

Improvement of the Quality Management System in a Company That Distributes Medical Devices and Equipment in Southern Sonora

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Abstract: This research aimed to generate improvement actions focused on strengthening the Quality Management System of a medical device and equipment distributor in southern Sonora, using an approach based on the ISO 9001:2015 standard. The study arose from the identification of areas of opportunity related to rework, outdated documentation, lack of change control, and deficiencies in risk management within the organization. The methodology employed was based on the PDCA cycle (Plan-Do-Check-Act), allowing for the development of improvement actions focused on document control and risk management. During the planning stage, a review of procedures, instructions, forms, and records related to the Quality Management System was conducted, identifying missing documentation and areas for improvement. Subsequently, documents such as risk management and corrective action procedures, instructions, and forms for risk identification and monitoring were developed and updated. During the verification phase, checklists were used to assess document compliance with the requirements established in ISO 9001:2015, achieving 100% compliance in the developed and updated documents. Furthermore, document monitoring and control actions were established using tools such as decision diagrams, change control forms, and authorization signatures, strengthening the traceability and updating of documented information within the Quality Management System. The results obtained strengthened document control, improved information standardization, and contributed to the continuous improvement of the Quality Management System, enhancing organizational performance and compliance with the established risk management requirements within the company.

Keywords: Quality, management, and risks.

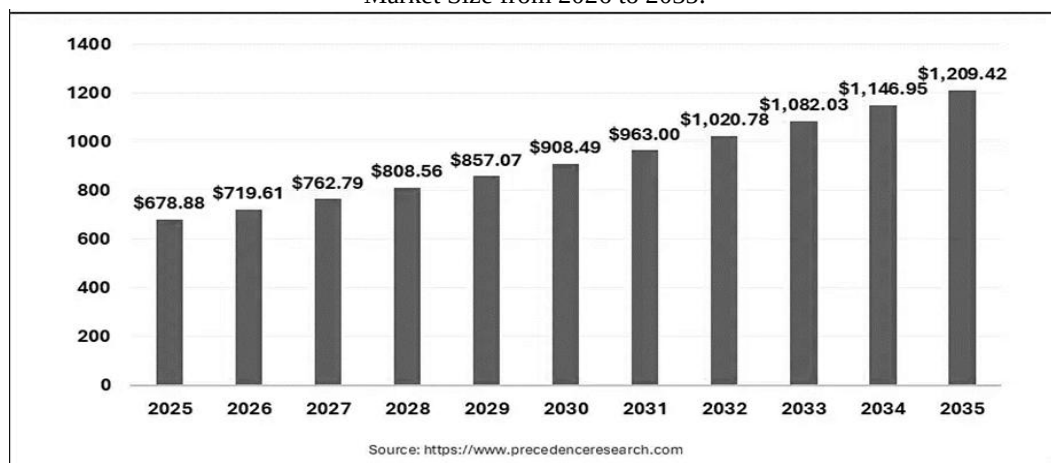
Introduction

The World Health Organization (WHO) defines medical devices as instruments, apparatus, equipment, or machines used for the prevention, diagnosis, monitoring, or treatment of diseases, as well as for detecting, measuring, restoring, correcting, or modifying bodily functions and structures for health purposes. Unlike medicines, their primary action is not achieved through pharmacological, immunological, or metabolic means (WHO, 2026).

In Mexico, the Federal Commission for Protection against Sanitary Risks (COFEPRIS) considers medical devices as supplies intended to prevent, diagnose, or treat diseases and contribute to the well-being of the population. Furthermore, this agency regulates their sanitary authorization and certifies compliance with Good Manufacturing Practices (GMP) in manufacturing companies (COFEPRIS, 2025), which comprise the set of procedures and controls applied during product manufacturing to minimize the risk of physical, chemical, and biological contamination (Gobierno de México, 2022).

The economic relevance of this sector is considerable. According to data from Precedence Research (2025), the global medical device market will reach a value of \$678.88 billion in 2025 and is projected to grow to \$719.61 billion in 2026, exceeding \$1.2 trillion by 2035 (see Figure 1).

