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.

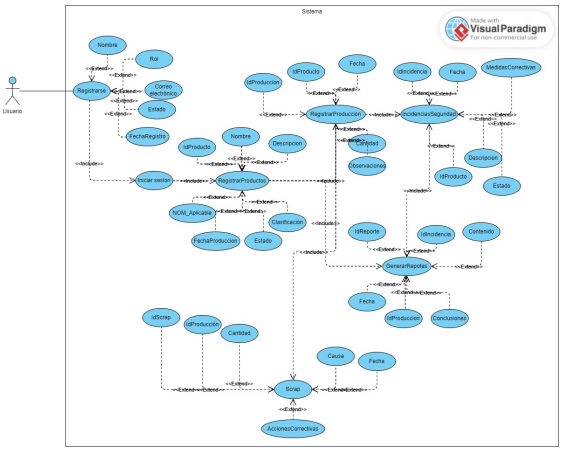


Fig. 1. Use case diagram

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

The use case diagram starts first with the user who must register to access the system. By entering your data such as name, email, role and

date of registration. These will be stored in the table called ”Usuarios” Later you will have access to the system where you will first find the ”ProductosMedicos” table, in which all the medical products that are handled in the place will be registered; establishing its identification name, the description of the product, the classification, the ”NOM” regulations that apply to the product and its date of creation. From the ”ProductosMedicos” table, it will be related to the ”Produccion” table where the data related to the production of a single product is established; such as its date, the amount produced and the amount of waste generated. Then there is the ”IncidenciasSeguridad” table, where all the information about each of the incidents that occurred during the production process of each of the products will be saved. In which data will be stored such as the date of the incident, the description of what happened, the number of the production in which it

occurred, the corrective measures that will be applied and the status of that incident. In the ”Reportes” table, each of the reports on each of the productions that have been carried out will be stored, which will take as a reference information on the safety incidents that have occurred, as well as on the production from which the report is being generated. It will also contain relevant information such as the date of its preparation, the content and the conclusions. Finally, it is necessary to mention the ”Scrap” table which contains information on the waste or residues that have been generated during the production process, such as the amount generated, the cause, the date of registration and the corrective actions that were taken

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.

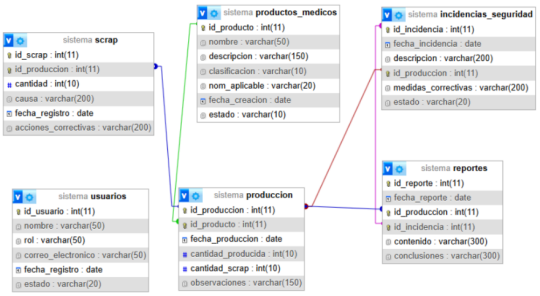


Fig. 2. Database model

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

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.

11 Recommendations

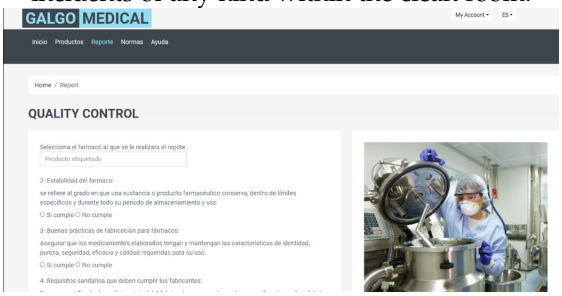
Detailed Planning: Establish a clear timeline with specific milestones to ensure development stays on track toward the deadline of the last week of November.

Exhaustive Documentation: Maintain complete documentation on the development process, decisions made, and changes made, which will facilitate future implementations or improvements.

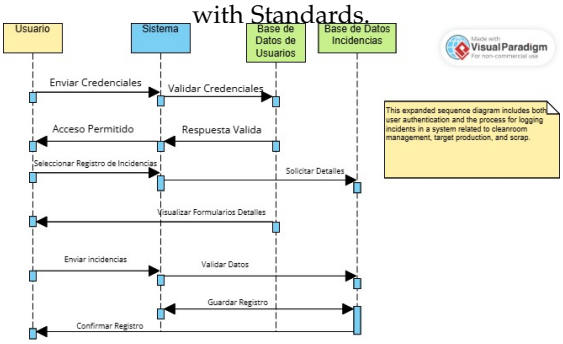
NOM Compliance: Ensure that all system functionalities align with the relevant Mexican Official Standards from the beginning to avoid rework.

Fig. 3. 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.



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.



Staff Training: Plan training sessions for staff who will use the system, ensuring a smooth transition and effective adoption.

Testing and Validation: Conduct continuous testing and validation of the system at each stage of development to identify and correct problems before final implementation.

Continuous Feedback: Establish a feedback mechanism with end users during development to ensure the system meets their needs and expectations.

12 Conslusion

In this second installment, we were able to model the first stage of our web system, through a graphical interface and a sequential diagram, which allows us to appreciate the behavior of user authentication, in turn to be able to look at the incident records, fill out the corresponding information and save the data correctly, we also established the three official Mexican standards on which the system will be based, 1. NOM-017: Related to safety at work 2. NOM-241: This standard regulates manufacturing practices in establishments that produce medical devices. ensure product quality and protect the health of consumers. 3. NOM-137 Regulates the procedures for labeling and traceability of medical devices. With this, our system moves on to the next and final phase, adapting the client-server model for our program and making it functional.