

**American University Kyiv**

A Capstone Project

ISO 13485:2016 IMPLEMENTATION AND INTERNAL AUDIT READINESS IN A  
UKRAINIAN MEDICAL DEVICE MANUFACTURER

ВПРОВАДЖЕННЯ СТАНДАРТУ ISO 13485:2016 ТА ГОТОВНІСТЬ ДО  
ВНУТРІШНЬОГО АУДИТУ НА УКРАЇНСЬКОМУ ПІДПРИЄМСТВІ З  
ВИРОБНИЦТВА МЕДИЧНИХ ВИРОБІВ

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Presented in Partial Fulfillment of the Requirements  
for the Degree

Master

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2026

## ABSTRACT

*This capstone examines* the implementation of ISO 13485:2016 quality management systems and internal audit readiness within a Ukrainian medical device manufacturer. The research addresses the problem of the gap between formal certification and actual operational effectiveness of quality management systems in emerging regulatory environments.

*This research is guided* by the following research questions: how the level of ISO 13485 implementation affects regulatory readiness and compliance performance; how internal audit practices influence the recurrence of nonconformities; and how management involvement impacts CAPA effectiveness.

*The aim of the research* is to evaluate the relationship between implementation depth, audit performance, and effectiveness of corrective action.

A mixed-methods single-case study design was applied. Quantitative data were collected through a clause-based gap analysis and internal audit metrics, while qualitative data were obtained through structured document analysis of QMS documentation. The sample consists of one Ukrainian medical device manufacturing organization in the pre-certification stage.

The results indicate a moderate level of ISO 13485 implementation (70.5%), with stronger performance in documentation and weaker integration in monitoring and improvement processes. Internal audits effectively identify nonconformities but have limited impact on preventing recurrence (32% repeat rate). CAPA processes demonstrate moderate effectiveness, with delays and incomplete closure.

The findings suggest that implementation depth, rather than certification status, determines regulatory readiness and quality performance. Management involvement is critical for improving CAPA effectiveness and reducing recurring issues.

The research contributes to theory by emphasizing implementation maturity and provides practical recommendations for improving QMS effectiveness in Ukrainian medical device organizations.

*Keywords:* ISO 13485, quality management system, internal audit, CAPA, medical devices, Ukraine.

## **Acknowledgments**

I would like to express my sincere gratitude to the individuals who played a pivotal role in the completion of my capstone project.

I also extend my deepest appreciation to Olga Katerna, Ph.D., Faculty Mentor, for her continuous support, insightful feedback, and academic supervision throughout the entire research process. Her professionalism, attention to detail, and ability to provide clear and constructive guidance significantly enhanced the quality of this work. I am particularly thankful for her dedication, thoughtful recommendations, and willingness to engage in meaningful discussions at every stage of the project. Her critical perspective and academic expertise encouraged me to think more analytically and to approach the research with greater depth and rigor.

I would also like to thank my peers for their support, collaboration, and positive environment throughout this educational journey, which helped me overcome various academic challenges.

Finally, my gratitude extends to everyone at American University Kyiv who contributed to my academic and personal growth during my studies.

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## LIST OF ABBREVIATIONS

**CAPA** — Corrective and Preventive Actions

**EU** — European Union

**ISO** — International Organization for Standardization

**MDR** — Medical Device Regulation

**QMS** — Quality Management System

**RBV** — Resource-Based View

**SOP** — Standard Operating Procedure

## CHAPTER 1. INTRODUCTION

### 1.1 Relevance of the Topic

The medical device industry is among the most highly regulated sectors worldwide. Compliance with international quality management standards, particularly ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes, has become a prerequisite for market access in the European Union and many other jurisdictions. With the full application of the EU Medical Device Regulation (MDR), regulatory expectations regarding quality management systems (QMS), risk management, documentation control, traceability, and post-market surveillance have significantly intensified. For Ukrainian medical device manufacturers, implementation of ISO 13485:2016 is not merely a formal certification objective but a strategic requirement. Ukraine's regulatory harmonization with the EU, increasing export ambitions, and the need to strengthen international partnerships create institutional and market pressure for adopting internationally recognized standards. Furthermore, in the context of war-related disruptions, supply chain instability, resource constraints, and workforce challenges, structured quality management systems contribute to operational resilience and risk mitigation. Despite the global diffusion of ISO 13485, limited empirical research investigates the implementation process and internal audit maturity in emerging economies such as Ukraine. Most prior studies focus on certification outcomes rather than examining how implementation depth influences measurable quality and compliance performance.

### 1.2 Problem Statement

Although ISO 13485:2016 provides a structured framework for quality management in medical device manufacturing, effective implementation remains a complex managerial challenge. Organizations frequently prioritize obtaining certification rather than developing a mature and continuously improving QMS. This creates a gap between formal compliance and actual organizational capability. In Ukraine, limited empirical evidence exists regarding how ISO implementation depth affects internal audit effectiveness, recurrence of nonconformities, and corrective action performance. Regulatory frameworks assume that certified organizations operate mature systems, yet in practice companies may struggle with documentation completeness, ineffective CAPA processes, insufficient management involvement, and recurring audit findings. This research addresses this gap by focusing on the implementation process rather than certification status and by evaluating internal audit practices as a mechanism influencing regulatory readiness and quality performance.

### **1.3 Aim of the Research**

The aim of this research is to examine how the implementation of ISO 13485:2016 requirements and the development of internal audit practices influence regulatory readiness, quality performance, and corrective action effectiveness in a Ukrainian medical device manufacturer.

### **1.4 Research Questions**

**RQ1:** What is the level of ISO 13485 implementation in the organization?

**RQ2:** How do internal audit practices influence the frequency and recurrence of nonconformities?

**RQ3:** What is the relationship between management involvement and the effectiveness of corrective and preventive actions (CAPA)?

### **1.5 Scientific and Practical Significance**

This research contributes to academic literature by shifting the focus from certification outcomes to implementation effectiveness and audit system maturity. It integrates management theory perspectives with regulatory compliance practice and provides empirical evidence from an emerging economy. From a practical standpoint, the research provides actionable insights for Ukrainian medical device manufacturers seeking EU market access, helping improve audit preparation, reduce recurring nonconformities, enhance CAPA effectiveness, and strengthen regulatory readiness.

### **1.6 Brief Description of Methodology**

This research adopts a single-case study design with mixed-method elements. Qualitative data include document analysis and audit documentation review. Quantitative data include gap analysis scores, nonconformity rates, CAPA closure time, and recurrence of findings. Data were analyzed using thematic coding and descriptive statistical analysis.

### **1.7 Limitations of the Research**

The research is limited to a single-case organization, which may restrict generalizability. Confidentiality constraints may limit access to certain performance data. The research is conducted within a defined time frame and does not include long-term longitudinal evaluation.

## CHAPTER 2. LITERATURE REVIEW

### 2.1 Introduction

This chapter synthesizes theoretical and empirical research relevant to ISO 13485:2016 implementation and internal audit readiness. The medical device sector operates under intensified regulatory pressure, particularly under the EU MDR framework. Contemporary scholarship increasingly shifts from certification status toward implementation depth and capability development. This chapter analyzes theoretical foundations, synthesizes contemporary empirical research, critically evaluates limitations, and identifies a clear research gap leading to the present research.

