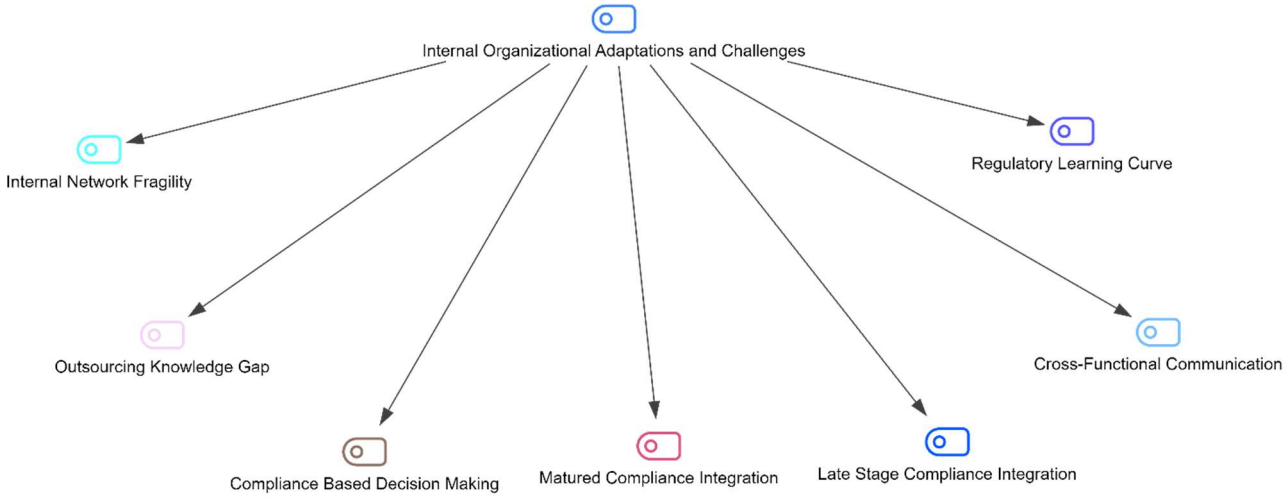

Figure 18 Theme 3: Internal Organizational Adaptations and Challenges

As shown in Figure 18, this theme encompasses seven subcodes reflecting regulatory tensions and progression arising during this transition, for many, *internal network fragility* and *outsourcing knowledge gaps* exposed structural weaknesses that had previously gone unexamined. The emergence of *compliance-based decision-making* further signaled a shift in strategic priorities, often privileging risk avoidance or conservative design choices over innovation, keeping it compliance-oriented. There were also learnings regarding the apt integration of compliance processes into firms' development processes, ranging *from mature compliance integration,* meaning firms learn to better integrate compliance processes into their daily operations, to *late-stage compliance integration,* each with its operational implications. This theme also reveals a steep regulatory learning curve experienced by teams navigating the regulatory demands and maintaining effective cross-functional communication.

Table 10 Coded Interview Excerpts Demonstrating Internal Organizational Adaptations and Challenges (Source: Own creation)

Code	Code Segment	Meaning Unit	Theme
Internal Network Fragility	*"So, I think if they have a question, they go to us and ask. But I think one problem could be that they don't know that there are specific regulations. They don't even know they must ask, which could be a problem."*	Teams may miss compliance steps due to a lack of regulatory awareness.	Internal Organizational Adaptations and Challenges
Outsourcing Knowledge Gap	*"The main problem could be that the external company is not that much into detail with the product, so we had to*	External partners lack product understanding and require training.	

Code	Code Segment	Meaning Unit	Theme
	train the company to do the usability testing because you must know the proper product to check if the person uses it correctly."		
Compliance-Based Decision Making	*"Clinical studies are a significant requirement under MDR. We must assess whether existing market data is sufficient or if new studies are needed. These new studies can become a critical obstacle, requiring significant time, money, and resources. For a small company like ours, they can ultimately bring a project to a complete halt."*	MDR clinical study demands can halt projects in small companies.	
Matured Compliance Integration	*"I think now it is well integrated. Yes, in the past it was not that. Well integrated, but like I said, we learned about it, and I think our development department is now very familiar with the processes. So, I think it is good now."*	Compliance processes are now well integrated through learning.	
Late-Stage Compliance Integration	*"The R&D team follows a design control process; the design transfer phase is where R&D and production align. At this stage, all changes are introduced, and from there, the production team takes over the remaining steps of the process."*	Compliance is addressed only at handover from R&D to production.	
Cross-Functional Communication	*"I think communication works quite well because we are a small company, and everyone generally tries to help. I am happy about that, especially about the assembly. For example, the documentation for MDR registration every year, everyone from research and development has their own project, right? And they know a lot better about their product than I do. And then they can always answer the questions, for example, sometimes."*	Small team size enables informal support and knowledge-sharing	
Regulatory Learning Curve	*"So, what we see, for instance, is the requirements for the MDR, what we have done, which testing, and we did many more tests than before. And this will help us get the registration faster in some markets because we have had to do these tests in the past, maybe additionally for these customers..."*	Extensive testing under MDR improves future registration efficiency.	

Table 10 presents the interview excerpts demonstrating how internal structures, communication practices, and decision-making processes have evolved under the weight of MDR compliance. A key insight arises from *Internal Network Fragility*, where concerns regarding a lack of knowledge about regulatory requirements are raised. This suggests that informal internal systems, while efficient for daily operations, might miss critical compliance dependencies. This knowledge gap in awareness can hinder product timelines and regulatory integrity, especially in smaller farms without formalized compliance checkpoints. *Outsourcing Knowledge Gap* further explains how external partnerships introduce operational risk. Interviewees shared instances where third-party vendors could lack product familiarity, requiring internal teams to dedicate additional time and resources for training. This also relates to the concern raised in the code *Document Complexity* of Theme 1 in *Regulatory Burden and Innovation Constraints,* about increased documentation workload due to outsourcing activities, and could also add psychological burden to the development engineers. This underscores a recurring tension in MDR compliance, while outsourcing can alleviate internal pressures and necessitate deeper knowledge transfer to ensure regulatory standards are met. *Compliance-based decision making* encapsulates the financial and resource strain firms face due to carrying out MDR-related clinical studies, especially for small firms, which could also result in temporary halts of projects. This reveals the impact of MDR compliance on how projects are executed and their future, directly influencing a firm's portfolio decisions. This has resulted in firms' improved ability to successfully embed compliance within development workflows, benefiting from accumulated experience and institutional learning. However, there are experiences about a reactive approach in teams, where compliance is only considered during handover between R&D and production, an approach that could risk missing early-phase compliance opportunities or generating costly rework. Furthermore, *Cross-Functional Communication* holds a strong relative strength in smaller firms due to their size, organizational structures, and company culture. The informal, open environment enables project-specific expertise to be shared quickly, especially when navigating product documentation for MDR. However, this flexibility may not scale well in larger organizations or during rapid growth. Finally, *the Regulatory Learning Curve* reflects a more positive adaptation showcased by firms over the transition period. For instance, conducting broader testing upfront may accelerate future registrations in diverse markets. This shift signals a growing internalization of compliance as a strategic asset rather than a reactive burden. Overall, the internal MDR adaptation is uneven but ongoing, despite knowledge gaps and misaligned integration points; there are also signs of institutional learning, as showcased by the firm.

