Management System for Quality and Safety in the Medical Products Industry, aligned with Mexican Official Standards

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1 Introduction

Did you know that Mexico has become the 14th largest exporter of medical devices worldwide? This growth reflects the growing importance of the manufacturing industry in the country and the need to comply with strict quality standards and safety regulations to ensure the health and well-being of patients. The purpose of this project is to develop a Management System for Quality and Safety in the Medical Products Industry, aligned with the Mexican Official Standards (NOM). However, this expansion also presents various challenges in the production of medical devices, where compliance with quality standards is crucial.

This comprehensive information system is designed to provide companies with an effective tool to manage and monitor production processes, as well as identify and mitigate problems that may arise. Through the generation of detailed reports, the system will not only contribute to the continuous improvement of the quality of the final product, but will also facilitate compliance with current regulations regarding industrial safety. By addressing key aspects such as scrap management and safety incident reporting, we seek to optimize production efficiency and promote a safe working environment for workers.

2 Propose

The main objective of the Quality and Safety Management System in the Medical Products Industry is to develop a platform that allows companies in the manufacturing sector to:

1.- Monitor and manage quality standards: Facilitate the monitoring of quality standards in the production of medical devices by recording and analyzing data related to production and scrap.

2.- Generate incident reports: Provide tools to document and analyze safety incidents, allowing the implementation of corrective and preventive measures that ensure a safe work environment.

3.- Align processes with NOM: Ensure that manufacturing practices comply with the relevant Mexican Official Standards, promoting continuous improvement and efficiency in production processes.

This system not only seeks to improve the quality of medical products but also contributes to the well-being of workers and compliance with national regulations, promoting a safer and more productive work environment.

3 SCOPE

- **Quality monitoring:** Monitor quality standards in the production of medical devices in accordance with Mexican Official Standards.
- **Scrap management:** Record and analyze scrap to improve efficiency and reduce costs.
- **Security reports:** Generate security incident reports to identify risks and apply corrective measures.

4 GENERAL DESCRIPTION

The Quality and Safety Management System for the Medical Products Industry is a comprehensive solution designed to help companies in the manufacturing sector manage and improve the quality of their products. This system allows for the monitoring of quality standards and the recording of data related to Scrap, as well as the generation of safety incident reports.

In addition, the system facilitates alignment with Mexican Official Standards, ensuring that manufacturing practices comply with current regulations. Its focus on continuous improvement and efficiency in production processes positions companies to achieve a safer and more productive work environment.

4.1 Product Functionality

4.1.1 User Management

As we manage this user it allow us to see all the features that the app allows to do, such as view, edit, and delete the different medical products that are in the system, as well it allows us to see all the reports that are being made by the user employee so we as management can check them.

All of this is possible thanks to our database that only allows certain users to have the status of management, this help us to have an order of our system.

4.1.2 NOM applied to the system

Mexico is a country whose medical product production is regulated by several Mexican Official Standards (NOM) to ensure safety, quality and efficacy. Here is information on some relevant NOMs: 1. NOM-017: Related to safety at work, this standard refers to the selection, use and maintenance of personal protective equipment in workplaces. 2. NOM-241: This standard regulates manufacturing practices in establishments that produce medical devices. Its objectives include ensuring product quality and protecting the health of consumers. 3. NOM-137-SSA1-2008: Regulates procedures for labeling and traceability of medical devices. This standard is essential for the identification of batches, expiration dates and storage conditions.

4.1.3 User Employee

The user employee allows us to enter the data required off all the batches of medical products and inform if they are some decrease in the production of the product so that data can be collected an make a solution for when these cases are eligible so as a company we do not have a significant amount of losses.

Just as the management user we as a employee only can access certain information that is selected for our user to access.