### 2.2 Theoretical Concepts

The Resource-Based View (Barney, 1991) frames ISO 13485 implementation as capability building rather than compliance. From the Resource-Based View, ISO 13485 implementation can be understood as the development of internal organizational capabilities that support quality consistency, risk control, and long-term regulatory readiness. In this perspective, documented procedures, internal audits, staff competence, and CAPA discipline are not only compliance tools but also strategic resources that improve operational reliability and organizational resilience. This approach is relevant to the present study because it helps explain why implementation depth may have a stronger effect on quality performance than certification status alone.

Institutional theory (DiMaggio & Powell, 1983) explains adoption pressures but highlights the distinction between symbolic and substantive compliance. Institutional theory is also relevant because medical device manufacturers operate in an environment of strong regulatory, normative, and market pressures. Organizations may adopt ISO 13485 formally in order to gain legitimacy, access international markets, or satisfy stakeholder expectations. However, institutional theory also helps distinguish between symbolic compliance, where standards are adopted mainly for formal legitimacy, and substantive compliance, where requirements are genuinely embedded into organizational routines and decision-making. This distinction is important for the present research because it supports the analysis of implementation quality rather than certification alone.

Governance and organizational learning perspectives conceptualize internal audits as feedback mechanisms that enable measurable improvement. From this perspective, internal audits and CAPA processes function as mechanisms of feedback, control, and continuous improvement. Their role is not limited to identifying deviations, but also includes supporting organizational learning, accountability, and process correction. This is particularly relevant in highly regulated industries, where sustainable

compliance depends on the ability of the organization to transform audit findings into structured corrective actions and measurable performance improvement. These theories jointly inform the operationalization of audit maturity and performance indicators in this research.

### **2.3 Contemporary Academic Research**

Recent academic research increasingly shows that ISO 13485 implementation should be viewed not only as a certification requirement, but also as a broader organizational process linked to quality maturity, regulatory readiness, and risk management. Scholars pay growing attention to how medical device companies develop internal systems, align documentation and processes with regulatory expectations, and strengthen their ability to respond to compliance challenges. In addition, recent studies examine the role of digitalization, implementation barriers, and sector-specific differences that shape the effectiveness of quality management systems. The studies presented in Table 2.1 summarize the main academic directions relevant to the first research question.

Recent studies (Pacheco et al., 2025; Linck et al., 2025; Kannaraya et al., 2025; Xavier et al., 2025) emphasize implementation maturity, regulatory alignment, digitalization, and implementation strategies.

The studies presented in Table 2.1 demonstrate that recent academic research increasingly approaches ISO 13485 implementation as a multidimensional organizational process rather than a purely formal certification requirement. A common pattern across the reviewed literature is the growing emphasis on implementation maturity, regulatory alignment, and the development of internal capabilities needed to sustain compliance in the medical device industry. In this sense, ISO 13485 is interpreted not only as a standard for documentation and control, but also as a framework for building quality-oriented routines, risk-based processes, and organizational discipline.

Several authors highlight the importance of strategic and managerial factors in successful implementation. Pacheco et al. (2025) focus on implementation strategies and identify organizational capabilities that support effective quality management system development. Similarly, Linck et al. (2025) shift attention from certification as an end result to the assessment of implementation maturity, proposing a more structured way to evaluate how deeply ISO 13485 requirements are embedded in organizational processes. These studies suggest that the quality of implementation may be more important than the formal status of certification itself.

Table 2.1. Overview of Recent Studies on ISO 13485 Implementation and Regulatory Compliance in the Medical Device Industry (RQ1)

Author(s)	Year	Country / Context	Research Focus	Methodology	Key Contribution
Pacheco et al.	2025	Global medical device industry	ISO 13485 implementation strategies	Conceptual and empirical analysis	Identifies best practices and organizational capabilities required for effective QMS implementation.
Linck et al.	2025	Medical device manufacturing sector	Maturity assessment of ISO 13485	Maturity model development	Proposes structured methodology to assess implementation maturity.
Kannaraya et al.	2025	Digital manufacturing environments	Digitalization of QMS data collection	Conceptual framework	Shows how digital systems improve compliance and traceability.
Xavier et al.	2025	SMEs in Brazil and Portugal	Risk management in medical device SMEs	Multiple case study	Highlights implementation barriers and regulatory readiness challenges.
Kahles et al.	2025	EU and US regulatory systems	Regulation of in vitro diagnostic devices	Comparative regulatory analysis	Explains differences between regulatory regimes affecting compliance.
Bondarets et al.	2023	Ukraine	Risk-oriented approach to medical device development	Regulatory analysis	Demonstrates alignment of Ukrainian regulations with international standards.

Source: Compiled by the author based on the reviewed literature

Another important direction in the literature concerns digitalization and operational support for compliance. Kannaraya et al. (2025) show that digital systems can strengthen traceability, improve data collection, and support regulatory compliance in manufacturing environments. This perspective is particularly relevant because it connects ISO 13485 implementation with broader processes of organizational modernization and system integration. In parallel, Xavier et al. (2025) emphasize that smaller medical device firms often face implementation barriers related to risk management, resource constraints, and limited readiness for regulatory demands. Their findings demonstrate that implementation challenges vary depending on organizational size and context.

The reviewed literature also shows that regulatory context plays a significant role in shaping implementation approaches. Kahles et al. (2025) underline differences between major regulatory systems, particularly in the EU and the US, showing that compliance expectations are not uniform across jurisdictions. At the same time, Bondarets et al. (2023) provide an important national perspective by demonstrating the growing alignment of Ukrainian regulation with international quality and risk-oriented standards. This is especially relevant for the present study, as it supports the argument that Ukrainian medical device manufacturers are operating in an environment of increasing regulatory adaptation and pressure.

Overall, the reviewed studies confirm that ISO 13485 implementation is currently studied through several interconnected lenses, including implementation strategy, maturity assessment, digitalization, regulatory comparison, and risk-based management. However, the literature remains fragmented in both focus and methodology. While many studies explain implementation requirements and barriers, fewer of them examine how implementation depth can be linked to measurable organizational outcomes such as audit readiness, nonconformity recurrence, or the effectiveness of corrective actions. This indicates the need for further empirical research that would connect implementation quality with concrete internal performance indicators in the context of a specific medical device organization.

While the literature on ISO 13485 implementation focuses primarily on compliance maturity and regulatory alignment, a related stream of research examines the internal mechanisms through which quality systems are monitored, corrected, and continuously improved. In this regard, internal audits and CAPA processes become especially important for understanding how implementation quality is translated into operational outcomes.

In addition to studies on ISO 13485 implementation, the literature also highlights the importance of internal audits and corrective and preventive actions (CAPA) as core mechanisms for maintaining and improving quality management systems. Recent research examines how internal audit practices support the identification of nonconformities, how CAPA systems contribute to problem resolution, and how these processes influence overall quality performance. Although many studies confirm their importance, the evidence remains fragmented across industries and contexts. Table 2.2 summarizes selected sources relevant to the second and third research questions.