Figure 1 Device
Market Size from 2026 to 2035.



Note: The data in the image helps visualize the potential market growth from 2025 to 2035.

Source: Precedence Research (2025).

Over the past two decades, the medical device industry in Mexico has experienced sustained growth in both economic and regulatory aspects. According to data from the National Institute of Statistics and Geography (INEGI, 2025), the Mexican Association of Innovative Medical Device Industries, and Grupo Prodena (2025), the sector's exports increased significantly, rising from US\$2.6 billion in 2003 to US\$10.7 billion in 2020. This growth has strengthened the country's competitiveness in the international market and has boosted economic growth and job creation in the sector.

In Sonora, the medical device industry has maintained sustained growth driven by technological advancements, process digitization, and the increasing demand for healthcare products. This dynamism has positioned the state among the leading medical device producers in Mexico, registering an average annual growth rate of 6.9% over the past five years (Bien Informado, 2024).

The company under study is located in the state of Sonora and is one of the leading distributors of medical supplies in northwestern Mexico. Its portfolio includes accessories, consumables, and medical furniture, supported by a network of strategically located distribution centers throughout the country. This infrastructure allows it to offer efficient and timely service, based on innovation standards aimed at meeting the current needs of the national healthcare sector. Its mission is to provide medical supplies that support the healthcare sector through innovation and sustainability, while its vision is to consolidate itself as a leading organization in the research and marketing of healthcare products, recognized for its best practices and social responsibility (IAASA, 2026).

In this context, the Quality Management System (QMS) is a fundamental tool to promote continuous improvement and strengthen the organizational commitment to quality (UNIR, 2023), its absence can generate operational inefficiencies, higher costs, loss of competitiveness and regulatory non-compliance (ISO, 2015).

The ISO 9001:2015 standard establishes the requirements for its implementation with a process-based approach and can be complemented by other standards related to occupational health and safety, energy management, and information security (Abril et al., 2006). When evaluating the QMS of the company under study according to this standard, a 12.5% non-compliance level was identified in the area of risk management, while the dimensions of quality policy, planning, quality control, continual improvement, and internal auditing achieved full compliance. Therefore:

What Quality Management System update actions are necessary to eliminate operational deficiencies and improve the performance of a company that distributes medical devices and equipment?

Therefore, the objective was set to: Generate actions that, with a focus on ISO 9000 and applied to the quality management system, contribute to the strengthening and improvement of the performance of the company distributing medical devices and equipment.

Materials and Methods

Object of Study

The object of study in this research was the Quality Management System of a company that distributes medical devices and equipment. This system encompasses the processes related to document control, management, and application of registration forms.

Materials

For the development of the research, computer tools, the ISO 9001:2015 standard, documented information from the company and a checklist were used, which allowed information to be collected, compliance with the requirements of the Quality Management System to be evaluated and areas of opportunity for organizational improvement to be identified.

Procedure

This section describes the steps of the established methodological path, which is based on Edward Deming's PDCA cycle (Zapata, 2016). *The phases were developed as follows:*

Planning: A diagnosis of the existing documented information was carried out against the requirements of the ISO 9001:2015 standard, using checklists to identify missing or incomplete documents.

Do: The updating and creation of documents was carried out, including the development of instructions and the modification of risk management procedures and corrective actions.

Verification: The effectiveness of the new documents was evaluated using indicators and checklists to ensure that they met traceability and quality standards.

Action: Monitoring mechanisms, such as decision tree diagrams and change control forms, were established to standardize improvements and ensure their permanence.

Results and Their Discussion

Following the established sequence in the procedure below, the results are presented:

Planning for the improvement of the quality management system

In this phase, areas of opportunity within the Quality Management System (QMS) related to risk management were identified. To this end, a systematic review of the organization's documented information was conducted, including procedures, instructions, forms, and records associated with this process. The analysis consisted of comparing the existing documentation with the requirements established in the ISO 9001:2015 standard, in order to determine the level of compliance and detect any potential documentation deficiencies (see Table 1).