5 BD Model Overview

5.1 Use Case Diagram

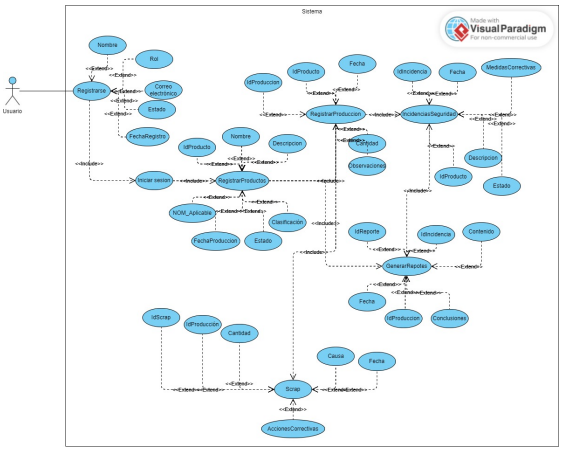

Fig. 1. Use case diagram

The use case diagram starts first with the user who must register to access the system by entering their data, such as name, email, role, and registration date. These will be stored in the table called “Usuarios”. Later, the user will have access to the system where they will first find the “ProductosMedicos” table, in which all the medical products handled at the site will be registered. This includes the product’s identification name, product description, classification, applicable “NOM” regulations, and its creation date.

From the “ProductosMedicos” table, it will be related to the “Produccion” table, where the data related to the production of a single product is recorded, such as the production date, the quantity produced, and the amount of waste generated. Then there is the “IncidenciasSeguridad” table, where all the information about each incident that occurred during the production process of each product will be stored. This includes data such as the incident date, description of what happened, the production number in which it occurred, corrective measures to be applied, and the incident’s status.

In the “Reportes” table, each of the reports related to each production carried out will be stored. These reports will reference information on the safety incidents that occurred, as well as the production from which the report is generated. It will also contain relevant information, such as the preparation date, content, and conclusions. Finally, the “Scrap” table is necessary, which contains information on the waste or residues generated during the production process, such as the amount generated, the cause, the registration date, and the corrective actions taken.

5.2 Entity-Relaionship Diagram

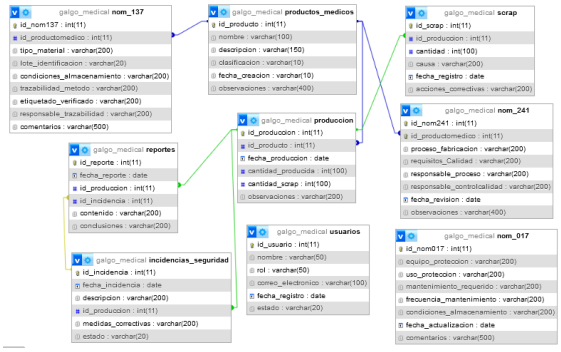

Fig. 2. Entity-relationship diagram

In the entity relationship diagram, first there is the ”usuarios” table, where each of the users authorized to access the system is stored. Then there is the ”productosmedicos” table, which stores the information of each of the products. This table contains a foreign key ”idproducto” which is related to the ”nom137” table, the ”production” table and the ”nom242” table. Then there is the ”produccion” table, which contains the information corresponding to the production of each of the medical products, where the ”idproduccion” field is a foreign key and is related to the ”reports” table, the ”incidenciasseguridad” table. The ”scrap” table refers to the waste generated in each of the productions, so it has a direct relationship with the ”produccion” table. In addition, it includes the three tables corresponding to the regulations described in the document (nom017, nom137 and nom241).

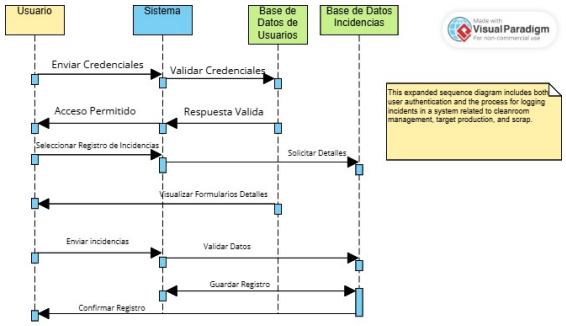

Fig. 3. Sequential diagram

5.3 Sequential diagram

5.4 Entity-Relaionship Diagram

6 Constraints

Compliance with Official Mexican Standards (NOM): The system must adhere to the applicable NOM, using technologies such as MySQL, PHP and JavaScript in a Visual Studio environment. It must be ensured that all tools and software are available with licenses for students, avoiding expenses on additional licenses. The implementation must be completed no later than the last week of November.