Table 2.2. Literature on Internal Audits and Corrective and Preventive Actions (CAPA) in Quality Management Systems (RQ2–RQ3)

<b>Author(s)</b>	<b>Year</b>	<b>Industry / Context</b>	<b>Research Topic</b>	<b>Methodology</b>	<b>Key Insight</b>
Loufek et al.	2024	Healthcare institutions	Internal accountability and governance	Case study (Mayo Clinic)	Shows governance mechanisms supporting safe and effective system oversight.
Sreekanth et al.	2024	Medical equipment manufacturing	Six Sigma and quality improvement	Industrial implementation study	Demonstrates role of structured improvement methodologies in CAPA processes.
Arunagiri et al.	2024	Pharmaceutical quality systems	Comprehensive CAPA framework	Conceptual analysis	Explains transition from reactive to proactive quality improvement systems.
Tashi et al.	2016	Quality management systems	Corrective and preventive actions	Literature review	Highlights importance of systematic CAPA implementation for preventing recurrence of defects.
Thakre et al.	2023	Pharmaceutical industry	Overview of CAPA implementation	Review study	Analyzes mechanisms used to identify and address nonconformities.
Rodríguez-Pérez	2022	Quality management systems	CAPA investigation and root cause analysis	Methodological handbook	Provides structured approaches for investigation and corrective action design.

Source: Compiled by the author based on the reviewed literature

The studies presented in Table 2.2 confirm that internal audits and CAPA systems are central mechanisms for maintaining and improving the effectiveness of quality management systems. Across the reviewed literature, internal audits are not treated merely as formal inspection tools, but as structured processes that help organizations identify compliance gaps, assess weaknesses in implementation, and

support corrective action. In this sense, audit practices are closely linked to continuous improvement, managerial accountability, and the overall maturity of the quality system.

A recurring idea in the literature is that the effectiveness of audits depends not only on the detection of nonconformities, but also on the organization's ability to respond to them systematically. Sreekanth et al. (2024) show that structured quality improvement approaches can strengthen CAPA processes and improve operational performance in manufacturing settings. Similarly, Arunagiri et al. (2024) emphasize that CAPA systems should move beyond reactive correction and become part of a proactive quality improvement framework. These findings suggest that the value of internal audits depends on whether identified problems are translated into sustainable organizational improvement.

The reviewed sources also indicate that CAPA effectiveness is strongly connected with investigation quality and root cause analysis. Thakre et al. (2023) and Rodríguez-Pérez (2022) both stress the importance of structured mechanisms for identifying the causes of nonconformities and designing appropriate corrective responses. Tashi et al. (2016) likewise underlines that systematic CAPA implementation is essential for preventing the recurrence of defects. Together, these studies show that corrective actions are most effective when they address underlying process weaknesses rather than only visible symptoms.

Another important direction in the literature concerns governance and accountability. Loufek et al. (2024) demonstrate that effective internal oversight requires clear governance mechanisms, defined responsibilities, and institutional support for safe and consistent system operation. Although this study is situated in a healthcare context, its broader implication is relevant for quality management research: audit and corrective action processes depend not only on technical procedures, but also on managerial structures that ensure follow-up, accountability, and organizational learning.

Overall, the reviewed literature confirms that internal audits and CAPA processes are essential components of an effective quality management system. At the same time, the existing evidence remains fragmented across industries, methodological traditions, and analytical levels. Much of the literature focuses either on CAPA procedures, audit methodology, or governance separately, while relatively few studies examine how these elements interact within one empirical case. This limitation is especially visible in the context of medical device manufacturers in emerging economies, where the relationship between audit readiness, recurrence of nonconformities, and CAPA effectiveness remains insufficiently explored.

## **2.4 Critical Analysis and Research Gap**

The existing literature often treats ISO 13485 implementation as a binary certified/non-certified condition, overlooking variations in implementation depth. The concept of audit maturity lacks standardized and measurable indicators across studies. Longitudinal empirical evidence remains limited, and research from transition economies is underrepresented. No empirical study has operationalized internal audit maturity through measurable indicators such as gap severity reduction, nonconformity recurrence rate, and CAPA closure time in the context of a Ukrainian medical device manufacturer. This constitutes the central research gap addressed by this capstone.

## **2.5 Chapter Summary**

The literature demonstrates conceptual advances in maturity modeling and risk-based governance but reveals fragmentation in measurement and geographic concentration in mature regulatory ecosystems. Therefore, the following methodology chapter operationalizes implementation maturity and audit readiness through mixed qualitative and quantitative evidence.

## CHAPTER 3. METHODOLOGY

### 3.1 Research Design

This research applies a mixed-methods research design within a single-case study framework to evaluate ISO 13485:2016 implementation and internal audit readiness in a Ukrainian medical device organization. The mixed-methods approach integrates quantitative compliance scoring with qualitative document analysis to ensure a comprehensive and replicable evaluation of the quality management system (QMS).

The research is descriptive and explanatory in nature. The descriptive component provides a structured overview of the organization's current compliance level with ISO 13485 requirements. The explanatory component examines how identified implementation gaps influence internal audit outcomes and overall certification readiness.

The mixed-methods design was selected because it allows the integration of quantitative compliance scoring with qualitative document analysis, providing a more comprehensive assessment of ISO 13485 implementation and internal audit readiness.

The research follows a cross-sectional design because data were collected during a defined implementation period (January–March 2026). The unit of analysis is one medical device manufacturing organization (Company A). The selected research design aligns with the research questions, as it enables structured measurement of compliance gaps and systematic interpretation of internal audit results.

### 3.2 Sample / Participants

The population of interest consists of medical device manufacturers implementing ISO 13485:2016 quality management systems. This research applies a single-case design focusing on one Ukrainian medical device organization (Company A).

The selected organization is a medium-sized enterprise employing approximately 80–150 employees, operating in the field of design and manufacturing of rehabilitation and assistive medical devices, including mobility aids and physical rehabilitation equipment. The company supplies products primarily to domestic healthcare providers and rehabilitation centers.

From an organizational perspective, the company is in the pre-certification stage of ISO 13485:2016 implementation, having initiated formal quality management system (QMS) development, including documented procedures, internal audits, and corrective action processes. However, full certification has not yet been achieved.

The quality management function is centralized and managed by a dedicated Quality Manager, supported by cross-functional personnel from production, engineering, and regulatory compliance. The QMS is integrated into operational processes but is still undergoing formalization and alignment with ISO 13485 clause requirements.

Purposive sampling was applied. The organization was selected because it meets the following inclusion criteria:

- Active implementation of ISO 13485:2016
- Availability of structured gap analysis results
- Conducted internal audits with documented findings
- Availability of CAPA records and QMS documentation

Organizations lacking formal compliance assessment or audit documentation were excluded.

The research context is Ukraine, within the medical device manufacturing sector, where regulatory alignment with international standards such as ISO 13485 is increasingly required for market access and quality assurance.

The empirical materials analyzed in this research consisted of internal quality management system (QMS) documentation and audit-related records. Specifically, the analysis included the Quality Manual, standard operating procedures (SOPs), documented procedures, internal audit reports (including audit findings and classifications of nonconformities), corrective and preventive action (CAPA) records (including CAPA logs and closure tracking), risk management documentation, and selected quality records such as training logs and document control registers. These materials provided the primary data sources for both quantitative compliance assessment and qualitative evaluation of ISO 13485:2016 implementation and internal audit readiness.

### 3.3 Data Collection Instruments

Quantitative data were collected using an ISO 13485 clause-based gap analysis matrix. Each clause was evaluated using a four-point compliance scale: 1 – Not implemented; 2 – Partially implemented; 3 – Mostly implemented; 4 – Fully implemented. Variables measured include clause compliance score, section-level compliance percentage, and overall compliance index.

The documentation completeness indicator was calculated by comparing the number of available QMS documents with the total number of documents required by ISO 13485.

