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Visualización de la Gestión de la Calidad en los Laboratorios de Ingeniería Biomédica-PUPR

Visualization of Quality Management in Laboratories of Biomedical Engineering-PUPR

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Resumen

Un Sistema de calidad para los laboratorios tiene como objetivo obtener las herramientas necesarias para minimizar vulnerabilidades, facilitar toma de decisiones, reducir errores prácticos o de mala comunicación, mejorar desempeño, lograr satisfacción de todas las partes interesadas (administrativas y estudiantes), y que el área pueda fortalecer sus cualidades de modo tal que se vuelva cada día más competitiva. En este contexto, el trabajo evalúo la implementación de la ISO 9001:2015 desde la perspectiva del diagnóstico de un sistema de gestión de calidad en los laboratorios del Departamento de Ingeniería Biomédica (BME) de la Universidad Politécnica de Puerto Rico (PUPR), identificando áreas de mejora y recomendando la implementación de un sistema de gestión de documentos, mejor asignación de recursos y promoción de la gestión proactiva de riesgos. Estas acciones buscan fortalecer su sistema de gestión de calidad, asegurando un compromiso continuo con la excelencia, la mejora en la investigación y educación en ingeniería biomédica.

Palabras clave: Sistema de calidad, satisfacción, laboratorios, Ingeniería Biomédica

Abstract

A quality system for laboratories aims to obtain the necessary tools to minimize vulnerabilities, facilitate decision-making, reduce practical or communication errors, improve performance, achieve the satisfaction of all interested parties (administrative and students), and enable the area to strengthen its qualities so that it becomes more competitive every day. In this context, the work evaluates the implementation of ISO 9001:2015 from the perspective of diagnosing a quality management system in the laboratories of the Biomedical Engineering Department (BME) at the Polytechnic University of Puerto Rico (PUPR), identifying areas for improvement and recommending the implementation of a document management system, better resource allocation, and the promotion of proactive risk management. These actions seek to strengthen its quality management system, ensuring a continuous commitment to excellence and improvement in biomedical engineering research and education.

Keywords: Quality System, Satisfaction, Laboratories, Biomedical Engineering.

1 Introduction

Biomedical Engineering emerges as a multidisciplinary field that merges the principles of engineering with biology and medicine, encompassing various areas including physiology, human biology, molecular imaging, and tissue reconstruction (Rondón *et al*., 2024). This convergence of knowledge leads to innovative solutions that improve quality of life and transform the medical landscape.

According to the definition by IEEE Engineering in Medicine and Biology, Biomedical Engineering encompasses any field that combines, in any proportion, biology or medicine with one of the branches of engineering. This breadth makes it a dynamic and diverse field, with applications in a wide range of areas (IEEE EMBS, 2016).

The development of new technologies, techniques, and materials in science has generated a wide variety of advances in medical treatment (Olivares *et al*., 2018; Cruz *et al*.,

2012; Rondón *et al*., 2023), highlighting the role of biomedical engineers as catalysts for progress in this field. Their work spans various sectors, from industry and academic institutions to hospitals and government agencies. Their tasks include the design, manufacturing, and testing of mechanical devices such as prosthetics and orthotics, as well as the development of electrical circuits and software for medical instrumentation.

The different biomedical engineering laboratories play a significant role in the development of medical technological innovations, devices, and procedures that have a direct impact on patient care and healthcare systems. Ensuring quality, safety, and reliability in practices and learning within these laboratories is essential. To address this need, many laboratories in the industry and academic areas have turned to the ISO 9001:2015 standard, a widely recognized framework for Quality Management Systems (QMS), to systematically improve their operations (International Organization for Standardization, 2015).

Carriel, Barros, and Fernández argue that quality management should not be viewed as an independent system within a company, but as a fundamental element of general administration. Its main function lies in the implementation of actions that materialize the directives established by the board of directors and lead to the achievement of organizational quality objectives (Carriel *et al.*, 2018).

To achieve this end, quality management relies on a carefully designed strategy that transforms the company's mission, vision, and values into tangible policies. From there, specific objectives and effective actions are established that drive continuous improvement at all levels of the organization (Paredes *et al*., 2018).

In the current context of university education, quality management has become a crucial element for the success and competitiveness of institutions. In this sense, the ISO 9001:2015 standard emerges as a powerful tool that facilitates the implementation of an effective and efficient quality management system.

Guerra and Java highlight two fundamental aspects of the ISO 9001:2015 standard: its strategic focus and the strengthening of risk-based thinking. The strategic focus allows institutions to align their processes and actions with their mission, vision, and objectives, ensuring greater efficiency and effectiveness in quality management. On the other hand, risk-based thinking facilitates the identification, prevention, and mitigation of risks that may affect the quality of education, promoting a culture of continuous improvement (Guerra & Jaya, 2016).