Table 11 Comparative Reflections on Internal Organizational Adaptations and Challenges (Source: Own creation)

Functional Team	**Convergence Point**	**Divergence Point**
Regulatory Affairs	Recognises the value of MDR in enhancing post-market surveillance and traceability; demonstrates evolving regulatory maturity	Faces challenges with documentation translation, legacy product transitions, and resource limitations
Research & Development	Incorporates design control process and increasingly collaborates with Regulatory Affairs and Quality Assurance to meet MDR standards	Initially fails to integrate regulatory expectations into early innovation stages; creativity-regulation gap persists.

Functional Team	Convergence Point	Divergence Point
Quality Assurance	Enhances QMS integration and cross-functional alignment; supports development teams in compliance-driven decision making.	Highlights residual internal gaps in regulatory awareness; depends on product risk class to justify external outsourcing.
Production	Implements revalidation practices and adjusts production timelines based on compliance triggers from R&D	Operates under tight timelines due to late-stage compliance inputs. Limited flexibility during design transfer
Sales & Marketing	Emphasizes that increased testing and compliance under MDR enhances market access; supports early regulatory planning	Concerns about structural weakness in cross-departmental collaboration and workload distribution

Table 11 highlights the comparative reflections of functional teams on *Internal Organizational Adaptations and Challenges.* There is a strong convergence of opinion across teams regarding significant internal reconfiguration, specifically in terms of team communication strategy and the distribution of compliance responsibilities. There is an acknowledgment of nonlinear adaptation, involving learning through trial and error, which reveals knowledge gaps, facilitates coordination, and promotes integration. There is a positive resonance for open and informal communication, which helps bridge regulatory silos, especially when documentation or product-specific insights are needed across departments. Similarly, there is a shared recognition that the *regulatory learning curve* has led to improved testing standards and better preparedness for future market entries, indicating the dual nature of MDR, while being burdensome has catalyzed internal process maturity over time. However, divergence in opinion occurs when compliance becomes embedded within organizational workflows. While some functional departments reported mature compliance integration, suggesting learning has taken place and processes are now embedded in development cycles, others describe late-stage compliance integration. This disconnect reflects a departmental variance in prioritizing early compliance and may indicate differing ownership levels or a lack of clarity regarding regulatory roles. Additionally, compliance-driven decision-making in strategic or project management roles emphasizes resource allocation and project feasibility, particularly in small companies. Here, clinical studies mandated under MDR can completely derail initiatives. In contrast, this issue is less pronounced in operational departments, where the primary challenge shifts from deciding whether to move forward to figuring out how to execute within limitations. There is notable variation in how internal weaknesses are recognized. For instance, the *code internal network fragility* indicates that some teams might not even realize they need to raise regulatory inquiries, highlighting a gap in regulatory literacy within the organization, often unnoticed by those in regulatory positions. Likewise, gaps in outsourcing knowledge are strongly felt by teams overseeing external vendors, yet are rarely recognized by teams not directly involved in vendor management. This suggests that although the need for MDR-driven internal changes is generally understood, the experience of these modifications varies significantly based on departmental roles, proximity to compliance responsibilities, and strategic awareness.

4.5. Theme 4: External Collaboration and Openness Barriers

The theme, *External Collaboration and Openness Barriers,* explores how regulatory environments interact with organizational openness, shaping how firms engage with external stakeholders, partners, and innovation networks.

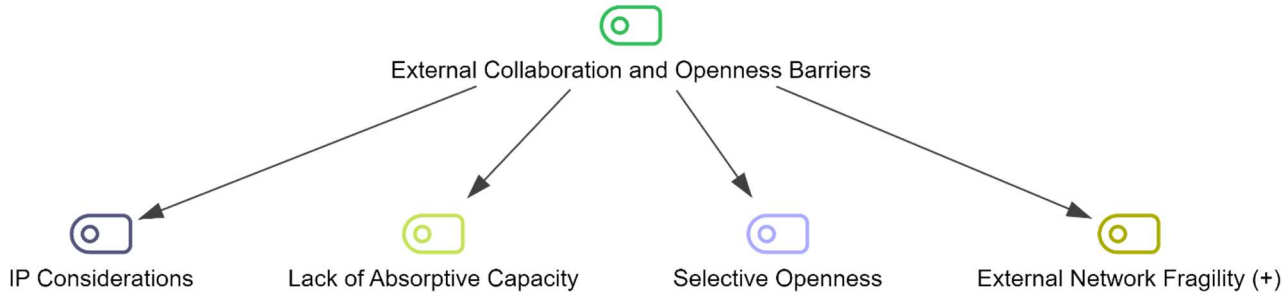

Figure 19 Theme 4: External Collaboration and Openness Barriers

As depicted in Figure 19, this theme comprises four interconnected subcodes reflecting strategic and structural constraints to openness. The code, *IP considerations*, capture firms' cautious stances on protecting proprietary knowledge in increasingly competitive and uncertain regulatory contexts. Simultaneously, a *lack of Absorptive Capacity* highlights internal limitations in effectively processing, integrating, or acting on external inputs from partners, suppliers, or the broader ecosystem. The notion of *selective openness* reveals a tension between collaboration and control, where firms engage externally only when perceived risks are low and can be strategically managed. Furthermore, the code, External Network Fragility, highlights the inefficiencies in managing a formal process for collaboration for new product development or carrying out any further innovative activities.

Table 12 Coded Interview Excerpts Demonstrating External Collaboration and Openness Barriers (Source: Own creation)

Code	**Code Segment**	**Meaning Unit**	**Theme**
IP Considerations	*"Not really. We don't have major IP concerns, possibly because our X method is over 30 years old. If competitors had wanted to replicate it, they likely would have done so by now. So currently, IP protection isn't a significant worry for us."*	IP protection isn't a significant concern due to the age of the core technology.	External Collaboration and Openness Barriers
Lack of Absorptive Capacity	*"Right now, we are not having that many collaborations. Usual problems are that we are saying we don't have time."*	Limited time and resources prevent engaging in collaborations.	
Selective Openness	*"What we do a lot, I would say, is that our students are doing their thesis. So, we collaborate with universities through our students. (..) Regarding startups and other*	Engages in safe, controlled collaborations but avoids broader open innovation.	