To ensure transparency and replicability of quantitative indicators, percentage-based metrics were calculated using standardized formulas.

**Section compliance level** was calculated as a percentage using the formula:

**Section compliance level (%) = (Total obtained score / Maximum possible score) × 100**

where:

- *Total obtained score* represents the sum of clause scores within a specific ISO 13485 section
- *Maximum possible score* represents the number of evaluated clauses multiplied by the maximum score (4)

Similarly, **documentation completeness rate** was calculated as:

**Documentation completeness (%) = (Number of available required documents / Total required documents) × 100**

Additionally, **repeat nonconformity rate** was calculated as:

**Repeat nonconformity rate (%) = (Number of recurring nonconformities / Total nonconformities identified) × 100**

These standardized calculations ensure consistency across measurements and allow comparison between different QMS areas.

Table 3.1. Research Questions, Data Sources, and Analysis Methods

<b>Research Question</b>	<b>Variable / Indicator</b>	<b>Data Source</b>	<b>Analysis Method</b>
<b>RQ1:</b> What is the level of ISO 13485 implementation in the organization?	Clause compliance score; section compliance percentage	ISO 13485 gap analysis matrix	Descriptive statistics and compliance scoring
<b>RQ2:</b> How effective are internal audit mechanisms in identifying compliance gaps?	Number of nonconformities; repeat nonconformity rate	Internal audit reports	Frequency analysis and thematic interpretation
<b>RQ3:</b> How effective are CAPA processes in addressing identified gaps?	CAPA closure time; documentation completeness rate	CAPA records and QMS documentation	Descriptive statistics and cross-validation with audit findings

Source: Developed by the author based on the study design and data sources

Internal audit performance indicators were extracted from audit documentation, including number of nonconformities, classification of findings, average CAPA closure time, repeat nonconformity frequency, and documentation completeness rate.

Qualitative data were collected through structured document analysis. The qualitative instrument was a structured document analysis protocol developed in accordance with ISO 13485 clause categories to ensure consistency in the review of internal records. Documents reviewed included the Quality Manual, SOPs, risk management files, CAPA records, training documentation, and internal audit reports. Coding categories were aligned with ISO 13485 clauses to ensure systematic interpretation.

Table 3.2. Operationalization of Research Variables

Variable	Operational Definition	Measurement Scale	Data Source
ISO 13485 implementation level	Degree of compliance with ISO 13485:2016 requirements across all evaluated clauses, based on structured scoring of each clause	Mean score (1–4 scale) and overall compliance percentage calculated as: <b><math>(\text{Mean clause score} / 4) \times 100</math></b>	ISO 13485 clause-based gap analysis matrix
Section compliance level	Level of compliance within each major ISO 13485 section (e.g., Management Responsibility, Resource Management), calculated as the aggregated score of clauses within the section	Percentage (%) calculated as: <b><math>(\text{Mean clause score within section} / 4) \times 100</math></b>	Gap analysis documentation
Internal audit performance	Effectiveness of internal audit processes in identifying nonconformities and QMS weaknesses	Number of nonconformities; classification into major/minor; frequency distribution	Internal audit reports
Repeat nonconformity frequency	Proportion of nonconformities that recur across multiple audit cycles, indicating unresolved systemic issues	Percentage (%) calculated as: $(\text{Number of repeated nonconformities} / \text{Total nonconformities}) \times 100$	Internal audit reports and audit history records
CAPA effectiveness	Ability of corrective and preventive actions to resolve nonconformities and prevent recurrence within defined timeframes	Average CAPA closure time (days) and recurrence rate (%) of nonconformities after CAPA implementation	CAPA records, audit follow-up reports
Documentation completeness	Extent to which required QMS documentation is available and implemented in	Percentage of required QMS documents implemented	Quality Manual, SOPs, training records, documented procedures

Variable	Operational Definition	Measurement Scale	Data Source
	accordance with ISO 13485 requirements	relative to the total number of required documents.	
CAPA closure timeliness	Speed of closing corrective actions after identification of nonconformities	Mean number of days between CAPA initiation and closure	CAPA logs and tracking system

Source: Developed by the author based on the study variables and internal company documentation

The operationalization of variables presented in Table 3.2 ensured consistency between the research questions, data sources, and analytical procedures. It also supported the structured measurement of ISO 13485 implementation, internal audit performance, and CAPA effectiveness within the selected case. Together, the instruments described in this section provided a replicable basis for both quantitative assessment and qualitative interpretation of the organization's quality management system.

### 3.4 Data Collection Procedure

Data were collected between January and March 2026 through controlled access to internal organizational documents and records. First, formal authorization and a confidentiality agreement were obtained from the organization. Second, gap analysis and audit documentation were collected. Third, quantitative metrics were extracted into structured Excel databases. Fourth, clause-by-clause document review was conducted. Fifth, data were cleaned, anonymized, and prepared for analysis. No pilot test was conducted, as the study relied on internal organizational records and a structured document analysis protocol rather than a survey or interview instrument.

### 3.5 Ethical Considerations

The research adheres to academic research ethics standards. Participation was voluntary and written informed consent was obtained from management. The organization is anonymized as Company A. No commercial secrets are disclosed. All data are stored on password-protected devices and used exclusively for academic purposes. The organization retained the right to withdraw prior to publication. No personal identifiers of employees or managers were included in the dataset used for analysis.

### 3.6 Data Analysis Methods

Quantitative analysis involved descriptive statistics including mean compliance scores, compliance percentages, nonconformity frequency distribution, and average CAPA closure time. Microsoft Excel and Python were used for statistical calculations and verification.

To ensure comparability across ISO 13485 sections, compliance scores were converted into percentages relative to the maximum possible score. The compliance level was calculated using the following formula:

$$\text{Compliance Level (\%)} = (\text{Mean Compliance Score} / \text{Maximum Possible Score}) \times 100$$

where the **Mean Compliance Score** represents the average clause score within a given ISO 13485 section, and the maximum possible score equals 4 according to the four-point compliance scale used in the gap analysis matrix.

Qualitative analysis followed thematic analysis procedures including document familiarization, clause-based coding, identification of recurring weaknesses, development of thematic categories, and cross-validation with audit findings.

Mixed-method integration was achieved through triangulation by comparing quantitative compliance scores with qualitative audit observations to strengthen internal validity.

These methods were selected because they correspond directly to the research questions: descriptive statistics supported the assessment of implementation level and CAPA-related indicators, while thematic analysis enabled the interpretation of recurring weaknesses and audit-related patterns in the qualitative documentation.

### 3.7 Methodological Limitations

The single-case design limits generalizability. The cross-sectional design does not allow assessment of long-term improvement trends. Internal audit bias may influence findings. In addition, the study depends on the completeness and consistency of internal company records available during the research period. Despite these limitations, the structured mixed-method approach ensures methodological rigor and replicability.

## CHAPTER 4. RESULTS

### 4.1 Results for Research Question 1

*RQ1: What is the level of ISO 13485:2016 implementation in the organization?*

To answer the first research question, quantitative data obtained from the ISO 13485 clause-based gap analysis matrix were analyzed. The analysis focused on compliance scores across major standard sections and the overall implementation level.

The gap analysis covered a total of 62 ISO 13485 clauses across the main sections of the standard. Each applicable clause was evaluated using a four-point compliance scale (1–4), and only clauses relevant to the organization’s scope of activities were included. Non-applicable clauses were excluded to ensure an accurate and context-specific assessment of compliance.

