

Quality Management Systems in Medical Devices: Barriers and Solutions in ISO 13485 Implementation

Nicoleta L. MANTA*

National University of Science and Technology Politehnica Bucharest, Bucharest, Romania

ORCID ID: <https://orcid.org/0009-0001-3692-1149>

nicoleta.manta1602@stud.fir.upb.ro

Sérgio D. SOUSA

ALGORITMI Research Centre, University of Minho, Guimarães, Portugal

ORCID ID: <https://orcid.org/0000-0002-3631-6440>

sds@dps.uminho.pt

Irina SEVERIN

National University of Science and Technology Politehnica Bucharest, Bucharest, Romania

ORCID: <https://orcid.org/0000-0002-0296-4730>

irina.severin@upb.ro

Abstract.

Drawing on the growing focus on regulatory efficiency, this paper examines the challenges that companies in the medical device (MD) sector face when implementing ISO 13485 and explores practical solutions for integrating the standard. There is a lack of research addressing the practical implementation of a dedicated Quality Management System (QMS), leaving a gap in guidance for MD manufacturers facing compliance challenges; this study systematically reviewed the existing literature to highlight recurring patterns and identify knowledge gaps. Based on a systematic review of the literature from 2016 to 2025, we address two questions: (1) What are the main challenges in implementing ISO 13485? and (2) What strategies have organizations used to overcome these challenges? Our research highlights five main challenges. These include resistance to organizational change, limited resources, lack of knowledge about QMSs, complex and fragmented regulations, and the absence of clear practical guidance in the standard. In particular, regulatory fragmentation, resource constraints, and organizational resistance often create delays, inefficiencies, and interpretative inconsistencies, especially in artificial intelligence-based medical technologies. To address these challenges, organizations have implemented process phasing, formed strategic partnerships, and provided customized training. Leadership commitment and early integration of QMS are key factors for success, especially for startups, while digital validation systems improve the traceability of documentation for regulatory audits. Harmonized regulatory frameworks, modular approaches to QMS, and ongoing assessments of identified risks can contribute to more sustainable implementation. Overall, our findings highlight the need for scalable models, regulatory alignment, and engaged leadership to drive quality, compliance, and innovation in the healthcare industry.

Keywords: ISO 13485, Quality Management Systems (QMS), Medical devices, Barriers and challenges, Solutions and best practices, Regulatory compliance

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Introduction

The medical devices (MD) industry is one of the most heavily regulated sectors worldwide, with patient safety representing an absolute priority that influences all stages of the product life cycle: design, manufacturing, installation, use, and post-market surveillance [1]. In such a context, quality management systems (QMS) play a key role for compliance and ensuring the performance and safety of MD [2]. Applying ISO standards can positively influence the quality of healthcare services. Emerging technologies like artificial intelligence (AI) and 3D printing challenge traditional regulatory and quality frameworks, requiring adaptation [3]. The integration of AI in medical device software creates new regulatory challenges requiring ISO 13485 alignment [4].

Over the past decades, ISO standards for QMS have become widely implemented internationally, with ISO 9001 among the most adopted, boasting nearly one million active certificates [5]. Its latest version, ISO 9001:2015, emphasizes risk-based thinking, continuous improvement and a process-oriented approach. However, in regulated sectors like the medical field, ISO 9001 lacks the required level of specificity, leading to industry-specific standards, such as ISO 13485 [6]. The current version, ISO 13485:2016, addresses stricter international Medical Device Regulations (MDR), and has undergone several revisions to align with evolving standards and technological advances. Adoption is critical for organizations seeking stronger quality management and regulatory compliance, often a natural step for companies already certified to ISO 9001 [7, 8]. As global healthcare expands, Asia is poised to emerge as a crucial hub for MD innovation, highlighting the need for strengthened collaboration between clinical, research, and industrial fields to transform scientific advancements into impactful medical technologies [9]. Jurisdictions like Canada and Australia show strong compatibility with the EU MDR and ISO 13485-based QMS, facilitating smoother transitions for manufacturers already aligned with European standards [10].