Table 1
Summary of the verification of documented information for risk management.

Category	Document evaluated	Status	Main observation
Procedures	Risk and opportunity management	Partial	The identification of applicable risks or precautions is missing.
Procedures	Corrective actions	Partial	The identification of applicable risks or precautions is missing.
Instructions	Risk identification	It fulfills	No comments.
Instructions	Risk assessment and monitoring	It does not comply	There is no documentary evidence.
Formats	Identification, risk matrix and action monitoring	It fulfills	They meet 100% of the evaluated criteria.
Records	Risks identified, monitoring and actions implemented	It fulfills	Documentary evidence exists for the required records.

Note: Prepared by the author based on a review of the documented information of the Quality Management System in accordance with ISO 9001:2015.

Based on this document review, the compliance and structure of existing documents were evaluated using checklists to analyze aspects related to document control and adherence to established requirements. To this end, improvement objectives and actions were established to correct the deficiencies identified in the documented information related to risk management.

According to the results obtained, a high level of compliance was evident in the documentation associated with risk management, particularly in the forms and records, which achieved 100% compliance. However, the procedures showed partial compliance due to the absence of the section regarding the identification of applicable risks or precautions in both the Risk and Opportunity Management Procedure and the Corrective Action Procedure. Likewise, the instructions registered the lowest level of compliance, stemming from the lack of the Instruction for Risk Assessment and Monitoring. These findings demonstrate that, although the organization has a solid documentary foundation for risk management, areas for improvement remain that could limit the effectiveness of the Quality Management System.

This problem is very common in companies. Authors such as Fonseca et al. (2023) explain that many organizations comply with the ISO 9001 standard only on paper (administratively), but neglect the constant monitoring of risks. Likewise, Santos and Rebelo (2024) point out that an effective quality system must constantly link the problems that occur (failures) to the risk matrix to prevent their recurrence. The company then doesn't need more forms, but rather to learn how to use the information generated by them for continuous improvement.

In this regard, the need was identified to update existing procedures, develop the missing instructions, and strengthen documentation mechanisms for risk identification, assessment, and monitoring. Addressing these opportunities will contribute to improved document control, strengthen the preventive approach promoted by ISO 9001:2015, and increase the organization's capacity to effectively manage risks that may affect the performance of its processes.

Generating improvement actions (Doing)

As a result of the document review of the Quality Management System, improvement actions were implemented aimed at strengthening risk management and ensuring compliance with the requirements of the ISO 9001:2015 standard. The actions carried out included the preparation of the Instruction for risk assessment and monitoring, as well as the updating of the risk and opportunity management procedures and corrective actions, incorporating the section on identification of applicable risks or precautions.

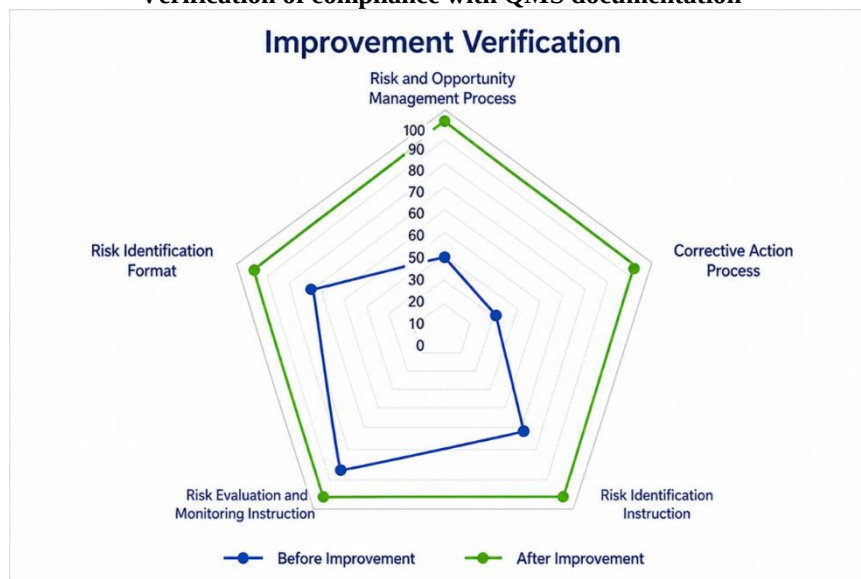
These improvements addressed the main areas for improvement identified during the diagnostic phase, specifically the lack of guidelines for risk assessment and monitoring, and the absence of documented criteria for risk identification in the analyzed procedures. This strengthened document control, information traceability, and the preventive approach of the Quality Management System, contributing to more effective risk management and the continuous improvement of organizational processes.