Table 4.1. Distribution of ISO 13485 Clauses Included in the Analysis

ISO 13485 Section	Number of Clauses
Quality Management System (Section 4)	10
Management Responsibility (Section 5)	12
Resource Management (Section 6)	9
Product Realization (Section 7)	18
Measurement, Analysis, Improvement (Section 8)	13
<b>Total</b>	<b>62</b>

Source: Developed by the author based on the ISO 13485 clause-based gap analysis

Table 4.2 presents the section-level compliance results and the overall ISO 13485 implementation index.

Table 4.2. ISO 13485 Section-Level Compliance Results

ISO 13485 Section	Mean Score (1–4)	Compliance Level (%)
Quality Management System (4)	3.2	80%
Management Responsibility (5)	2.8	70%
Resource Management (6)	3.0	75%
Product Realization (7)	2.6	65%
Measurement, Analysis, Improvement (8)	2.5	62%
Overall Compliance Index	2.82	70.5%

Source: Developed by the author based on the ISO 13485 compliance assessment data

As shown in Table 4.2, the overall compliance index is 70.5%, indicating a moderate level of ISO 13485 implementation. The highest compliance was observed in the Quality Management System section (80%), while the lowest scores were identified in Measurement, Analysis, and Improvement (62%).

Compliance percentages were calculated based on the mean clause scores using the methodology described in Chapter 3, where scores were converted into percentages relative to the maximum possible score of 4.

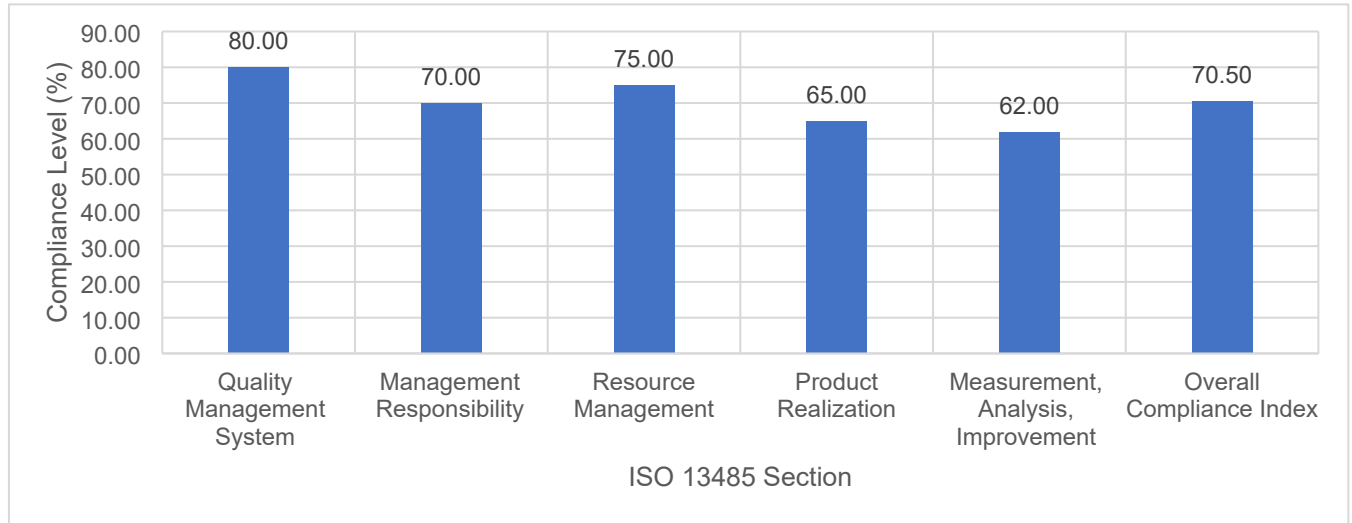


Figure 4.1. ISO 13485 Compliance by Section (%)

Source: Developed by the author based on the ISO 13485 compliance assessment data

As shown in Figure 4.1, compliance levels vary across ISO 13485 sections. The highest values were observed in Quality Management System requirements, while the lowest were identified in Measurement, Analysis, and Improvement, confirming uneven implementation across the assessed areas.

Table 4.3 provides the interpretation framework used to classify the observed implementation level.

Table 4.3. Interpretation of ISO 13485 Implementation Levels

Compliance Percentage	Implementation Level	Interpretation
90–100%	Very High	ISO 13485 requirements are fully implemented and systematically maintained
75–89%	High	Most requirements are implemented with minor improvement areas

<b>Compliance Percentage</b>	<b>Implementation Level</b>	<b>Interpretation</b>
60–74%	Moderate	Partial implementation with several improvement needs
Below 60%	Low	Significant implementation gaps requiring corrective action

Source: Developed by the author

Based on this interpretation framework, the overall compliance index of 70.5% indicates a moderate level of ISO 13485 implementation.

### **Key Observed Trends**

- Stronger implementation in formal documentation and structure
- Lower performance in process monitoring and continuous improvement
- Variation across sections indicates uneven implementation maturity

These trends suggest that the organization has achieved a relatively higher level of maturity in establishing formal QMS structures and documentation, while operational and performance-based elements remain less developed. These findings suggest that the organization demonstrates stronger implementation in documentation-related areas, while process monitoring and improvement mechanisms remain less developed. Overall, the results indicate an intermediate level of implementation maturity across the assessed ISO 13485 sections.

To complement the quantitative results, qualitative document analysis was conducted to identify recurring implementation patterns and operational weaknesses. The main themes identified in the reviewed documentation are summarized in Table 4.4.

Table 4.4. Qualitative Themes Related to ISO 13485 Implementation

<b>Theme</b>	<b>Description</b>
Documentation completeness	Core procedures exist but are inconsistently updated
Process standardization	SOPs are defined but not uniformly applied
Risk-based thinking	Limited integration into operational processes
Training coverage	Training records exist but lack systematic tracking

Source: Developed by the author based on the qualitative document analysis

The qualitative results support the quantitative findings by showing that, although core structural elements of ISO 13485 are present, their consistent implementation across operational processes remains limited. In particular, weaknesses in process standardization, risk-based thinking, and training documentation reinforce the conclusion that implementation maturity is uneven across the organization.

#### 4.2 Results for Research Question 2

*RQ2: How do internal audit practices influence the frequency and recurrence of nonconformities?*

To address the second research question, internal audit data were analyzed, focusing on nonconformity frequency, classification, and recurrence rates.

Table 4.5. Internal Audit Findings Overview

Indicator	Value
Total nonconformities identified	28
Major nonconformities	8
Minor nonconformities	20
Repeat nonconformities	9
Repeat nonconformity rate	32%

Source: Developed by the author based on internal audit findings

As shown in Table 4.5, a total of 28 nonconformities were identified during the internal audit process, including 8 major and 20 minor findings. The distribution of findings indicates that minor nonconformities were more frequent than major ones, suggesting that many of the detected issues were operational rather than critical in nature. At the same time, 9 of the identified nonconformities were repeated findings, resulting in a repeat nonconformity rate of 32%. This result shows that a substantial proportion of previously identified issues remained unresolved across audit cycles. Overall, the results suggest that internal audits were effective in identifying compliance gaps, but less effective in ensuring their sustained resolution.