Code	Code Segment	Meaning Unit	Theme
	companies, it's not known at the moment. I would say it's not happening."		
External Network Fragility	*"We need to have more contact points. So, I think one important thing would be to go out more to participate in congresses. Talk to the doctors and professors from the university to have more conversations. So that it's not like, oh, now we have this contact, but we don't have anything right now. So, when it, you know, that chance is gone. So, having more constant contact with the outside would be better. So, if you say, oh, now, it would be good to collaborate, or now I could use the experience of someone you already have, like your network. Yeah. Yeah, I think the good old networking thing is important."*	Lack of continuous external engagement leads to missed opportunities.	

Table 12 presents the insights from interviewees that shed light on the subtle yet consequential barrier to external collaboration under MDR faced by resource-constrained environments. The code, *IP Considerations,* reveals a relaxed posture of the firm, driven not by strategic secrecy but by the maturity and ubiquity of the firm's core technology. This lack of perceived IP vulnerability removes a commonly cited barrier to openness. However, a significant limiting factor would *be the lack of absorptive capacity,* where interviewees highlighted the limited collaboration due to resource scarcity in terms of time and personnel, which prevents proactive engagement with external knowledge sources. Selective Openness reveals a strategic, resource-based, and relational filtering of openness that firms incorporate (Dahlander & Gann, 2010). Firms often scan for opportunities with low-risk, low-friction formats that can yield returns in terms of innovation, while avoiding regulatory overburden. This approach reflects a tendency to maintain tight control over information and relationships, and only opening in contexts perceived as manageable or beneficial without operational risk. Such selectivity can be seen as both a protective mechanism and a loss of opportunity in sectors where innovation increasingly relies on distributed collaboration. The code, *External Network Fragility,* reveals the temporal vulnerability of potential partnerships. There is a need to search for opportunities strategically and maintain a formal communication channel to keep the collaboration alive for future partnerships. This fragility highlights a significant challenge in developing innovation ecosystems for smaller firms.

Table 13 Comparative Reflections on External Collaboration and Openness Barriers (Source: Own creation)

Functional Team	Convergence Point	Divergence Point
Regulatory Affairs	Acknowledges external collaboration with consultants and supports it when strategically aligned	Experiences difficulties in managing diverse international distributor demands and expresses concern over potential breaches of confidentiality.
Research & Development	Supports open collaboration with research partners, startups, and universities	Heavily constrained by internal absorptive barriers, unclear roles, weak internal collaboration, low resources, and no formal systems.
Quality Assurance	Open to controlled external engagements under defined contract-based systems.	Expresses a complete lack of prior processes or experience in external innovation collaborations
Sales & Marketing	Emphasizes the need for strong market proximity via direct customer interaction and physical training	Highlights the R&D team's limited experience and external engagement, underscoring a gap in integrating market feedback into development processes.

Table 13 illustrates the comparative reflections on *External Collaboration and Openness Barriers* perceived across different functional departments. There is a shared recognition that external collaboration is necessary and strategically valuable. However, this openness is filtered through varying degrees of caution, operational readiness, and functional priorities. A core convergence is seen across the teams' willingness to engage externally under controlled conditions. Regulatory Affairs supports collaboration with consultants when aligned with strategic or compliance goals, and Quality Assurance echoes this by endorsing external partnerships within clear contractual boundaries. Similarly, Research & Development expresses openness toward working with universities, startups, and research institutions. Sales and Marketing reinforces this orientation by stressing the importance of maintaining proximity to the market through customer-facing interactions and training, implicitly advocating for deeper integration of external voices into innovation processes.

Moreover, divergence arises in the underlying constraints and implementation challenges each department perceives. Regulatory Affairs expresses concern over managing the complex and diverse expectations of international distributors. However, the risk of confidentiality breaches remains a concern. Research & Development, while rhetorically open to collaboration, is often constrained by internal barriers, such as unclear roles, lack of formal systems, limited resources, and fragmented internal coordination. Sales & Marketing provides a more externally focused divergence by raising concerns on R&D's limited external engagement and inefficient use of market feedback in development cycles. This observation highlights a disconnect between front-end insights and back-end innovation execution, which could hinder market responsiveness and the relevance of innovation. The divergence here is not due to resistance to openness, but rather frustration over missed opportunities resulting from structural or cultural limitations in upstream teams.

4.6. Theme 5: Strategic and Ethical Reflections

The theme of *Strategic and Ethical Reflections* captures the introspective and forward-looking considerations that firms face while navigating the MDR landscape. As illustrated in Figure 20, this theme encompasses four subcodes that highlight the impact of regulatory demands on operational responses, while also raising further questions about innovation direction, organizational ethics, and strategic coherence.

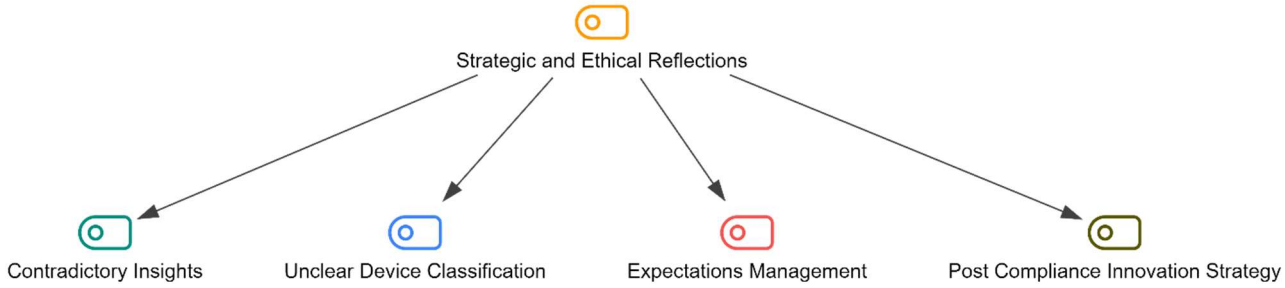

Figure 20 Theme 5: Strategic and Ethical Reflections

Contradictory Insights reflect the uncertainty that arises when internal experiences and external guidance conflict, creating ambiguity in decision-making. *Unclear Device Classification* highlights regulatory grey areas that disrupt long-term planning and increase the risk of missteps. Meanwhile, *Expectations Management* underscores the ethical tension of aligning what can realistically be delivered under MDR with what partners, regulators, and end-users anticipate. Finally, the *Post-Compliance Innovation Strategy* emphasizes a forward-looking assessment, prompting companies to reassess their innovation priorities and schedules after the initial compliance demands have stabilized.