7 Assumptions and Dependencies

7.1 Assumptions

Regulatory Compliance: The industry will comply with the required NOMs and regulations. Resource Availability: Resources (hardware, software, personnel) will be available on schedule. Data Access: Necessary data will be accessible and in compatible formats. Personnel Training: Personnel adequately trained to use the system. Sufficient Infrastructure: Existing IT infrastructure will support the new system. Interdepartmental Collaboration: Effective collaboration between quality, production, and safety. Sufficient Budget: Budget available for all phases of the project.

7.2 Dependencies

Regulatory Stability: The project is dependent on Mexican regulations (NOM) remaining stable to avoid significant modifications to software development. Technology Vendors: Dependency on vendors for software components, development tools, and libraries required for system implementation. Integration with Existing Systems: The system must integrate appropriately with other existing enterprise systems such as ERP and inventory systems. Data Availability: The quality of data required for system management is dependent on the availability and accuracy of information provided by source systems. Staff Adoption: Staff must adopt the system and participate in the testing phase to ensure operational requirements are met. Technical Support: Dependency on IT support staff for installation, maintenance, and troubleshooting during software implementation and operation. Industrial Safety Information Flow: The system is dependent on integration and access to data from industrial safety sensors and systems to ensure proper quality and safety monitoring.

8 Specific Requirements

8.1 Functional Requirements

Quality Management:

Recording and monitoring of incidents that affect product quality. Generation of reports that identify quality problems and provide statistics on performance. Industrial Safety Management:

Monitoring of industrial safety measures, including information from sensors. Generation of reports on safety incidents and corrective measures adopted. Documentation Management:

Version control of relevant documents (manuals, operating procedures). Storage and access to audit records and compliance reports. Compliance with Mexican Standards (NOM):

Specific functionalities that ensure compliance with applicable NOMs (such as NOM-241 for medical devices). Module for verifying compliance with regulations, with updates when there are regulatory changes. Generation of Customized Reports:

Capacity to generate reports in different formats (PDF, Excel). Advanced filters to segment data and generate detailed reports according to the user's needs. User and Role Management:

Secure role-based access to the system, where each user has specific permissions. Administration module to manage roles and access.

8.2 Non-functional requirements

Scalability:

The architecture must be scalable to support a growing number of users and data, ensuring good performance. Performance:

The system must be able to generate reports and perform critical operations with minimal wait time. Compatibility:

Compatible with modern browsers. Responsive web application for access from desktop computers or laptops.

9 Technologies Used

For the general development of the page, HTML5, CSS and JavaScript will be used for the programming of the project and design, in addition to the design section, Bootstrap will also be used for the creation and use of more complex designs. To create the database, MySQL will be used as the main manager for the development of the database, and phpMyAdmin will be used to connect the database with the main code of the page.

10 User Interface Features

10.1 Main Dashboard

Clear display of key quality and safety indicators. Real-time graphics for effective monitoring. Intuitive Navigation: Easy-to-use navigation menu, with quick access to all sections of the system. Structured Forms:

Simple and well-organized data entry forms to facilitate the collection of information. Report Generation:

Option to create customized reports on quality and safety, with historical data analysis. Responsive Design:

Interface adaptable to different devices (computers, tablets, mobile phones), allowing access from anywhere. Interactivity:

Interactive elements such as buttons and graphics that facilitate decision making and improve the user experience.

10.2 Products interface

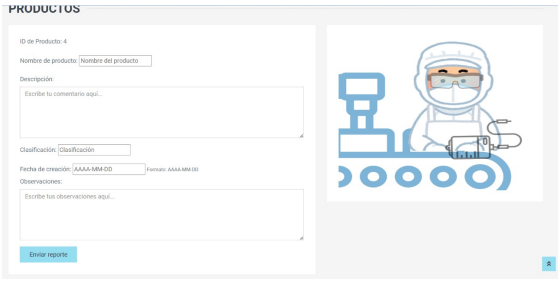

Fig. 4. Products Table

In the ”products” table, the user is responsible for registering each of the medical products within the system. The following data is entered: Product name, description, classification, creation date and observations. Once the product data has been entered, it will be saved in the table for later use.