As a result of identifying the gaps in current research regarding the practical implementation of ISO 13485, this paper proposes the following research questions (RQ):

- RQ1: What were the main challenges encountered in implementing the ISO 13485 standard?
- RQ2: What solutions were adopted to overcome these challenges?

Therefore, this paper aims to investigate the common barriers to implementing the ISO 13485:2016 standard in the MD industry and to propose possible solutions for overcoming them.

The remaining paper is organized into five sections. The literature review synthesizes existing research on ISO 13485 implementation. The methodological section presents the approach used to plan, conduct, and disseminate the analysis. The next section - results - is divided into three subsections: an overview of the ISO 13485 standard, barriers and solutions to implementation, and analysis of barriers and solutions in implementing ISO 13485. This section examines the main challenges in implementation, including financial constraints, organizational resilience, and regulatory complexity, as well as effective solutions to address these barriers. The discussion section interprets the main findings, compares them with previous research, and presents directions for future investigations. The final section - conclusions - summarizes the main perspectives and implications for the MD sector.

Literature review

The medical QMS standard focuses on the specific requirements for manufacturing, installing and maintaining MD, emphasizing risk management, rigorous documentation, traceability and compliance with applicable regulations [2, 6]. Moreover, the standard mentioned earlier provides a solid framework for complying with the strict regulations imposed by institutions such as the U.S. Food and Drug Administration (FDA) or the European Commission (EC) under the MDR [1]. Given the complexity and frequent changes of software-based MD, structured risk assessments and digital traceability are essential for maintaining compliance with ISO 13485 [11]. At the same time, aligning clinical evaluation processes with quality system requirements remains a persistent challenge for manufacturers striving to meet the ever-evolving expectations of EU regulators [12].

Nevertheless, implementing ISO 13485:2016 is not without its challenges. The standard's complexity, the lack of harmonization across international regulations, the need for exhaustive documentation, and difficulties encountered by research organizations or projects lacking a designated manufacturer are just a few of the barriers that limit the efficiency and sustainability of QMS in this field [13, 14, 15]. Despite its widespread adoption and regulatory significance, ISO 13485 remains underexplored in terms of future structural alignment challenges, particularly regarding its deviation from the ISO High-Level Structure (HLS) and the potential implications for long-term compatibility [16]. There is a significant lack of research addressing the practical implementation of dedicated QMS, leaving a gap in guidance for MD manufacturers navigating compliance challenges [8].

Despite MD industry role in driving innovation, medical device start-ups often struggle with limited resources and understanding QMS requirements, which further complicates certification and regulatory approval [1]. Additionally, these challenges can be exacerbated by both internal and external factors, such as customer pressure, the influence of major players, insufficient leadership support, or a low degree of organizational formalization [7]. In

an increasingly digitalized medical environment, the transition toward paperless validation systems has become essential for device manufacturers, optimizing compliance and minimizing risks tied to physical documentation [17]. Thus, it becomes evident that ISO 13485 implementation strategies must be tailored to the specific characteristics of each organization, as well as to the regional or national context in which it operates.

Methodology

To study the barriers and solutions [18] related to the implementation of ISO 13485 in QMS for MD, this research adopts a comprehensive literature review methodology. To address the research questions, a review of the relevant literature in this field was conducted. For clarity on how the search and analysis were carried out, a structured protocol was followed as in Lepasepp and Hurst [19], divided into three main stages: planning, conducting and disseminating the review. This methodology ensures a systematic and transparent approach to synthesizing existing knowledge and identifying key themes related to challenges and best practices in QMS implementation [8, 18].