Table 14 Coded Interview Excerpts Demonstrating Strategic and Ethical Reflections (Source: Own creation)

Code	**Code Segment**	**Meaning Unit**	**Theme**
Contradictory Insights	*"Not really. If everything is properly documented, it is not considered a limiting factor. MDR may require more precise documentation, but beyond that, it does not significantly restrict us in the production unit."*	Some view MDR as restrictive, while others consider it manageable as long as the documentation is precise.	Strategic and Ethical Reflections
Unclear Device Classifications	*"Yes, we discussed the issue of equivalence. The EU should create a shared database that manufacturers can access to find necessary information and establish transparency. Building an information infrastructure would allow companies to exchange data, benefiting industry and society safely."*	Lack of shared MDR databases limits clarity and transparency in device classification.	
Expectations Management	*"Sometimes there's a disconnect between our expectations and what new distributors expect from us, especially when they're just entering the*	Misaligned expectations with new distributors can	

Code	Code Segment	Meaning Unit	Theme
	market. This mismatch can lead to dissatisfaction if we cannot meet their assumptions or timelines."	lead to dissatisfaction.	
Post Compliance Innovation Strategy	*"Just yesterday, we discussed a key topic: with MDR nearly completed, we now need to decide what's next, where to invest our resources, time, and people. Each business unit manager is expected to submit ideas for future product focus."*	With MDR nearly complete, focus is shifting toward future innovation planning.	

Table 14 presents interview excerpts that define aspects that extend beyond immediate operational concerns to reveal deeper strategic and ethical considerations prompted by MDR implementation. These reflections signal a transition point, where firms are coping with compliance and beginning to reassess long-term innovation strategies and relational dynamics within their ecosystems. As there are now signs of release of previously restricted resources during the MDR transition, which has resulted in a long-term break from innovation projects for firms, the Subcode *Contradictory Insights* capture a central tension in how MDR is perceived across the organization. While some stakeholders consider MDR an overwhelming constraint, other functional departments have a varied view of it as an entirely manageable process, provided documentation is accurate and comprehensive. *Unclear Device Classification* addresses a more structural concern: the absence of a shared regulatory knowledge infrastructure. This resulted in a need for an EU-wide database to enhance transparency in device equivalence and classification, enabling companies to benchmark more effectively and reduce redundancy. Without such infrastructure, firms operate in regulatory silos and navigating ambiguity alone. This limitation slows compliance and raises questions about inter-industry knowledge equity and systemic inefficiencies that could be mitigated through collective solutions. The subcode, *Expectations Management*, highlights the ethical and strategic risks of misaligned stakeholder expectations, particularly when collaborating with new distributors. It is essential to note that unmet expectations regarding timelines and deliverables can quickly lead to dissatisfaction, ultimately damaging commercial relationships and brand credibility. This disconnect highlights a broader challenge in regulated innovation environments: balancing what is technically feasible, regulatory permissible, and commercially desirable, while maintaining trust among partners. Finally, the code, *Post Compliance Innovation Strategy,* reflects a pivotal shift in organizational mindset, refocusing on forward-looking innovation planning. Business units are being tasked with proposing new directions and investment areas, indicating a reawakening of strategic intent. This could mean that firms that can pivot quickly from compliance to innovation may reclaim lost momentum; however, for other firms that remain entangled in regulatory inertia, they may continue to lag.

Table 15 Comparative Reflection on Strategic and Ethical Reflections (Source: Own creation)

Functional Team	Convergence Point	Divergence Point
Regulatory Affairs	Shared concern for managing stakeholder expectations (investors, distributors) through transparency and timelines.	Emphasizes the need for centralized EU databases and expresses frustration with unclear classifications in MDR

Functional Team	Convergence Point	Divergence Point
Research & Development	Acknowledges MDR interpretation complexity (aligned with Regulatory Affairs), albeit from a comparative viewpoint	Considers minimal regulatory constraints on collaboration and product development
Production	Considers MDR is manageable if documentation is in place, aligned with others on the importance of structured compliance	Downplays innovation barriers, suggesting that compliance is not a limiting factor, which contradicts the views of the Regulatory Affairs and Sales teams.
Sales & Marketing	Strong alignment on expectation management, importance of transparent communication, real-time updates, and distributor education	Highlights resource constraints and post-MDR strategic realignment, focuses beyond compliance to innovation planning.

Table 15 highlights the comparative reflections of different functional teams on *Strategic and Ethical Reflections.* There is a notable convergence on the idea or perception of how MDR has introduced procedural demands and strategic and ethical complexity. This could be seen in terms of transparency, classification clarity, and stakeholder communication. There is a shared view between Regulatory Affairs and Sales & Marketing on the importance of setting realistic timelines and maintaining clear, transparent communication with stakeholders, such as distributors and investors. This shared concern reflects an acute awareness of how regulatory delays or ambiguities can quickly escalate into reputational risks or commercial dissatisfaction if not appropriately managed. This alignment indicates a growing recognition that MDR compliance must be framed not merely as a legal necessity but also as a component of trust-building and relationship stewardship. Similarly, there is a joint concern between R&D and Regulatory Affairs, acknowledging the interpretive challenges of MDR, especially around the device classification. However, Regulatory affairs focus on structural frustrations, such as the lack of a centralized EU database, while R&D companies prefer more predictable systems like the FDA's predicate model (U.S. Food and Drug Administration, 2022). This shared frustration highlights a cross-functional need for regulatory clarity, particularly when classification decisions directly impact product design, approval timelines, and market entry strategies.

There is a clear divergence in the perception of MDR's impact on innovation and strategic planning. The production team represents the most distinct outlier; it views MDR as a largely unproblematic process, provided documentation is handled correctly. This perspective aligns with their operational focus and suggests that, from a production standpoint, MDR is more about procedural rigor than strategic limitation. However, this still downplays the broader innovation constraints emphasized by Sales & Marketing, Regulatory Affairs, and R&D. For instance, Sales & Marketing prompts a strategic realignment post-MDR due to stalled innovation timelines, emphasizing a renewed focus on future product development. A further difference arises in perceptions of collaboration within MDR. R&D, while acknowledging classification uncertainties, R&D asserts that regulatory limitations have not substantially impeded product development or external collaborations. This perspective differs from that of Regulatory Affairs and Sales, which believe that compliance has had a direct impact on

workflows and the company's overall approach to innovation. This contrast highlights that while compliance is a shared experience, its perceived strategic implications differ significantly by function, influenced by its closeness to innovation strategy, market engagement, or execution.

4.7. Summary and Discussion of Results

The following chapter presents an integrated summary and discussion of the empirical findings generated through the case study of Spiegelberg GmbH, a German SME operating in the medical device industry. This study examined the challenges faced by small and medium-sized medical device enterprises *in implementing open innovation practices while operating under the Medical Device Regulation (MDR).* This inquiry is situated at the intersection of two critical domains, namely the strategic pursuit of open innovation and the intensive framework of the European Medical Device Regulation (EU MDR). To shed light on this inquiry, the study employed a qualitative case study design, enabling an in-depth exploration of organizational experiences, perceptions, and practices across multiple functional departments. Data were collected through semi-structured interviews with stakeholders across various functional departments, including Research & Development, Regulatory Affairs, Quality Assurance, Production, and Sales & Marketing. A qualitative analysis tool, MAXQDA, was used to systematically code and analyse these interviews, applying a thematic analysis approach that combined deductive coding (codes inspired by the literature and the conceptual framework) with inductive insights emerging from the interviewees' narratives.