10.3 Production interface

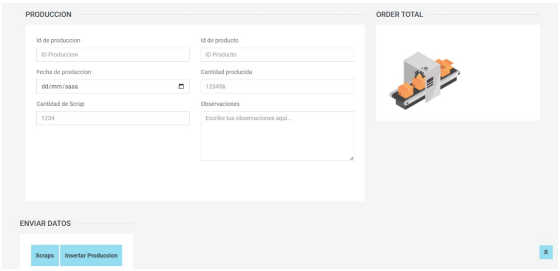

Fig. 5. Production Table

In the ”production” table, the user is responsible for entering the information related to the production of each of the medical products registered in the system. To do this, the following data is entered: Production ID, product ID, production date, quantity produced, scrap quantity and observations. After saving the information, it can be used for the report, scrap and safety incident tables.

10.4 Scrap interface

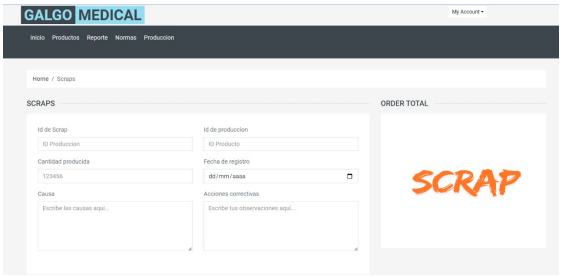

Fig. 6. Scrap Table

On the ”Scrap” screen, the user is responsible for filling out the requested fields corresponding to this section, which refers to the products that did not comply with quality regulations or that had defects in their production. On this screen, the following data is entered: Production ID, quantity produced, registration date, cause and corrective actions.

10.5 Report interface

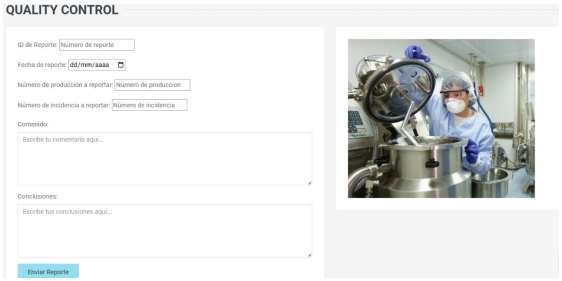

Fig. 7. Report Table

In the ”report” table, the user is responsible for entering the information pertaining to the report that is made for each of the productions carried out. The following data is entered into the report: Report ID, report date, corresponding production number, incident number, content or important information, and conclusions. Once the report data has been entered, it will be stored in the ”report” table and will be saved in the system database.

Fig. 8. New Interface Design Perspective

The interface that presents the title of incidents in pharmaceutical products and also in the manufacture of medical products, such as intravenous hoses, blood transfusions, serum bags, the interface allows those in charge of the areas, line managers, to be able to record their incidents of any kind within the clean room.

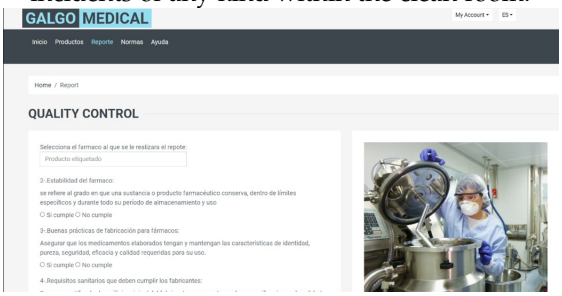

Fig. 9. Quality control interface

Quality control in the medical products industry is one of the most rigorous, and its objective is to guarantee effectiveness and safety, ensuring compliance with current regulations. For this reason, the application implements the development of this information system, adding value to the medical area, not only in the registration of incidents, but also in compliance with Standards.

10.6 Design interface

The PPE ”Personal Protective Equipment” in the clean room area establishes the sanitary measures for entry, this includes the use of shoe covers, a gown or the use of a cap, a cap, protective glasses, in some cases the face shield is necessary and the use of a face mask. The 017 STPS standard establishes that the employer must provide all the aforementioned elements for work within the area.