Verification of the implementation of the developed documentation

To verify the effectiveness of the improvements implemented in risk management, a review was conducted of the procedures, instructions, and forms incorporated into the Quality Management System. Using checklists, compliance with criteria related to change control, validity, traceability, and updating of documented information was evaluated.

The results showed a strengthening of document control and greater standardization of documents related to risk management. The incorporation of the risk identification form was also confirmed; this form was not part of the documentation available before the implementation of the improvement actions. Similarly, it was verified that the procedures, instructions, and forms integrated the elements established in the corresponding checklists, ensuring their alignment with the requirements of the Quality Management System (see Figure 2).

Figure 2
Verification of compliance with QMS documentation

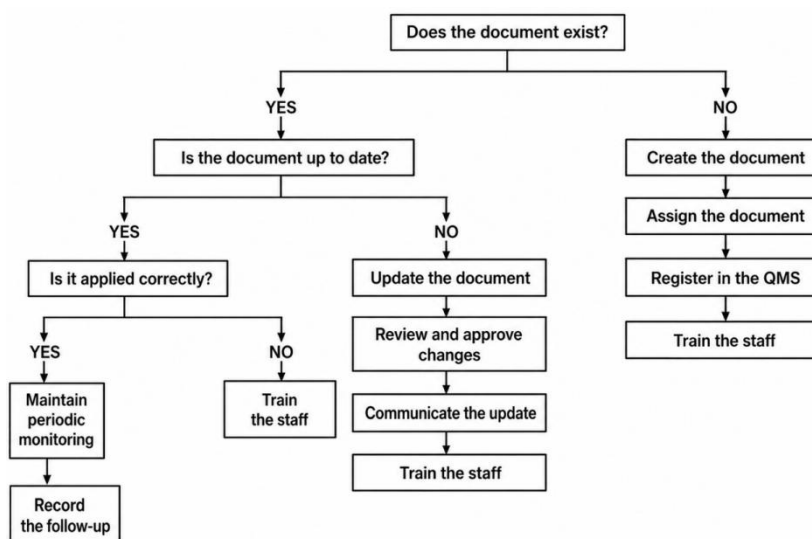


The results presented verified that the documentation related to risk management complies with the established requirements for document control within the Quality Management System. It was also confirmed that the procedures, instructions, forms, and records include elements such as document identification, change control, validity, traceability, and corresponding approval, contributing to the standardization and continuous improvement of the documented information. Similarly, the application of the developed documents was monitored to verify their use within the processes related to risk management.

Establishment of monitoring actions for document control (Act)

Based on the results obtained during the verification of the developed documentation, actions were established to monitor, trace, periodically review, and control documents related to risk management within the Quality Management System. These actions ensure the updating, validity, and correct application of the procedures, instructions, forms, and records implemented to maintain continuous improvement and strengthen document control. Figure 3 shows the sequence of actions to follow to achieve this.

Figure 3
Sequence of actions for document control



Based on Figure 3, it is determined whether a document requires creation, updating, modification, or approval before its implementation and monitoring, facilitating the control and tracking of documented information. Change log forms and authorization signatures were incorporated, strengthening the Quality Management System's document control by ensuring the traceability of modifications, version control, and formal validation of documentation by those responsible for its creation, review, and approval. These actions contribute to the continuous updating and improvement of documented information.