The overall analysis was structured around the conceptual framework developed to map the interaction between CE Certification phases and core attributes of open innovation. This framework served as a lens for identifying friction points and a diagnostic tool for understanding the regulatory structure. The following summary explains each phase of the CE certification process in relation to the specific innovation barriers that emerged from the empirical data:

Classification: This phase represents the foundational stage in CE certification, where medical devices are assigned a regulatory category based on their risk profile and intended purpose. This phase was characterized by unclear device classification and innovation perception gaps in this case study, resulting in strategic uncertainty. This ambiguity around MDR classification rules led to delays in regulatory planning and hindered early engagement with external innovation partners. Furthermore, there were internal disagreements on what constituted “innovation” under a compliance-heavy regime, which fragmented the firm's innovation agenda across departments. Moreover, this phase is crucial for establishing a strong foundation for subsequent collaborations, and failing to do so could lead to difficulties in creating consistent risk management frameworks, ultimately impacting trust in the partnership (Schuhmacher et al., 2016). Chesbrough (2003) emphasizes that early-stage knowledge inflows and outflows are vital for external scouting, ideation, and opportunity recognition. However, regulatory uncertainty restricts this by limiting the firm’s ability to plan collaborations, meaning that for SMEs with limited legal and regulatory infrastructure, this early phase of opacity often hinders their ability to engage in open innovation activities.

Development: This phase encompasses internal activities, including R&D, documentation preparation, and knowledge structuring. Furthermore, the empirical data revealed several key constraints, including *IP concerns, documentation complexity, timeline compression due to MDR, regulatory learning curves, cross-functional communication gaps, and outsourcing knowledge gaps.*

These codes collectively illustrate a phase overwhelmed by operational and cognitive overload. For Spiegelberg, balancing the need to develop safe, innovative products with MDR's exhaustive documentation demands has strained resources and slowed the innovation cycle. Moreover, outsourcing research and regulatory activities that are part of a firm's non-core functions may seem efficient. However, it often leads to a fragmented internal understanding and delayed responsiveness in small to medium-sized enterprises (SMEs), in contrast to larger corporations (Brant & Lohse, 2014).

Assessment: This phase involves clinical evaluations and conformity assessments conducted by third parties, primarily with Notified Bodies. Prominent issues underlying this phase include notified body bottlenecks, clinical data misalignment, and market access bottlenecks. The firm faced difficulties with inconsistent feedback from Notified Bodies and departments, which cited differing interpretations of clinical evidence standards. In some cases, even internally accepted data sets proved insufficient during conformity assessment, resulting in duplicated efforts and budget overruns. These findings are consistent with broader literature on regulatory overload in the medical device sector (MedTech Europe, 2022). Notably, clinical data misalignment limits the firm's ability to pursue open innovation strategies that rely on co-development or parallel experimentation. These bottlenecks during this stage also discourage partnerships with startups or research institutions, which may be viewed as non-compliant or unreliable collaborators. Hence, this phase converts interdependence into a liability, conflicting with the very principles of openness.

Certification: The expectation to achieve strategic clarity and market readiness during this phase is evident among numerous companies. However, the analysis reveals *uncertainty regarding CE marking and contradictory insights* among functional teams. It was also revealed that clarity was lacking in identifying the appropriate compliance path and interpreting guidance from various regulatory consultants and Notified Bodies. This uncertainty has created strategic hesitancy in firms, preventing them from finalizing launch strategies or engaging confidently with distribution and innovation partners due to the risks of penalties and product recalls (Carl & Hochmann, 2023). This phase challenges both the predictability and scalability of open innovation from a regulatory perspective. Moreover, *contradictory insights* across functional departments indicated a lack of internal alignment, further weakening the firm's innovation posture during the certification phase, which added interpretive volatility and made it difficult for firms to commit to open development paths or long-term innovation investments.

Market entry: This phase reveals deeper organizational tensions around risk, timing, and collaboration faced by SMEs. Codes such as *innovation fatigue, shadow innovation, lack of absorptive capacity, multi-market regulatory misalignment, market access bottlenecks, and expectations management* were prevalent issues regarding navigating extensive regulatory hurdles, leading to signs of burnout and disengagement among the functional departments. In response, engagement in *shadow innovation* was seen as informally advancing ideas outside the structured pipeline to bypass regulatory drags. This highlights the emotional and strategic costs of highly regulated innovation systems, as *Innovation fatigue* diminishes internal openness, while external misalignment erodes trust in global partnerships (Nnamseh et al., 2020).

Compliance maintenance: The final phase of CE certification was associated with codes such as compliance-based decision-making, selective openness, external and internal network fragility, post-compliance innovation strategy, and strategic and ethical reflections, revealing firms' approaches to work on a compliance-first basis to explore new research and innovation opportunities. There were also incidents highlighting the exercising of strategic openness only in low-risk areas with caution, which resulted in erosion of internal trust and knowledge flows along fragile external ties, further hindering proactive innovation planning. The firm's selective openness reveals an adaptive yet ultimately constrained approach to innovation, where external engagement is weighed more heavily in terms of regulatory risks than opportunities (Dahlander & Gann, 2010).

4.7.1. Cross-Departmental Insights: Code Matrix Browser Analysis

Code System	Regulatory Affairs	R&D	Sales & Marketing	Quality Assurance	Production
Strategic and Ethical Reflections					
Contradictory Insights		50.0%			50.0%
Unclear Device Classification	50.0%	50.0%			
Expectations Management	50.0%		50.0%		
Post Compliance Innovation Strategy	50.0%		50.0%		
External Collaboration and Openness Barriers					
IP Considerations		100.0%			
Lack of Absorptive Capacity	25.0%	25.0%	25.0%	25.0%	
Selective Openness	33.3%	33.3%		33.3%	
External Network Fragility (+)	25.0%	25.0%	25.0%	25.0%	
Internal Organizational Adaptations and Challenges					
Internal Network Fragility	25.0%	25.0%	25.0%	25.0%	
Outsourcing Knowledge Gap	33.3%	33.3%		33.3%	
Compliance Based Decision Making	25.0%	25.0%		25.0%	25.0%
Matured Compliance Integration	33.3%	33.3%		33.3%	
Late Stage Compliance Integration	50.0%				50.0%
Cross-Functional Communication	25.0%	25.0%		25.0%	25.0%
Regulatory Learning Curve	20.0%	20.0%	20.0%	20.0%	20.0%
Market Access Challenges and Regulatory Delays					
Innovation Perception Gaps	33.3%	33.3%	33.3%		
Multi-Market Regulatory Misalignment	33.3%	33.3%		33.3%	
Notifed Body Bottleneck	33.3%	33.3%		33.3%	
Market Access Bottelnecks	33.3%	33.3%	33.3%		
Timeline Compression due to MDR	50.0%		50.0%		
CE Marking Uncertainity	33.3%	33.3%	33.3%		
Regulatory Burden and innovation Constraints					
Documentation Complexity	20.0%	20.0%	20.0%	20.0%	20.0%
Clinical Data Misalignment	50.0%	50.0%			
Shadow Innovation	50.0%	50.0%			
Regulatory-Creativity Tension	25.0%	25.0%	25.0%	25.0%	
Opportunity Cost of Compliance	20.0%	20.0%	20.0%	20.0%	20.0%
Innovation Fatigue	20.0%	20.0%	20.0%	20.0%	20.0%
Opportunity Evaporation	50.0%	50.0%			