11 GENERATION OF REPORTS

Reports are important ...or the general development of the page, HTML5, CSS and JavaScript will be used for the programming of the project and design, in addition to the design section, Bootstrap will also be used for the creation and use of more complex designs. To create the database, MySQL will be used as the main manager for the development of the database, and phpMyAdmin will be used to connect the database with the main code of the page.

12 RECOMMENDATIONS

To ensure the continued success and effectiveness of the *Galgo Medical* system, the following recommendations are proposed:

12.1 Detailed Planning and Timeline Management

Develop a comprehensive timeline with clearly defined milestones to guide the development process. This timeline should include checkpoints for design, implementation, testing, and final deployment, ensuring the project stays on track to meet the deadline set for the last week of November.

12.2 Exhaustive Documentation

Maintain thorough and well-organized documentation for all stages of development, including decisions made, system architecture, code changes, and testing results. This documentation will serve as a foundation for future system enhancements, troubleshooting, or onboarding of new team members.

12.3 Scalability and System Expansion

Plan for the system to be scalable, allowing for future integration of additional functionalities and products. Expand the application to support a wider range of products and services while maintaining compliance with regulatory standards. Consider implementing modular designs to facilitate updates and extensions without significant system downtime.

12.4 User Segmentation by Production Areas

Incorporate features to manage users by production areas, such as:

- Manufacturing
- Molding
- Receiving
- Shipping
- Human Resources

This segmentation will enhance the system’s ability to assign permissions and track activities more effectively, fostering a more secure and organized workflow.

12.5 Staff Training and Support

Introduce a dedicated training module within the system to educate employees on its use. Include video tutorials, user guides, and interactive demos to ensure all staff are confident in operating the system. This initiative will reduce user errors and improve overall system adoption.

12.6 Testing and Validation

Implement a robust testing and validation process throughout the development lifecycle. Employ unit tests, integration tests, and user acceptance tests to identify and address issues at every stage, minimizing disruptions during deployment and ensuring system reliability.

12.7 Compliance with NOM Standards

Continuously ensure that all functionalities align with the applicable Mexican Official Standards, including NOM-017, NOM-241, and NOM-137.

Regular audits and reviews should be conducted to ensure ongoing compliance and prevent potential rework.

12.8 Feedback Mechanisms

Establish a feedback system for end users to provide insights on system usability and functionality. Use surveys, focus groups, or embedded feedback forms to gather input, ensuring that the system evolves to meet the actual needs of its users.

12.9 Safety Measures and Workplace Integration

Verify that employees have access to the necessary equipment for safe operations and ensure that production areas are equipped with preventive measures, such as emergency response protocols and safety equipment. These features will foster a safer and more efficient working environment.

12.10 Vision for Continuous Improvement

Adopt a mindset of continuous improvement by regularly evaluating system performance and seeking opportunities to enhance efficiency. Leverage user analytics, performance metrics, and industry trends to guide updates and maintain the system's relevance in a dynamic production environment.

By implementing these recommendations, the *Galgo Medical* system will be positioned as a robust, scalable, and user-friendly platform, driving efficiency and compliance while meeting the needs of an evolving medical manufacturing industry.

13 Conclusion

In this last installment, we were able to establish the comprehensive operation of the system, which begins with the authentication of users. Subsequently, it allows viewing and managing records related to medical products, production, scrap, security incidents, and provides options to fill in the information corresponding to the reports accurately and efficiently.

In addition, the use of the three official Mexican standards applicable to the sector was established:

- **NOM-017:** Related to safety at work, ensuring optimal conditions for employees.
- **NOM-241:** Regulates manufacturing practices in establishments that produce medical devices, guaranteeing product quality and the health of consumers.
- **NOM-137:** Establishes the procedures for labeling and traceability of medical devices, facilitating their control and monitoring.

The system is specifically designed for the medical product manufacturing sector, with a focus on **clean room** and **antistatic room** environments, in which various products can be registered according to their technical specifications.

Additionally, the system allows for the recording of incidents, the generation of production reports and their proper follow-up. The main purpose of this is to improve the management of resources and time in the production plant, thus contributing to a comprehensive vision of **continuous improvement**.

With these features, the system not only optimizes operational processes, but also promotes compliance with national regulations, strengthening competitiveness and efficiency within the medical product manufacturing sector.