The application of the ISO 9001:2015 standard not only benefits quality management in general but also has a positive impact on the three fundamental dimensions of higher education:

Teaching: Improves the planning and development of courses, promotes the evaluation and monitoring of learning.

Research: Encourages a culture of scientific and technological research, optimizes the management of research projects.

Extension: Strengthens the institution's link with society, promotes community participation in the institution's activities, and responds to the needs and demands of the social environment (Martínez, 2016).

Vélez and Anchundia define the ISO 9001 standard as an international standard that establishes the requirements for a quality management system. Unlike other standards in the ISO family, ISO 9001 is the only one that can be certified, meaning that an independent body can evaluate and verify that the organization meets the established requirements (Vélez & Anchundia, 2022).

The main objective of this research is to conduct a diagnostic study for the implementation of a Quality Management System in the laboratories of the Biomedical Engineering Department at the Polytechnic University of Puerto Rico that adheres to the ISO 9001:2015 standard. This research focuses on:

- Evaluating the current state of the system for the implementation of ISO 9001:2015 in BME laboratories.
- Identifying areas for improvement and providing optimization recommendations.

The study acknowledges that the application of the ISO 9001:2015 standard may vary between laboratories due to differences in size, resources, and organizational culture. Additionally, the research is conducted within the limitations of available resources and access to sensitive information from the participating laboratories.

2 Theoretical Framework

2.1 History of ISO 9001:2015 and Its Importance

The ISO 9001 standard has become a global benchmark for quality management. Its origin dates to the 1970s when the need to ensure product quality and the growing demand for suppliers with quality assurance programs led to the creation of an international standard.

Key milestones in the history of ISO 9001:

-1979: The British Standards Institution (BSI) creates the BS 5750 standard, which becomes the reference for the first version of ISO 9001.

-1987: The first version of ISO 9001 is published, developed by the Technical Committee 176 of the International Organization for Standardization (ISO).

-1994, 2000, 2008, and 2015: Revisions are made to the ISO 9001 standard to adapt it to the needs and changes of the global market.

-2015: The latest version of ISO 9001 is published, characterized by a focus on continuous improvement and customer satisfaction (Sánchez, 2017).

2.2 Management System

University laboratories play a fundamental role in the training of professionals and the development of scientific research. However, to reach their full potential, they require efficient and effective management that ensures the quality of their processes and results. In this context, the implementation of a management system becomes a crucial tool for success.

Fragua and Gambo point out that a management system allows university laboratories to achieve the following objectives:

Strategic Planning:

-Align laboratory planning with the university's strategic planning.
-Establish strategic objectives and monitor their fulfillment.

Risk Reduction:

-Identify and mitigate risks associated with laboratory activities.
-Promote a culture of safety and accident prevention.

Efficiency and Effectiveness:

-Define a clear and efficient organizational structure.
-Manage laboratory knowledge effectively.
-Strengthen laboratory management within the university.

Quality:

-Consolidate the culture of quality in the laboratory.
-Ensure the quality of research and analysis results.

Sustainability:

-Ensure the long-term sustainability of the laboratory.
-Optimize resource use.

Training:

-Effectively address the university's training interests.
-Provide students with high-quality practical training.

Customer Satisfaction:

-Define processes necessary to achieve the satisfaction of external customers and students.
-Ensure the quality of services provided.

Documentation:

-Ensure the documentation issued by the laboratory.
-Establish an efficient document management system.

Organization:

-Organize tasks efficiently and effectively.
-Establish a standardized work system.

Image:

-Improve the laboratory's image at the national and international levels.
-Strengthen the laboratory's reputation as a center of excellence.

Productivity:

-Increase productivity levels by clarifying process interactions.
-Optimize time and resource use.

Continuous Improvement:

-Foster a culture of continuous improvement in the laboratory.
-Constantly identify and implement improvement measures (Fragua & Gamboa, 2017).

2.3 Quality

It is a fundamental concept for the success of any organization. The ISO 9001:2015 standard defines quality as the degree to which a set of characteristics fulfills established requirements. These requirements can be set by stakeholders, both internal and external, by legal regulations, or by the organization's own management (Sánchez, 2017).

2.4 Benefits and Challenges in Implementing ISO 9001:2015 in Laboratories

Adopting the ISO 9001:2015 standard in laboratories, including those in the biomedical engineering sector, offers several notable benefits. These include greater process efficiency, better documentation and traceability, higher customer satisfaction, and a culture of continuous improvement. Laboratories that implement ISO 9001:2015 often experience a reduction in errors and defects, leading to cost savings and increased competitiveness. However, challenges are also associated with the implementation of ISO 9001:2015, especially in laboratories where teaching, research, and development are fundamental to their activities.