Figure 21 Code Matrix Display Showing Functional Team Distribution of Thematic Subcodes

In essence, to complement the thematic analysis and to understand innovation-related challenges and how they were perceived across different functional units within this case study, the Code Matrix Browser tool in MAXQDA was employed. The tool enables a visual comparison of how frequently each code appears in the interview transcripts, categorized by functional department, as illustrated in Figure 21. The analysis draws upon insights from nine semi-structured interviews, each lasting approximately 45 minutes. Furthermore, thematic codes were mapped onto functional roles, with

interviewees representing key innovation stakeholders across the firm, including early-stage development (Innovation Manager, Development Engineer) and regulatory compliance (two Regulatory Affairs Specialists), as well as quality assurance, production leadership, Sales & Marketing, and strategic R&D oversight (Head of R&D). This positional diversity allowed for a rich, triangulated view of MDR compliance and its impact on open innovation dynamics at both operational and strategic levels. The visual matrix in Figure 19 illustrates several important patterns. For instance, Regulatory Affairs and R&D consistently emerged as the most engaged functions in *Unclear Device Classification, Clinical Data Misalignment, Shadow Innovation, and Opportunity Evaporation,* reflecting their role in interpreting MDR and navigating CE certification pathways. Notably, IP-related concerns were exclusively reported by the R&D department (100%), suggesting that confidentiality risk and intellectual property protection are not widely shared concerns across other units, highlighting a potential blind spot in cross-functional collaboration under open innovation models. Furthermore, the mention of R&D in these codes suggests that regulatory processes frequently disrupt iterative development cycles, compelling development teams to delay projects or pursue *shadow innovations.*

The Sales and Marketing function primarily focused on addressing *Innovation Perception Gaps and Market Access Bottlenecks.* This aligns with the customer-oriented role, which is often disrupted by internal uncertainty regarding regulatory approval timelines and inconsistent product readiness across European Union (EU) markets. Meanwhile, the Production department reflected on themes such as compliance-based decision-making, Late-stage compliance integration, highlighting operational scalability and constraints due to regulatory delays, and shifting innovation priorities. Similarly, Quality Assurance features across multi-market *regulatory misalignment and outsourcing knowledge gaps reveal its integral yet* reactive position in the innovation lifecycle. Thus, there are two contributions by Code Matrix, firstly revealing the challenges widely recognized across the organization and suggesting system-level constraints. Second, it highlights function-specific vulnerabilities, underscoring the fragmentation of innovation ownership across departments.

4.7.2. Theoretical Implications

This research provides insights into the intricacies of open innovation, innovation governance in regulated industries, and responsible research and innovation (RRI), particularly in the context of small and medium-sized enterprises in the medical device sector.

Extending the Understanding of Open Innovation and Regulatory Compliance Tension: While numerous quantitative analyses have been conducted to quantify the impact faced by SMEs operating under the EU MDR, relatively few in-depth subjective analyses have been conducted to identify and understand the core of the subject matter. This study enriches the theoretical discourse on open innovation by exposing its structural friction with stringent regulatory frameworks, particularly the EU Medical Device Regulation (MDR). While existing literature acknowledges the challenges in balancing openness with intellectual property protection, this study demonstrates that additional layers of complexity are introduced by regulatory compliance, including documentation overload, clinical data standardization, and audit preparedness, which tend to restrict both inbound and outbound knowledge flows. Moreover, these insights contribute to a more nuanced understanding of how regulatory imperatives can hinder absorptive capacity and slow innovation cycles, particularly

among smaller firms with limited resources. The findings empirically validate the theoretical proposition that open innovation must be adapted rather than adopted in regulated environments.

Innovation Governance Challenges in SMEs: This research reveals that organizational misalignments, such as weak cross-functional integration, regulatory learning gaps, and fragmented decision-making, are not merely operational inefficiencies but also structural inhibitors to open innovation. This supports the argument that governance models in regulated industries must strike a balance between compliance-driven rigor and exploratory agility in the face of resource constraints (Blind, Petersen, & Riillo, 2017).

Reframing Responsible Research and Innovation (RRI): The concept of Responsible Research and Innovation is enhanced with empirical depth by highlighting its situational limitations. Although the emphasis is on anticipatory ethics, stakeholder inclusion, and societal alignment (Waltraud Zilch, 2022). However, the findings suggest that these ideals are often subordinated in SMEs due to regulatory fatigue and compliance overload. This initiates a reframing of RRI not as a normative ideal but as a bounded practice shaped primarily by organizational capacity, market timelines, and regulatory complexity.

4.7.3. Practical Implications

From a managerial perspective, the study provides actionable insights and recommendations for SMEs operating in similarly regulated sectors.

- Integrating regulatory considerations early in the innovation planning process is emphasized through this study. Departments such as Research & Development and Regulatory Affairs must collaborate from the initial ideation stage to prevent late-stage compliance setbacks and resource-intensive redesigns that often discourage collaboration. Furthermore, tools such as regulatory readiness checklists and cross-functional innovation councils may facilitate this integration.

- The findings in this study highlight the significance of developing absorptive capacity not only within Research & Development but also throughout the entire organization. Moreover, investments in employee training, cross-functional knowledge development, and enhancements to internal documentation processes can help mitigate dependence on external consultants and foster institutional learning. This approach is crucial for promoting responsibility, collaboration, and iterative innovation within the organization.

- The study promotes a strategic approach to openness, wherein firms differentiate between high-risk and low-risk domains for external engagement. This way, companies expand into new market opportunities for low-risk product profiles and find suitable strategies for high-risk product portfolios. For instance, co-development partnerships could focus on post-market improvements rather than early-stage prototypes for non-core technologies, thereby balancing compliance obligations with opportunities for innovation.

- In order to sustain innovation under regulatory constraints, SMEs must actively focus on strengthening internal and external knowledge networks. This could be achieved by internally appointing cross-functional roles such as “innovation champions” within each department to help maintain a consistent knowledge flow and ensure that innovation is not siloed within technical or regulatory units. Additionally, an innovation manager can actively seek long-term partnership opportunities with universities, research institutions, and regulatory-aware consultants, thereby creating a trusted ecosystem for collaboration.