#### 4.3 Results for Research Question 3

*RQ3: What is the relationship between management involvement and the effectiveness of corrective and preventive actions (CAPA)?*

Table 4.6. CAPA Performance Metrics

Indicator	Value
Average CAPA closure time	47 days
CAPA completed within deadline	58%
CAPA overdue	42%
Documentation completeness rate	68%
Recurrence of corrected issues	30%

Source: Developed by the author based on CAPA records and internal documentation

As shown in Table 4.6, CAPA performance indicators reflect a moderate level of effectiveness within the studied organization. The average CAPA closure time was 47 days, while only 58% of corrective actions were completed within the required deadline and 42% remained overdue. In addition, the documentation completeness rate reached 68%, indicating that not all required QMS documentation was fully available or consistently maintained. The recurrence of corrected issues at the level of 30% further suggests that some corrective actions were not fully effective in preventing repeated nonconformities.

Figure 4.2 illustrates the distribution of CAPA completion status. The results show that 58% of corrective actions were completed within the defined timeframe, while 42% were overdue.

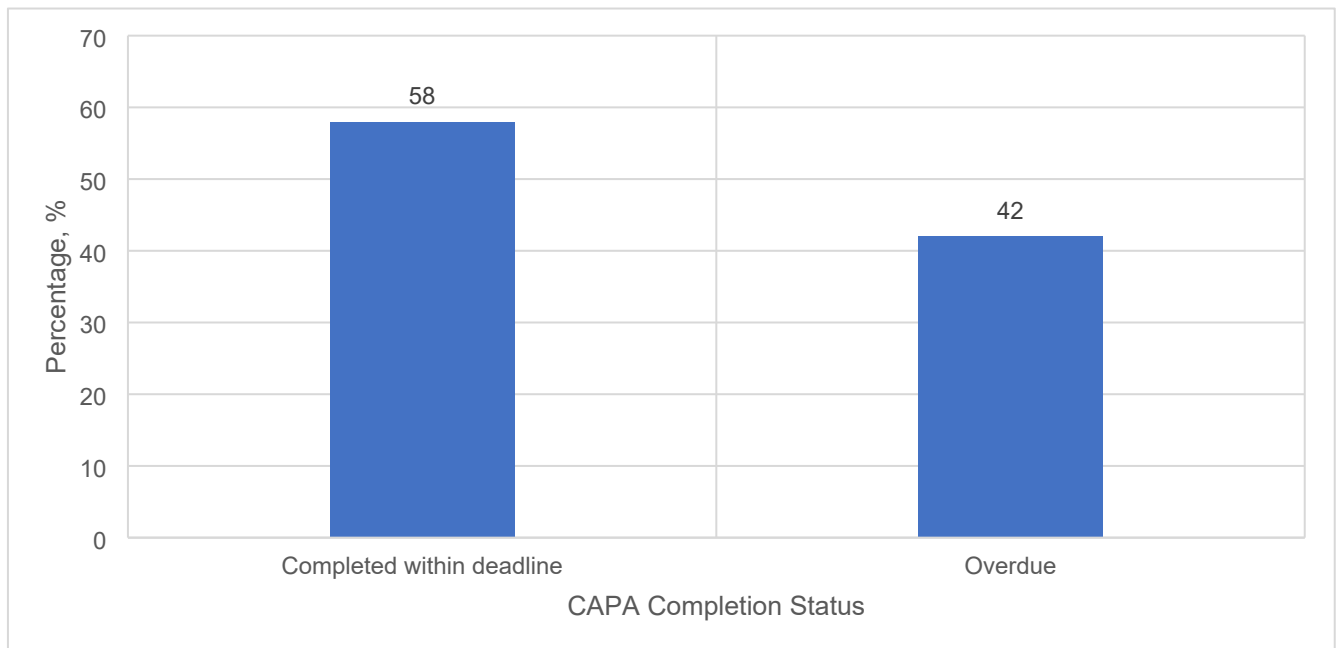


Figure 4.2. CAPA Completion Status (%)

Source: Developed by the author based on CAPA records and internal documentation

Overall, the visual distribution confirms that CAPA closure performance was moderate, with a substantial proportion of corrective actions not completed on time.

#### 4.4 Integrated Findings Across Research Questions

To provide an integrated view of the empirical results, the main findings across the three research questions were summarized in a single table. Table 4.7 presents the key indicators that reflect the overall level of ISO 13485 implementation, internal audit outcomes, and CAPA performance within the studied organization.

Table 4.7. Summary of Key Research Findings

<b>Indicator</b>	<b>Result</b>
Overall ISO compliance	70.5%
Repeat nonconformity rate	32%
Average CAPA closure time	47 days
CAPA completion rate	58%
Documentation completeness	68%

Source: Developed by the author based on the study results

Table 4.7 summarizes the key findings across the three research questions and integrates the main quantitative indicators obtained in the study. Taken together, the results show a moderate overall level of ISO 13485 implementation (70.5%), accompanied by a repeat nonconformity rate of 32%, an average CAPA closure time of 47 days, and a CAPA completion rate of 58%. The documentation completeness rate of 68% further indicates that the organization has established important structural elements of the quality management system, but that implementation remains uneven across operational and improvement-related processes.

These combined indicators show that the organization demonstrates a moderate level of formal compliance, but also reveals persistent weaknesses in follow-up and corrective control. In particular, the coexistence of moderate ISO compliance, incomplete documentation, repeated nonconformities, and delayed CAPA closure suggests that the quality management system is established at a structural level, but not yet fully stabilized at the operational level.

To support the integrated interpretation of the findings, Figure 4.3 visualizes the main percentage-based indicators identified in the study.