Planning the review

During the planning stage, a set of well-established academic databases was selected to ensure the comprehensiveness and quality of the literature reviewed. The databases searched include Scopus, Web of Science, IEEE Xplore, Science Direct, Emerald, Google Scholar and Wiley. These sources were chosen due to their broad coverage of peer-reviewed literature in the fields of medical technology, regulatory science and QMS. The literature search focused on scientific publications, primarily peer-reviewed journal articles, published between 2016 and 2025 and addressing topics such as ISO 13485 implementation [20] in medical device QMS, barriers or challenges encountered, proposed solutions, strategies or best practices. The selected time frame (2016–2025) reflects the period between the most recent official revision of ISO 13485 (published in 2016) and the year of writing this article (2025). Additionally, initial scoping searches were conducted to refine search terms and confirm the relevance and volume of literature available on the topic.

Inclusion and exclusion criteria were clearly defined and are presented in Table 1. The search strategy utilized a combination of relevant keywords, including "ISO 13485", "medical device", "QMS", "barriers", and "solutions", combined using Boolean operators to improve precision and relevance.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Scientific publications, primarily peer-reviewed academic journal articles	Non-peer-reviewed publications (e.g., editorials, newsletters, blog posts, corporate whitepapers, etc.)
Published between 2016 and 2025	Articles outside the target date range
Written in english	Articles written in languages other than english
Focus on ISO 13485:2016 implementation in the MD sector	Articles unrelated to ISO 13485
Indexed in academic databases such as Scopus, Web of Science, IEEE Xplore, ScienceDirect, Emerald, Google Scholar, or Wiley	Articles published in non-academic or unindexed sources
Full-text articles with accessible content for data extraction	Articles with restricted or unavailable full-text access
Articles focused on the implementation of QMS within the MD sector	Articles not related to QMS implementation in the MD sector
Studies aligning with the RQ and scope of this review	Studies not aligned with the RQ

Conducting the review

In the second stage of the review process, a rigorous and structured approach was followed to ensure that only the most relevant and quality studies were retained for further analysis. Following the initial database search, the collected records underwent a multi-step screening procedure aimed at refining the dataset and confirming adherence to the predefined inclusion and exclusion criteria.

The selection process involved multiple stages, including the removal of duplicates, screening titles and abstracts and performing full-text analysis to assess eligibility. First, duplicate entries were identified and eliminated. After duplicate removal, studies that did not meet the predefined inclusion criteria—such as language, publication

date, or thematic scope—were excluded. The remaining articles then proceeded to an initial screening phase based on titles and abstracts. This step served to eliminate clearly irrelevant materials and refine the selection.

Articles considered relevant were then fully evaluated to confirm their fit with the research scope, eligibility criteria and relevance to key topics such as QMS in MD, barriers and solutions in ISO 13485 implementation. At this stage, articles without accessible full-text versions or those that deviated significantly from the study's thematic focus were excluded. Following this review cascade, a total of 25 articles were included in the final selection. To manage and organize the data effectively, an analytical database was developed, where each article was categorized based on key variables such as publication year, methodological approach, type of study and main findings. This structure facilitated a transparent and traceable review process, ensuring that all decisions were well documented. A noticeable increase in publications related to ISO 13485 and quality management in MD was observed during 2022–2025. This growing interest in the subject may be attributed to the accelerating influence of digitalization, as well as increased pressure from customers on MD companies to obtain quality certifications such as ISO 13485:2016, to demonstrate their credibility and regulatory compliance. In addition, large companies and their suppliers often require such certifications to maintain business relationships and ensure supply chain quality.

To understand the dissemination of the 25 selected articles on QMS in MD, we analyzed their publication journals. Each article appeared in a different journal, reflecting the topic's interdisciplinary nature. This wide range of publication sources highlights the interdisciplinary interest in QMS within the context of MD. However, none of these publication sources focus specifically on the intersection of QMS and MD without delving into healthcare or a particular medical subdomain. Moreover, there appears to be no journal dedicated solely to ISO 13485 and its implementation in MD. This step-wise filtering and evaluation process not only guaranteed methodological rigor but also helped maintain the relevance of the selected literature to the central RQ concerning the implementation of ISO 13485 in MD QMS, including identified barriers and proposed solutions.