- The study has found a recurring challenge between innovation objectives and regulatory constraints, due to the misalignment in priorities and communication gaps. However, this could be managed efficiently by establishing a dedicated *Compliance-Innovation-Facilitator,* a cross-functional role responsible for bridging the objectives of R&D, regulatory Affairs, and other departments.

- This study revealed challenges regarding shadow innovation and the tendency of teams to innovate informally or opt for incremental changes to bypass compliance checks. However, SMEs should consider implementing “innovation logs” where informal ideas, prototypes, or experiments can be explored and documented before formal validation. This approach preserves the agility and creativity that drive innovation while ensuring traceability and later integration into compliance pathways.

- The study presents implications for policymakers and regulators as the fragmentation observed across departments and the inconsistencies in guidance from notified bodies indicate a need for more transparent, harmonized, and SME-sensitive regulatory communication. Implementing early dialogue mechanisms and adaptive compliance pathways could significantly alleviate the innovation-inhibiting effects currently experienced under the Medical Device Regulation (MDR).

4.7.4. Limitations and Future Research Scope

Like most qualitative studies, this research is subject to certain limitations that must be acknowledged to contextualize the findings and clarify their scope of generalizability. Given the nature of the research, a single-case study analysis was employed to derive in-depth insights, enabling a rich, context-sensitive understanding of the firm’s experience under the EU MDR. However, it may not completely capture the diversity of regulatory innovation practices across firms of different sizes, sectors, or geographies. Therefore, it is advised that the findings should only be interpreted as analytically generalizable rather than statistically representative. Furthermore, the data sources were limited to semi-structured interviews conducted across different functional departments. However, this cross-functional representation provided valuable internal perspectives; the study did not incorporate external actors such as notified bodies, clinical partners, industry associations, or regulatory consultants. As a result, this analysis may lack a complete view of the systemic and institutional factors that shape how innovation unfolds within and beyond firm boundaries. While the thematic analysis conducted with the support of MAXQDA enabled a structured and rigorous interpretation of the qualitative data, the researcher's interpretive lens shaped the hybrid deductive and inductive coding approach. Despite efforts to enhance trustworthiness through triangulation and code consistency, qualitative findings are inherently subjective and context-dependent. Additionally,

as MDR implementation is still evolving, some of the reported challenges and perceptions may reflect a transitional period rather than stabilized norms.

Furthermore, future comprehensive studies can be done to explore the possible research areas:

- A cross-case comparison study of different EU countries or across continents, regulatory groups for medical devices could be explored. These studies may potentially investigate how firm size, market maturity, and national regulatory perspectives influence the relationship between compliance and innovation.

- Expanding the stakeholder field to encompass external partners could provide helpful insights and enable a systemic understanding of how open innovation is brokered across institutional boundaries.

- Quantitative validation of qualitative findings could help assess the prevalence and impact of these phenomena on various aspects.

- Further research into digital regulatory tools and data-driven innovation management systems in supporting MDR alignment and cross-functional collaboration with SMEs presents a highly relevant and underexplored topic.

In summary, this section focuses on interpreting the study's findings using the developed conflict-mapping framework, offering theoretical contributions and practical recommendations for SMEs on balancing innovation with compliance.

Conclusions

None of us is as smart as all of us; these words from the American business writer Ken Blanchard remind us of the importance of collective intelligence and collaboration, which are the core principles of open innovation. However, opportunities for collaboration are often under threat in complex and highly regulated industries, and significant conflicts arise with institutional structures designed to enforce safety, reliability, and compliance. Moreover, this tension is particularly pronounced in SMEs with limited resources, and innovation must coexist with stringent regulatory obligations.

The study revealed significant challenges faced by SMEs in the medical device sector when attempting to adopt open innovation practices under the Medical Device Regulation (MDR). Furthermore, the findings highlight that stringent regulatory requirements, including *documentation complexity, compliance costs, and market access bottlenecks*, have a severe impact on SMEs. This emphasizes the need for adaptive regulatory strategies that can strike a balance between compliance and innovation.

The study conducts a comprehensive literature review, establishing a robust theoretical foundation for understanding open innovation and its significance for SMEs. This review further reveals inherent conflicts between open innovation principles and MDR requirements, particularly in the CE certification process, where compliance obligations often restrict knowledge sharing and external collaborations. However, cross-industry approaches have demonstrated that adaptive regulations, SME-specific support frameworks, and co-creation environments are crucial for sustaining innovation in regulated sectors.

A conflicting mapping framework that connected open innovation attributes with MDR components was successfully developed through this study. Moreover, this framework effectively identified key areas of conflict, including transparency and IP protection, collaborative knowledge sharing, and regulatory confidentiality, as well as rapid prototyping and documentation compliance.

The study employs a qualitative case study methodology, considering Spiegelberg GmbH as the case company. The research captured in-depth insights from stakeholders in Research and Development, Regulatory Affairs, Production, and Sales. This approach provided a nuanced understanding of how different functional departments experience and manage regulatory challenges, revealing common pain points and adaptive practices.

Finally, the empirical research findings were interpreted using the developed conflict-mapping framework, highlighting critical regulatory challenges and their impact on open innovation. Furthermore, based on these insights, the study recommended practical solutions for SMEs, including early regulatory integration, strategic openness, strengthening knowledge networks, and adaptive compliance management. These recommendations offer actionable guidance for small and medium-sized enterprises (SMEs) seeking to innovate within the MDR framework.

While offering rich qualitative insights, this study is limited by its single case focus on a German SME and its reliance on internal stakeholder perspectives. Exploring research areas that involve multi-case and cross-national comparisons could yield more insight. Ultimately, the findings of this study suggest that regulation and innovation can coexist without being opposing forces. However, with the right structures and methodologies, they can operate in tandem to support responsible and collaborative progress in medical technology development.

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Appendices

Appendix 1. Interview Guide Research & Development

Interview Guide – R&D

1. Introduction & Consent

Thank you for taking the time to participate in this interview. This conversation is part of a master's thesis research project aimed at understanding how small and medium-sized enterprises (SMEs) in the medical device sector navigate Open Innovation while complying with the European Medical Device Regulation (MDR). Your insights are incredibly valuable. The interview will take approximately 30–35 minutes. With your permission, the interview will be recorded and used solely for academic purposes. All responses will be anonymized in the final report. Do I have your consent to record this interview?

2. Background & Role

1. Can you briefly describe your role and responsibilities at Spiegelberg?
2. Could you briefly walk me through the typical product development lifecycle here?
3. At what stages does the R&D team engage with regulatory requirements (e.g., MDR/CE)

3. Innovation Process vs. Regulatory Constraints

1. How does your department approach innovation, especially in early-stage product development?
2. In what ways has MDR impacted your innovation timelines or freedom to experiment?
3. What are the biggest regulatory-related challenges your team faces during development?
5. How do MDR processes affect prototyping, testing, and iteration?
6. Does compliance pressure lead to more risk-avoidant or conservative design choices?