Maintaining flexibility and innovation while adhering to strict quality management processes can be a delicate balance. Additionally, resource limitations, resistance to change, and the need for staff training are common chal-

lenges faced by laboratories in their quest for ISO 9001:2015 compliance (Palma *et al*., 2018).

2.5 Current State of QMS Implementation

2.5.1 Description of the Biomedical Engineering Department Laboratories

Below are descriptions of the BME laboratories following the guidelines of the Polytechnic University of Puerto Rico (Polytechnic University of Puerto Rico, 2024):

Biosystems Circuits and Electronics Laboratory: Designed to develop the necessary skills for conducting electrical measurements and implementing and testing standard electronic circuits. The experimental verification of fundamental electrical circuit laws is required in all experiments conducted. The laboratory uses electrical measurement devices such as multimeters, oscilloscopes, and RLC meters, as well as other necessary equipment like power supplies, function generators, and protoboards for constructing and testing electrical and electronic circuits. Practical electronic circuits, including diodes, transistors, and operational amplifiers, are studied and applied. Computer software is also used to simulate the circuits implemented and studied in the laboratory.

Rehabilitation Engineering Laboratory: Applies and integrates knowledge in mechatronics, assistive technologies, and orthopedics and prosthetics to provide solutions aimed at restoring human functions for the upper and lower extremities. The laboratory's objective is to be a space for designing assistive robotic arms and exoskeletons, orthopedic devices and prosthetics, as well as therapeutic technologies for individuals with disabilities. The purpose is based on studying interdisciplinary fields such as robotics, electronics, computer-aided design, mechanical design, and rehabilitation engineering. Additionally, it maintains open communication channels with potential end-users, rehabilitation engineers, rehabilitation clinics, assistive technology providers, and industry to exchange information and advanced technologies.

Gait and Movement Analysis Laboratory (Biomechanics): Provides practical introduction to the experimental analysis of human movement biomechanics. The goal is to learn to use computer software for data acquisition and analysis. Kinematic analysis is conducted using optoelectronic and electromagnetic motion sensors. The kinematics of movement is related to muscle activity data provided by electromyography (EMG). Kinetic analysis of movement is performed using strain gauges and force sensors, including force plates for balance control experiments.

Computer Modeling Simulation and Analysis Laboratory: Focuses on preparation in multiple areas of biomedical engineering, such as: Introduction to Computer-Aided Drawing and Design (CADD); Engineering design process, drawing, solid modeling, dimensioning, and tolerances; Graphical communication in biomedical engineering; 2D and 3D construction, visualization, sketching, and standard lettering techniques using CADD; Projections; Multi-view drawings for engineering design and production; Basic dimensioning and tolerances. The mission is to learn to design, write, and implement MATLAB scripts and subroutines to solve simple engineering problems. Topics to be solved include selecting the MATLAB environment and repetition structures, user-defined functions, data input and output, 2D plotting, and creating a simple graphical user interface (GUI). Additionally, techniques and computer tools are introduced to model, predict, analyze, and understand dynamic behavior in biomedical systems.

Tissue Engineering & Bioimpedance Laboratory: Provides an aseptic and controlled environment for cell culture and the creation of living tissue structures. This laboratory facilitates the culture of autologous tissues across the research spectrum. When tissues and organs are replaced with prostheses, various complications can arise. Technologies developed here allow for the cultivation of new tissues, such as cartilage, blood vessels, cardiac tissue, and organ tissue, both outside and within the patient's body. The Tissue Engineering and Bioimpedance Laboratory is a modern facility. Research conducted here extends to tissue engineering, biomaterials, and bioimpedance. Facilities include a cell culture chamber, ideal for conducting tissue engineering experiments, and a Bioimpedance Analyzer for the electrical characterization of biological tissues. Tissues are thoroughly tested to determine their mechanical and electrical properties (Polytechnic University of Puerto Rico, 2024).

3 Experimental Procedure

3.1 Type of Research

The study employs a mixed methods research design to comprehensively evaluate the implementation and effectiveness of the Quality Management System (QMS) following ISO 9001:2015 standards in Biomedical Engineering laboratories. Mixed methods research allows for the collection and analysis of both quantitative and qualitative data, providing a holistic understanding of the QMS and its impact.

3.2 Data Collection

Multiple data collection methods were used for the research:

3.2.1 Document Analysis

Relevant documentation for the QMS, including manuals, procedures, and quality records, was analyzed to evaluate the alignment of laboratory practices with ISO 9001:2015 requirements. This analysis helped identify dis-

crepancies and areas of non-compliance.

3.2.2 Surveys

A structured questionnaire was designed and distributed to laboratory staff involved in various aspects of the QMS. The survey aimed to assess their knowledge of ISO 9001:2015 standards, their perception of the QMS's effectiveness, and their suggestions for improvement.