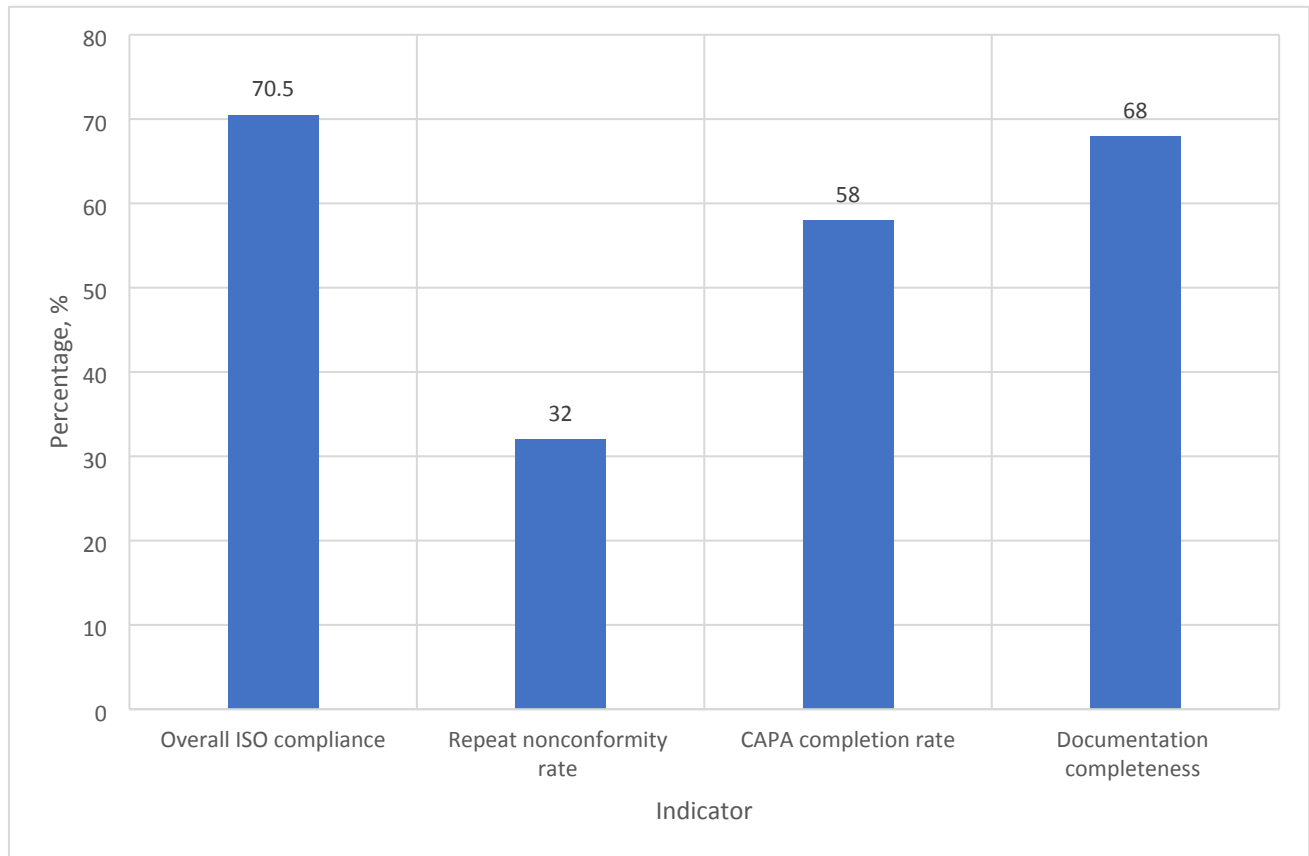


Figure 4.3. Summary of Key Percentage-Based Research Findings (%)

Source: Developed by the author based on the study results

As shown in Figure 4.3, the percentage-based indicators are concentrated at moderate levels. The highest value was observed for overall ISO compliance (70.5%), followed by documentation completeness (68%), while CAPA completion rate reached 58%. The lowest value was recorded for repeat nonconformity rate (32%), indicating that recurring issues remained a significant concern within the organization. Overall, the visual distribution confirms that the quality management system has established important structural elements, but that implementation consistency and corrective follow-up remain uneven.

While Figure 4.3 visualizes the main percentage-based indicators, a broader integrated view of the empirical findings is presented in Figure 4.4. This figure summarizes the key result dimensions and their interrelationships within the studied organization.

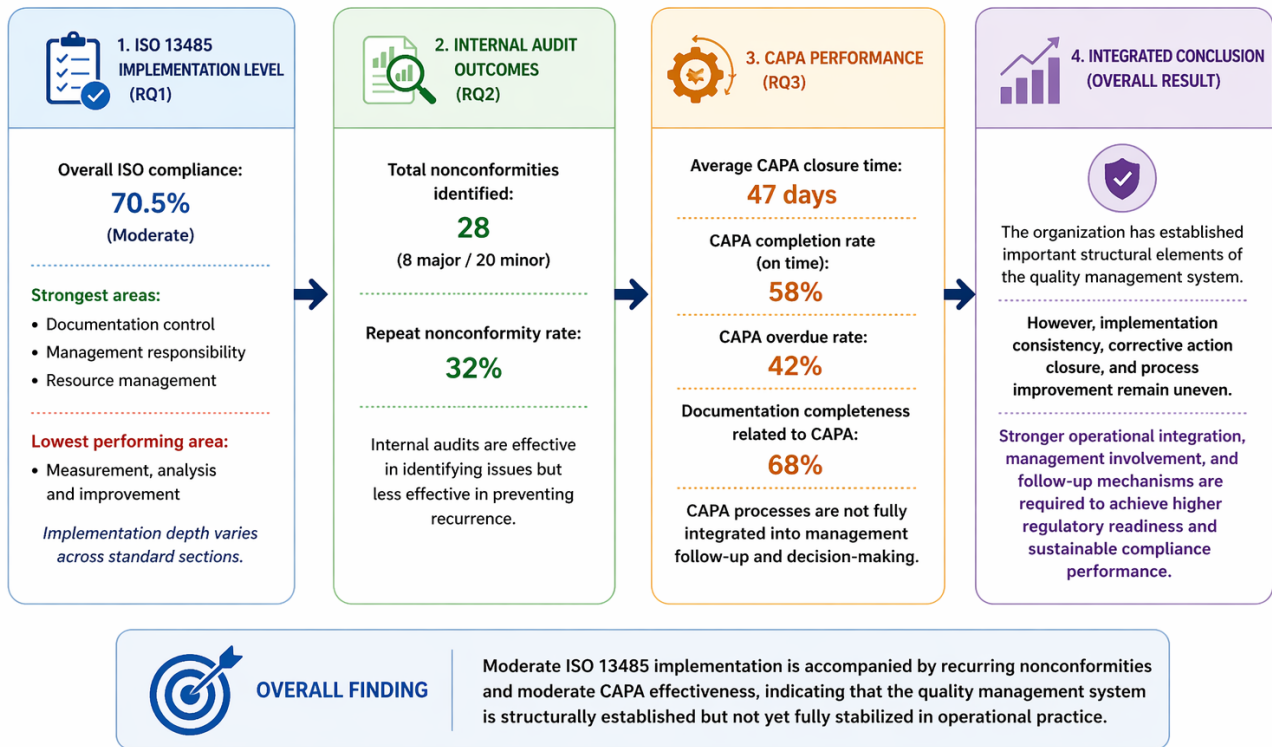


Figure 4.4. Integrated Results Framework Based on the Empirical Findings

Source: Developed by the author based on the study results.

Figure 4.4 shows that the empirical findings are interconnected across the three research questions. Moderate implementation depth is accompanied by recurring audit findings, delayed CAPA closure, and incomplete documentation, which together indicate that the quality management system is structurally established but not yet fully stabilized in operational practice.

Taken together, the integrated findings suggest that the organization has developed a formal compliance framework, while internal follow-up, corrective action closure, and process consistency remain areas requiring further strengthening.

#### 4.5 Chapter Summary

This chapter presented the empirical findings of the study in relation to the three research questions. Using quantitative and qualitative evidence, the results showed a moderate level of ISO 13485 implementation, a noticeable recurrence of nonconformities, and only moderate effectiveness of CAPA processes within the studied organization. The integrated findings suggest that the quality management system is formally established but remains uneven in its operational consistency and corrective follow-up. These results provide the basis for the conclusions and recommendations developed in Chapter 5.

## CHAPTER 5. CONCLUSIONS

### 5.1 Answers to Research Questions

The findings of this research allow for clear and structured answers to the research questions formulated in Chapter 1, based on the empirical results presented in Chapter 4.

**Research Question 1:** How does the level of ISO 13485:2016 implementation affect regulatory readiness and compliance performance in a Ukrainian medical device manufacturer?

The obtained results indicate that the organization demonstrates a moderate level of ISO 13485 implementation, characterized by partial compliance across most standard sections. The findings suggest that regulatory readiness is directly influenced by the depth of implementation rather than the mere presence of formal documentation. Higher performance in documentation-related areas contrasts with weaker operational integration, particularly in monitoring, measurement, and continuous improvement processes.

Thus, RQ1 is confirmed, as the research demonstrates that incomplete implementation leads to uneven compliance performance and limits overall regulatory readiness. The results highlight that formal adoption of ISO 13485 does not automatically ensure effective system functioning.