4. Collaboration & Open Innovation

1. To what extent does your team collaborate with external stakeholders (Eg. Suppliers, startups, academia), and what are the common challenges you encounter with these collaborations?
2. Have regulatory concerns (eg. IP risks, documentation ever limit your ability to co-develop with external partners)?
3. Are there systems or processes in place to encourage the exchange of external ideas? Are they used effectively?

5. Communication & Cross-Functional flow

1. How does your team coordinate with Regulatory Affairs during early-stage innovation?
2. Are regulatory requirements communicated early enough to guide design decisions?
3. Are there challenges in balancing technical feasibility with compliance feedback?

6. Workarounds & Best Practices

1. Have you or your team developed any effective workarounds or solutions to strike a balance between innovation and compliance?
2. Are there tools, templates, or systems that help manage regulatory expectations without stifling creativity?

7. Outlook

1. In your view, does the current regulatory landscape support or hinder innovation?
2. If you could change one thing in the MDR to better support innovation, what would it be ?

Appendix 2. Interview Guide Regulatory Affairs

Interview Guide – Regulatory Affairs

1. Introduction & Consent

Thank you for taking the time to participate in this interview. This conversation is part of a master's thesis research project that focuses on understanding how small and medium-sized enterprises (SMEs) in the medical device sector navigate Open Innovation while complying with the European Medical Device Regulation (MDR). Your insights are incredibly valuable. The interview will take approximately 25–30 minutes. With your permission, the interview will be recorded and used solely for academic purposes. All responses will be anonymized in the final report. Do I have your consent to record this interview?

2. Background & Role

1. Can you briefly describe your role and responsibilities at Spiegelberg?
2. What is your involvement in MDR or CE compliance processes?

3. Regulatory Process & Innovation Constraints

1. What are the biggest compliance challenges you face when new innovations are introduced?
2. What are the most significant challenges in ensuring compliance under MDR?
3. How has MDR changed the way your team operates or makes decisions?
4. Are there particular aspects of MDR that are more difficult for SMEs like Spiegelberg to comply with?
5. How do you handle risk assessments and clinical evaluation requirements in relation to innovation timelines?
6. What could be the challenges of outsourcing test activities or clinical evaluations? How good is this strategy?

4. Collaboration & Cross-Department Flow

1. How closely does your team work with R&D during early-stage development?
2. Are there any recurring communication gaps or conflicts between regulatory and technical teams?
3. Do you feel that regulatory inputs are well integrated into the product design process?

5. External Relations & Notified Bodies

1. What challenges have you faced while working with Notified Bodies under MDR?
2. Has MDR impacted your ability to collaborate with external partners (e.g., clinical evaluators, legal, startups)?
3. How do you balance transparency and confidentiality when engaging in open innovation practices?

6. Strategies & Improvements

1. Have you implemented any internal strategies or tools to ease MDR compliance?
2. Are there any best practices or lessons you've learned that help manage the balance between innovation and regulation?
3. If there was one thing you could simplify in the MDR framework, what would it be and why?

7. Wrap-up

1. Is there anything else you would like to add regarding innovation and regulatory compliance at Spiegelberg?
2. Would you be open to a short follow-up if additional questions arise?

Appendix 3. Interview Guide Sales & Marketing

Interview Guide – Sales & Marketing

1. Introduction & Consent

Thank you for taking the time to participate in this interview. This conversation is part of a master's thesis research project focused on understanding how small and medium-sized enterprises (SMEs) in the medical device sector navigate Open Innovation while complying with the European Medical Device Regulation (MDR). Your insights are incredibly valuable. The interview will take approximately 25–30 minutes. With your permission, the interview will be recorded and used solely for academic purposes. All responses will be anonymized in the final report. Do I have your consent to record this interview?

2. Background & Role

1. Could you briefly describe your role and responsibilities in managing distributor relationships and product launches?
2. At what point do you become involved in the product development or market readiness process?

3. Impact of MDR/CE on Market Access

1. Have MDR or CE-related requirements delayed or complicated distributor onboarding or product launches in any region?
2. How do regulatory timelines (e.g., CE marking approval) affect your go-to-market planning with distributors?
3. Have you observed distributors prioritizing products from other markets due to faster regulatory clearance?
4. In what ways has MDR influenced how you communicate product value or features?
5. Do you notice competitors gaining an advantage in other markets where such regulations are less strict?

4. Distributor Expectations & Communication

1. What kind of regulatory documentation or guarantees do distributors typically ask for before launching a product?
2. Have any distributors expressed frustration or concerns related to MDR or delays in certification?
3. How transparent can you be with distributors regarding compliance status during early discussions?
4. Have you had to alter how you present the value or readiness of a product due to regulatory processes?
5. Are there any noticeable changes in customer trust, product adoption, or sales cycles since MDR was introduced?

5. Internal Collaboration & Launch Planning

1. How does your team align with Regulatory Affairs and R&D to ensure timely product availability for distributors?
2. Are there formal processes in place for syncing launch readiness with CE certification timelines?

6. Reflections & Strategic Outlook

1. In your view, does MDR support or limit market competitiveness for SMEs like Spiegelberg?
2. What would help you better navigate distributor relationships while balancing regulatory constraints?

Appendix 4. Interview Guide Production

Interview Guide – Production

1. Introduction & Consent

Thank you for taking the time to participate in this interview. This conversation is part of a master's thesis research project focused on understanding how small and medium-sized enterprises (SMEs) in the medical device sector navigate Open Innovation while complying with the European Medical Device Regulation (MDR). Your insights are incredibly valuable. The interview will take approximately 25–30 minutes. With your permission, the interview will be recorded and used solely for academic purposes. All responses will be anonymized in the final report. Do I have your consent to record this interview?

2. Background & Role

1. Can you briefly describe your role and responsibilities at Spiegelberg?
2. How is your department involved in the product development and launch process?
3. What kind of documentation or traceability processes are involved in your day-to-day work?

3. Operational Impact of MDR/CE

1. How does the MDR affect production planning or operational processes?
2. Are there specific regulatory requirements that cause delays or rework during manufacturing?
3. Are there any recurring operational bottlenecks tied to regulatory changes?
4. Have you had to adjust any procedures, equipment, or quality systems due to MDR?

4. Innovation & Change Management

1. When new product innovations or design changes are proposed, how do you ensure they align with compliance requirements during implementation?
2. Does the MDR limit your ability to adopt new production methods or test alternative materials/processes?
3. Do you feel that the current regulatory environment discourages innovation in manufacturing?

5. Communication & Cross-Functional Collaboration

1. How does the production team communicate with R&D and Regulatory Affairs when new devices or changes are introduced? Are there any challenges that you encounter?
2. Do you feel you're involved early enough in the process to plan for regulatory or technical changes?

6. Best Practices & Outlook

1. Have you or your team implemented any solutions to balance compliance with efficiency and innovation?
2. From a production perspective, what improvements in MDR implementation would help your team work more effectively?

Appendix 5. Code System

Code System

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