3.2.3 Data Analysis

Quantitative data from the surveys were analyzed using statistical software (SigmaXL version 10), allowing for the calculation of descriptive statistics and the identification of trends and patterns in the responses.

4 Discussion and Results

4.1 Compliance with ISO 9001:2015 Requirements

The laboratory has made substantial progress in aligning its practices with ISO 9001:2015 requirements. Key elements of compliance include:

Risk-Based Thinking: Risk assessments have been integrated into laboratory processes, allowing for the proactive identification and mitigation of potential issues.

Customer Focus: The laboratory has established mechanisms to collect and analyze feedback from internal and external stakeholders, including students and faculty.

Continuous Improvement: Regular management reviews and performance evaluations are conducted to monitor the effectiveness of the QMS and identify areas for improvement.

Despite these positive steps, challenges remain, including:

Documented Processes: Processes within the laboratory, including research design, equipment calibration, and data management, have been documented and mapped to meet ISO 9001:2015 process requirements.

Resource Allocation: Ensuring adequate resources for the maintenance and improvement of the QMS remains a challenge, given the dynamic nature of biomedical engineering research.

Staff Training: Ongoing efforts to educate and engage laboratory staff in quality management principles are crucial for maintaining compliance and promoting a quality culture.

Document Management: Although procedures have been developed, challenges related to document control and accessibility persist.

4.2 Identification of Areas for Improvement

4.2.1 Gaps and Non-Conformities

Through the diagnostic analysis of the Quality Management System (QMS) following ISO 9001:2015, various gaps and non-conformities have been identified. These areas include:

Document Control: Improved document management procedures are needed to optimize traceability and ease of access.

Risk Management: While risk assessments have been introduced into laboratory processes, there is room to refine risk identification and mitigation strategies further to enhance student and faculty safety and increase educational reliability.

4.3 Root Cause Analysis

To address these identified gaps and non-conformities, a root cause analysis was conducted (Quesada *et al*., 2010). This analysis involved investigating the underlying factors contributing to these issues:

Document Control: The lack of a centralized document management system was identified as a root cause. Solutions proposed include improving training and implementing document management software. The need for document control arises from methods used between faculty-to-faculty and student-to-faculty communications. For faculty-to-faculty control, the cause was attributed to documents lacking a specific system for sending and storing them, causing delays due to lost time. For student-to-faculty control, the absence of a specific system for sending and managing all documents caused situations and non-conformities for both parties. Documents are handled through the university's official program, email, physical copies, and other methods, impacting student grades and delaying faculty work.

Resource Allocation: Inadequate resource allocation stems from budget constraints and limited understanding of the long-term benefits of the QMS. Advocacy for increased resources and training to illustrate the value of quality management is suggested. Resource allocation should focus on laboratory improvements and creating new opportunities with teaching-research labs. While the department manages resources well, areas for improvement were identified. Resource distribution does not reach each lab and new opportunity areas equally, affecting continuous improvements in department labs.

Risk Management: The root cause analysis revealed that risk assessments are often conducted reactively rather than proactively. A cultural shift towards proactive risk management and better risk assessment tools is recommended. In most circumstances, the department has proactively managed potential risks, but improvements in risk management are possible.

4.4 Recommendations for Improvement

Based on the identified gaps, non-conformities, and root cause analysis, the following recommendations are proposed to enhance the effectiveness of the QMS within the biomedical engineering laboratory:

Implement a Document Management System: Introduce a robust document management system to ensure version control, accessibility, and traceability of documents within the QMS.

Review Resource Allocation: Review how resources are distributed among different laboratories and new opportunities that may arise within the department.

Promote Proactive Risk Management: Foster a culture of proactive risk management by providing training on risk assessment techniques and integrating risk analysis into laboratory processes. These recommendations aim to address identified improvement areas and contribute to the continuous improvement of the quality management system within the laboratory.

5 Conclusions

The implementation of a Quality Management System (QMS) in the laboratories of the Biomedical Engineering Department at the Polytechnic University of Puerto Rico represents a commitment to excellence and continuous improvement. Through this process, significant progress has been made in aligning practices with ISO 9001:2015 requirements, promoting efficiency, safety, and quality in all operations. Areas of strength have been identified, such as the integration of risk-based thinking, customer focus, and the promotion of continuous improvement. However, challenges such as document management, resource allocation, and proactive risk management require attention and action to ensure an effective and efficient QMS. In summary, the diagnosis of the Quality Management System in the Biomedical Engineering laboratories of PUPR demonstrates a continuous commitment to excellence, safety, and quality in all activities. With the implementation of the proposed recommendations, the department is expected to further strengthen its capabilities and remain at the forefront of biomedical engineering research and education.

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