Disseminating the review

The final stage of this systematic review involved a comprehensive reporting and dissemination process to synthesize and communicate the main findings. Building on the structured dataset developed in Stage 2, descriptive analyses were conducted to outline the characteristics of the selected studies, such as year of publication, study design, methodological approaches, and journals in which the articles were published. This descriptive overview provided a clear view of current research on barriers and solutions related to ISO 13485 implementation in the MD sector.

Beyond this quantitative summary, a thematic analysis was conducted to identify and categorize the main research themes emerging from the literature. These themes included “barriers to implementation”—such as resource constraints, documentation complexity, and regulatory fragmentation [1, 10, 12]; “strategies for overcoming challenges”—including digital validation systems, stakeholder alignment, and DevOps integration in regulated environments [17]; and “impact on organizational performance”—reflected in improved customer satisfaction, enhanced process efficiency, and innovation responsiveness [5, 6]. These thematic dimensions were systematically analyzed to highlight recurring patterns and identify gaps in the current knowledge base surrounding ISO 13485 implementation in the MD industry. This stage concludes with a discussion section that contextualizes the results, followed by recommendations for future research and final conclusions, which address the RQ outlined in the introduction of the paper.

Results and further discussions

Overview of ISO 13485 standard

ISO 13485, developed from ISO 9001, was designed specifically to accommodate the strict quality and regulatory needs of the MD sector, integrating risk management principles to enhance organizational preparedness and ensure product traceability [8]. While ISO 9001 focuses on general quality management and continuous improvement, ISO 13485 prioritizes regulatory compliance and product safety, introducing additional requirements such as extensive documentation and formal risk practices. Unlike ISO 9001, which emphasizes process optimization, ISO 13485 aligns more closely with international regulatory expectations [1].

Serving as the internationally recognized standard for QMS in MD development, ISO 13485 ensures compliance with regulatory requirements across various markets. It defines necessary procedures for design, production, installation, and maintenance to guarantee product safety and efficiency. Certification to ISO 13485 supports companies in establishing credibility and facilitates access to global markets [1, 2]. Furthermore, the increasing reliance on AI-driven systems necessitates additional regulatory adaptation to ensure these devices meet international quality standards while maintaining accountability in automated decision-making [4].

Barriers and solutions to implementation

To provide a structured overview of the challenges encountered in the implementation of ISO 13485 and the strategies proposed to address them, a summary is presented below in Table 2. It synthesizes key findings from the reviewed literature, highlighting recurring issues and their associated responses.

Table 2: Barriers and proposed solutions in ISO 13485 implementation

Categories	Barriers	Solutions	Sources
Limited resources	Financial constraints, limited staff, lack of information, time pressure, costly audits, integration issues, few ISO-certified suppliers	Early regulatory dialogue, phased QMS rollout, optimize resource allocation	[9, 20, 21]
QMS knowledge gaps	Lack of QMS knowledge, insufficient guidance, no training, unclear responsibilities, weak leadership, low awareness of data rules	Tailored QMS design, training programs, raise awareness align with regulations, clarify ownership, embed quality culture.	[1, 17]
Change resistance	Organizational resistance, cultural shift challenges, difficulty adopting new methodologies	Training, coaching, process restructuring, supportive leadership	[17, 20]
Regulatory challenges	Complex, fragmented regulations, lack of harmonization, reliance on external consultants, uncertainty, innovation risk, AI-MD regulatory fragmentation, certification delays	Harmonized AI- SaMD (Software as a Medical Device) frameworks, certified ISO 13485 specialists, clear regulatory strategies, dedicated working groups, international alignment	[4, 9, 21, 22, 23]
Process complexity	Normative standards lack practical guidance, inconsistent compliance, delays, inefficiencies, strict monitoring, traceability, legal burden, no feature release without QMS approval, AI algorithm validation complexity	Clear documentation for AI changes, ongoing risk assessment, evaluation matrices, optimal implementation paths, simplified compliance processes, structured structured traceability targets.	[4, 10, 14, 24]