Conclusions and Recommendations

The research identified areas of opportunity related to document control and risk management within the Quality Management System of the company studied, particularly in the updating and monitoring of documented information. In response to these needs, improvement actions were implemented based on the PDCA methodology and the guidelines of the ISO 9001:2015 standard, aimed at strengthening the procedures, instructions, forms, and records associated with risk management.

The results obtained demonstrated the achievement of the research objective, as actions were developed and implemented that contributed to strengthening the Quality Management System and improving organizational performance. Furthermore, the verification of the prepared documentation confirmed 100% compliance with the evaluated criteria regarding change control, traceability, validity, and document approval. Finally, the established monitoring actions strengthened the tracking of documented information and promoted continuous improvement and more effective risk management within the organization.

Recommendations

- Maintain the periodic review and updating of documents related to risk management.
- Conduct periodic internal audits to verify the application and effectiveness of the implemented documentation.
- Establish indicators that allow for the evaluation of the performance of corrective actions and risk management.
- Promote the incorporation of technological tools that facilitate document control and the automation of processes in the Quality Management System.

References

- [1]. April Sánchez, CE, Enriquez Palomino, A., & Sanchez Rivero, J. (2006). Manual for the integration of quality, environment and occupational risk prevention management systems. Madrid: Confemetal Foundation.
- [2]. Bien Informado. (08 de Noviembre de 2024). Bien Informado. Obtenido de Bien Informado: <https://bieninformado.mx/destacan-bc-y-sonora-en-la-industria-medica/>
- [3]. COFEPRIS. (2025). COFEPRIS. Retrieved from COFEPRIS: <https://www.gob.mx/cofepris/acciones-y-programas/dispositivos-medicos-397319>
- [4]. Gobierno de México. (03 de Enero de 2022). Gobierno de México. Obtenido de Gobierno de México: <https://www.gob.mx/senasica/articulos/con-buenas-practicas-ganamos-todos>
- [5]. Fonseca, L., Amaral, A., & Oliveira, J. (2023). Quality 4.0: The next frontier for ISO 9001 and risk-based Thinking about performance. Total Quality Management & Business Excellence, 34(7/8), 912–930. <https://doi.org/10.1080/14783363.2022.2117563>
- [6]. IAASA. (2026). IAASA. Obtained from IAASA: <https://instrumentosyaccesorios.com/quienes-somos/>
- [7]. INEGI. (2025). Statistics of the trade sector in Mexico. Retrieved May 8, 2025, from <https://www.inegi.org.mx/temas/comercioemp/>
- [8]. International Organization for Standardization. (2015). International Organization for Standardization. Retrieved from International Organization for Standardization: <https://www.iso.org/obp/ui/es/#iso:std:iso:9000:ed-4:v1:es>
- [9]. Organización Mundial de la Salud (OMS). (s. f.). Dispositivos médicos. Recuperado el 10 de julio de 2026 de <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices>
- [10]. Precedence Research. (December10, 2025). Precedence Research. Retrieved from Precedence Research: <https://www.precedenceresearch.com/medical-devices-market>
- [11]. Prodense. (September4, 2025). Prodense. Obtained from Prodensa: <https://www.prodensa.com/insights/blog/medical-device-manufacturing-in-mexico>

- [12]. Santos, G., &Rebelo, M. (2024). Integrating risk-based thinking with corrective actions: A framework for robust ISO 9001:2015 management systems. *International Journal of Quality & Reliability Management*, 41(2), 415–433. <https://doi.org/10.1108/IJQRM-03-2023-0092>
- [13]. World Health Organization (WHO). (2026). Medical devices. Retrieved July 10, 2026, from <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices>
- [14]. UNIR. (May 18, 2023). UNIR. Retrieved from UNIR: <https://mexico.unir.net/noticias/economia/que-es-sistema-gestion-calidad/>
- [15]. Zapata, A. (2016). PVHA Quality Cycle. Bogotá: National University of Colombia.