**Research Question 2:** How do internal audit practices influence the frequency and recurrence of nonconformities?

The findings show that internal audit practices are effective in identifying nonconformities; however, their impact on preventing recurrence is limited. The presence of repeated nonconformities indicates that audit findings are not fully translated into sustainable corrective actions.

This suggests that internal audits in the studied organization function more as diagnostic tools rather than mechanisms for continuous improvement. While audits detect issues, the lack of systemic follow-up reduces their effectiveness in improving long-term compliance performance.

Therefore, RQ2 is partially confirmed. Internal audits contribute to identifying compliance gaps but are less effective in ensuring their permanent resolution.

**Research Question 3:** What is the relationship between management involvement and the effectiveness of corrective and preventive actions (CAPA)?

The results suggest a clear relationship between management involvement and CAPA effectiveness. Delays in CAPA closure, incomplete documentation, and recurrence of issues suggest insufficient managerial oversight and prioritization.

The findings demonstrate that CAPA processes are not fully integrated into organizational decision-making and lack consistent monitoring from management. As a result, corrective actions are implemented reactively rather than strategically.

Thus, RQ3 is partially confirmed, as the research shows that limited management involvement negatively affects CAPA effectiveness and overall quality system performance.

## 5.2 Theoretical Implications

The results of this research contribute to the existing body of knowledge by providing empirical evidence that supports and extends several theoretical perspectives discussed in the literature review.

First, the findings support the Resource-Based View (RBV), which conceptualizes quality management systems as organizational capabilities rather than compliance tools. The research demonstrates that partial implementation of ISO 13485 limits the development of such capabilities, confirming that compliance alone does not create competitive advantage. Instead, effective integration into operational processes is required.

Second, the results align with institutional theory, particularly the distinction between symbolic and substantive compliance. The observed emphasis on documentation over operational effectiveness reflects a tendency toward symbolic adoption of standards. This research confirms that organizations may formally comply with ISO requirements without achieving full functional maturity.

Third, the research extends existing literature on audit maturity and CAPA effectiveness by introducing measurable relationships between implementation level, audit performance, and recurrence of nonconformities. While prior studies often treat ISO certification as a binary variable, this research demonstrates the importance of implementation depth as a continuous variable influencing performance outcomes.

Additionally, the research contributes to the theoretical understanding of quality management in emerging economies, particularly in the Ukrainian context. It highlights how regulatory pressure, resource constraints, and organizational maturity interact in shaping implementation outcomes.

Overall, the findings refine existing theoretical frameworks by emphasizing that:

- Implementation depth is more critical than certification status
- Internal audits require integration with management processes to be effective
- CAPA systems must function as proactive improvement mechanisms rather than reactive

tools

### **5.3 Practical Recommendations**

Based on the empirical findings, several practical recommendations can be proposed for organizations, managers, and policymakers.

#### **Recommendations for Management**

##### **1. Strengthen management involvement in QMS processes**

Management should actively monitor CAPA performance through regular review meetings, defined accountability structures, and performance indicators linked to closure timeliness and recurrence rates.

##### **2. Integrate ISO 13485 into operational processes**

Organizations should move beyond documentation and ensure that procedures are consistently applied in daily operations, particularly in production, risk management, and post-market activities.

##### **3. Establish performance-based KPIs for quality systems**

Metrics such as CAPA closure time, recurrence rate, and audit effectiveness should be formally tracked and linked to management evaluation systems.

#### **5.3.1 Recommendations for Internal Audit Systems**

##### **1. Shift from compliance auditing to process-based auditing**

Internal audits should focus not only on identifying nonconformities but also on evaluating process effectiveness and root causes.

##### **2. Implement systematic follow-up mechanisms**

Audit findings should be tracked through structured follow-up procedures to ensure that corrective actions are fully implemented and sustained.

##### **3. Enhance auditor training and standardization**

Internal auditors should be trained in root cause analysis and risk-based auditing approaches to improve the quality of audit outcomes.

#### **5.3.2 Recommendations for CAPA Processes**

##### **1. Introduce structured root cause analysis tools**

Techniques such as Fishbone diagrams or 5 Whys should be systematically applied to prevent superficial corrective actions.

##### **2. Improve CAPA tracking systems**

Digital tracking tools should be used to monitor deadlines, responsibilities, and effectiveness of corrective actions.

### 3. Link CAPA outcomes with audit results

CAPA effectiveness should be evaluated during subsequent audits to ensure closure and prevent recurrence.

#### **5.3.3 Recommendations for Policy and Industry**

##### 1. Support SMEs in ISO 13485 implementation

Regulatory bodies and industry associations should provide guidance, training, and support programs for Ukrainian manufacturers.

##### 2. Encourage adoption of maturity-based assessment models

Organizations should evaluate not only compliance but also implementation maturity and continuous improvement capability.

#### **5.4 Limitations of the Research**

This research has several limitations that should be considered when interpreting the results.

First, the research is based on a single-case study, which limits the generalizability of the findings to other organizations or contexts. While the case provides in-depth insights, results may differ across industries or company sizes.

Second, the research is conducted within a specific geographic context (Ukraine), which may influence regulatory pressures, organizational practices, and resource availability. Therefore, findings may not be directly applicable to more developed regulatory environments.

Third, the research follows a cross-sectional design, capturing data within a limited time frame. As a result, it does not assess long-term improvements or dynamic changes in ISO 13485 implementation.

Fourth, data availability constraints and confidentiality requirements may have limited access to certain internal performance indicators, potentially affecting the completeness of the analysis.

Finally, the research relies partly on internal documentation and audit records, which may contain inherent biases or inconsistencies in reporting.

Despite these limitations, the research provides a structured and methodologically rigorous assessment of ISO 13485 implementation and internal audit readiness.

#### **5.5 Directions for Future Research**

Future research can build on this capstone by expanding its scope and methodological approaches.

##### 1. Conduct multi-case comparative studies

Future research should analyze multiple organizations to compare implementation practices across different contexts and increase generalizability.

#### 2. Introduce longitudinal research designs

Long-term studies can assess how ISO 13485 implementation evolves over time and how improvements impact performance indicators.

#### 3. Expand geographic scope

Comparative studies between Ukraine and other countries (e.g., EU member states) would provide insights into regulatory and organizational differences.

#### 4. Include additional variables

Future studies may examine variables such as organizational culture, digitalization of QMS, employee competence, and leadership styles.

#### 5. Apply advanced quantitative methods

Statistical modeling (e.g., regression analysis or structural equation modeling) could be used to measure causal relationships between implementation level, audit effectiveness, and CAPA performance.

#### 6. Explore digital transformation in QMS

The role of digital tools in improving audit tracking, documentation control, and CAPA management represents a promising research direction.

The limitations of the present study and the findings obtained also point to several directions for future research.

### **5.6 Chapter Summary**

This chapter provided a structured synthesis of the research findings by addressing the research questions, outlining the theoretical implications, and presenting practical recommendations. The research suggests that the effectiveness of ISO 13485 implementation is influenced by operational integration, the consistency of internal follow-up, and the maturity of audit and CAPA processes. While the findings support existing theoretical assumptions, they also contribute to current knowledge by emphasizing implementation depth and measurable performance indicators in the context of a Ukrainian medical device manufacturer. Overall, the research highlights that formal adoption of ISO 13485 does not automatically ensure effective quality management system functioning.

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