Analysis of barriers and solutions in ISO 13485 implementation

To provide more clarity on the barriers and solutions presented in Table 2, each category has been analyzed individually to highlight the specific challenges encountered and the corresponding strategies implemented to address them. The analysis is structured as follows:

- a) Limited resources: Limited financial, human, and informational resources—combined with time pressure—pose significant barriers to the effective implementation of ISO 13485, especially for Small and Medium-sized Enterprises (SMEs). These constraints affect early development and make it difficult to fully adopt and integrate a QMS, particularly due to the cost and complexity of audits and system alignment [20, 21]. Resource-based innovation models can help SMEs overcome these limitations through strategic partnerships. Small companies face more obstacles in aligning management systems. In emerging markets, the limited availability of ISO 13485–certified suppliers and the absence of supportive procurement policies create substantial barriers for local manufacturers aiming to meet international quality standards [25]. To address this, Fearis & Petrie [24] recommend a phased approach, starting with core QMS elements and scaling toward commercialization [24]. Early collaboration with regulators can reduce compliance risks and improve resource allocation [9]. This approach reduces risks while optimizing resource use, making QMS implementation more manageable for companies with different maturity levels.

- b) QMS knowledge gaps: Lack of knowledge and experience in quality management – including the need for staff training and understanding of the requirements of the standard – is a major barrier to implementing ISO 13485 [1, 17]. Kheir et al. [1] note that low management commitment and unclear ownership further impede progress [1]. Awareness and adequate training on regulatory frameworks and data integrity policies are also essential to ensure the effectiveness of the system [17].

To overcome these barriers, the development of customized management systems aligned with the requirements of ISO 13485 can increase compliance [1]. Comprehensive education and awareness programs for staff on regulatory frameworks and data policies help improve adherence and overall effectiveness of the system [17]. Also, clarifying responsibilities and ensuring management involvement are essential for building an effective and sustainable QMS.

- c) Change resistance: Organizational resistance to change and challenges in shifting organizational culture, including the transition to new methodologies, limit successful implementation of ISO 13485 [17, 20]. As Sharma and Luthra [20] emphasize, this resistance often stems from employees' reluctance to adapt to new quality management processes, particularly in smaller organizations with limited change management experience [20]. To address these barriers, implementing organizational training, coaching, and restructuring work processes facilitates smoother cultural transitions and adoption. Management support and clear communication, as noted by McDermott et al. [17], are other elements that can help reduce resistance and improve acceptance of new QMS requirements [17].
- d) Regulatory challenges: Due to the complexity of regional regulatory requirements and the lack of international harmonization, companies often face significant challenges in understanding and applying relevant standards. Unclear and evolving regulations cause companies to rely heavily on external specialist consultants [21]. Regulatory uncertainty discourages investment in innovation and affects motivation to implement robust QMS like ISO 13485 [9]. AI-SaMD regulations remain fragmented across different countries, making standardization difficult and posing challenges for companies seeking ISO 13485 certification in multiple regions [4]. Software-based medical technologies must also align with quality system principles to ensure traceability, risk control, and lifecycle documentation [23], while certification requires navigating complex standards; without a clear strategy, companies risk delays and uncertainty. To overcome this, harmonized AI-MD frameworks [4] and support from certified specialists help streamline the implementation process, ensure compliance, and minimize regulatory risks.
- e) Process complexity: QMS standards define required outcomes but do not provide specific implementation methods. The lack of practical guidance on applying these normative requirements may lead to delays and inefficiencies in QMS setup [24]. Modular implementation can simplify complex processes, particularly for smaller firms with limited experience. In MD development, no feature is released without QMS-approved procedures. Complex documentation, traceability, and legal responsibility requirements may discourage full QMS adoption in smaller companies [14]. While AI-driven MD must meet ISO 13485's rigorous quality management criteria, evolving AI algorithms require continuous monitoring and validation [4]. Developing clear documentation for AI changes and continuously assessing risks within the QMS helps both maintain compliance with ISO 13485 and support innovation [4]. Using evaluation matrices to evaluate implementation options and select the optimal path helps reduce costs and uncertainty [24].

Discussion

The transition to digital validation systems is a significant driver, improving both process efficiency and regulatory compliance [17]. However, significant limitations remain in the adoption of digital transformation. As McDermott et al. [17] note, many organizations struggle to integrate these systems with existing quality processes. Implementation faces barriers, including knowledge gaps in quality management principles [1, 17], and cultural resistance to process change [20]. Resource limitations are especially problematic for SMEs, particularly during early phases [21], with funding and skilled personnel often insufficient to maintain compliance [20].

While ISO 13485 aims to support global compliance, achieving full regulatory harmonization is challenging. The standard lacks detailed country-specific guidance, causing interpretation issues [10]. Rapid

technological evolution has highlighted gaps, particularly for AI-driven and software-based devices, where harmonized MDR standards introduce operational ambiguity, as emphasized by Francesconi et al. [23].

Based on the identified barriers to implementation, future studies should focus on three areas. First, SME-specific implementation models are needed to address resource constraints [20] and knowledge gaps [1, 17], through phased approaches [24] and strategic partnerships. Second, the rapid evolution of medical technologies requires research focused on integrating AI-based devices and software with ISO 13485 requirements [4, 23], including standardized frameworks for continuous algorithm validation [4]. Third, comparative regulatory studies across regions [10], could alleviate harmonization challenges and country-specific barriers, addressing resource limitations, technological complexities, and regulatory fragmentation that currently hinder the effective adoption of a QMS.

Conclusion

This study examined the barriers and solutions arising in the implementation of ISO 13485 QMS in the MD industry. While the standard ensures product safety and regulatory compliance, barriers identified (RQ1) include financial and staffing constraints, lack of information and training, unclear responsibilities, weak leadership, and organizational resistance. Complex, fragmented regulations, regulatory uncertainty, and AI-MD regulatory fragmentation contribute to delays and risks. The normative nature of ISO 13485 causes inconsistent compliance, inefficiencies, and strict traceability and validation demands. These challenges vary depending on resource availability and regulatory context [1, 4, 9]. For MD startups and SMEs, QMS offers a path to meet regulatory expectations and foster continuous improvement, as noted by Kheir et al. [1]. However, resource limitations [20, 21] and expertise gaps [1, 17] necessitate customized strategies, such as phased implementation [24] and strategic collaborations.

To address these challenges, the solutions adopted (RQ2) involve early regulatory dialogue, phased QMS rollout, and optimized resource allocation. Tailored QMS design, comprehensive training programs, raising awareness to align with regulations, clarifying ownership, and embedding a quality culture have also been implemented. Overcoming organizational resistance requires training, coaching, process restructuring, and supportive leadership. Regulatory challenges are tackled through harmonized AI-SaMD frameworks, certified ISO 13485 specialists, clear strategies, and international alignment, while AI-driven technologies benefit from clear documentation, ongoing risk assessment, and simplified compliance processes [9]. To enhance regulatory alignment, a coherent global framework that integrates ISO 13485 while addressing jurisdictional fragmentation remains critical, especially for high-risk devices like implants [10]. The current misalignment generates interpretative inconsistencies and hampers innovation [10, 21].

In the context of AI-driven technologies, the findings highlight the need for regulatory convergence between ISO 13485 and software lifecycle standards to ensure consistency and sustained post-market performance [4]. As Francesconi et al. [23] emphasize, such integration must accommodate ongoing algorithm validation demands.

Moreover, this study is limited by the lack of large-scale longitudinal research tracking organizations through ISO 13485 implementation. Most current evidence comes from cross-sectional case studies, which provide snapshots but lack the comparative perspective needed to understand how implementation challenges change as QMS matures. Key practical implications include the importance of executive-level support [8], the adoption of digital validation workflows [17], and enhanced cross-sector collaboration to close knowledge gaps [9].

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