Improving the Cleaning Certification Process in the Manufacturing Area

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Abstract

By addressing the shortcomings and inefficiencies in the present Cleaning Certification procedure used by biotechnology manufacturing companies, this project seeks to modernize and streamline it. The technique experiences lags and disconnects from vital systems like Manufacturing Execution System (MES) and Laboratory Information Management System (LIMS), impacting product release timing. The Define, Measure, Analyze, Design, Verify (DMADV) methodology is used in this project to thoroughly comprehend the current process, gather and analyze data, and create a digital platform that smoothly combines Manufacturing Execution System (MES) and Laboratory Information Management System (LIMS). The initiative aims to increase operational effectiveness, decrease waste, and maintain regulatory compliance by speeding up sample testing and automating the Certification process. A new age of excellence in biotechnology manufacturing is ultimately intended, which will redefine industry norms.

Key Terms — Biotechnology industry, Cleaning Certification, DMADV methodology, and Lean Manufacturing.

Problem Statement

The Cleaning Certification process plays a pivotal role within the biotechnology manufacturing industry, ensuring the proper cleaning and validation of equipment used in production. Nevertheless, this process encounters several challenges that necessitate attention and improvement. Firstly, there are recurrent delays in verifying samples within the Laboratory Information Management System (LIMS), which can often last from a week to several months. These delays can profoundly impact product release dates, potentially impeding market availability and operational timelines. Secondly, the Cleaning Certification process, in its entirety, proves to be time-consuming and labor-intensive, replete with manual steps that contribute to inefficiencies in the workflow. Addressing these challenges is essential for enhancing the overall efficiency and efficacy of the Cleaning Certification process within the biotechnology manufacturing industry.

Methodology

The research methodology employed in this study is rooted in the DMADV (Define-Measure-Analyze-Design-Verify) approach, with a primary emphasis placed on the Design phase (Refer to *Figure 1*). This approach is a structured framework widely utilized for process improvement and optimization. In the context of this research, it serves as a robust framework to systematically address and enhance the Cleaning Certification process within the biotechnology manufacturing industry.

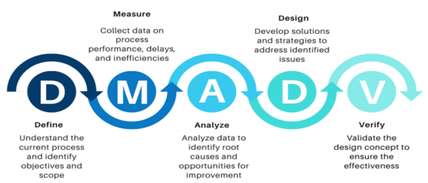

Figure 1: DMADV Methodology

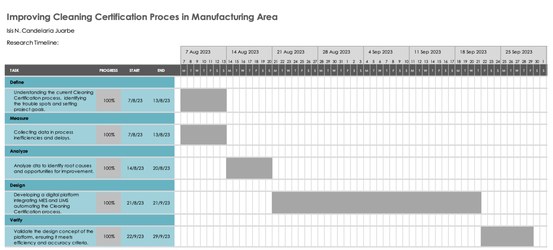

Figure 2: Gantt Chart Project Timeline

Results and Discussion

DEFINE PHASE

Table 1: Project Charter

Project Description	Design a Cleaning Certification platform for the manufacturing area.
Project timeline	August 2023 – September 2023
Project Goal	Provide a visible improvement to the Cleaning Certification process through a platform.
Benefits	**Simplified process**- Integrated platform design with all the systems needed to perform the Cleaning Certification Report. **Efficiency improvements** - Reduced time processing and sample delays. **Resource optimization** - resource efficiency and environmental sustainability by decreasing waste and manual interventions.
Project Support	Manufacturing Manager and BTS Manager.
Project Member	Graduate student, SME (8).

Figure 3: Current process of the Cleaning Certification

MEASURE PHASE

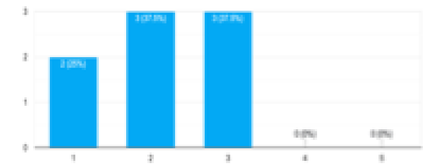

Figure 4: How satisfied are you with the current process of the Cleaning Certification?

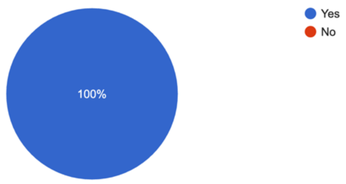

Figure 5: Do you think that the Cleaning Certification Process needs to improve?

ANALYZE PHASE

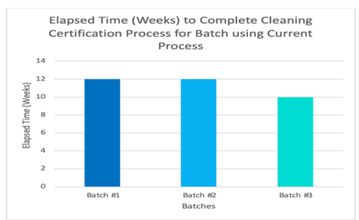

Figure 6: Graphic of three batches elapsed Time in weeks to complete the Cleaning Certification Process using the current process

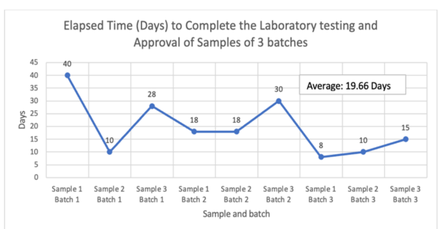

Figure 7: Graphic of three batches samples elapsed Time in days to complete the laboratory testing and approval

DESIGN PHASE

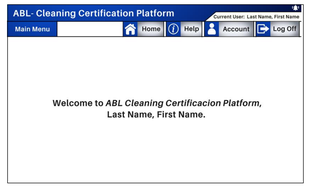

Figure 8: Cleaning Certification Platform Home page

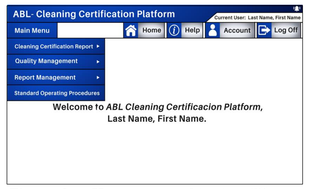

Figure 9: Home page with the different options in the Main Menu

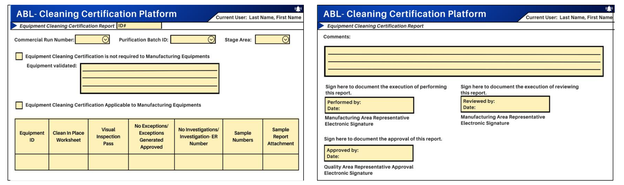

Figure 10: Example of how will look the Cleaning Certification Report

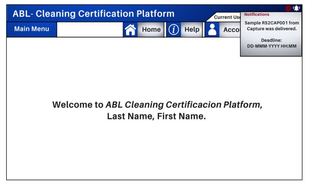

Figure 11: Example of the notifications activated program when a sample is delivered

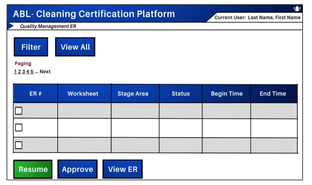

Figure 12: Quality Management ER page

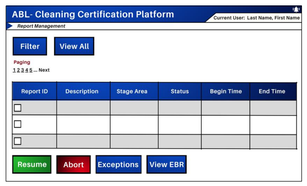

Figure 13: Report Management page

VERIFY PHASE

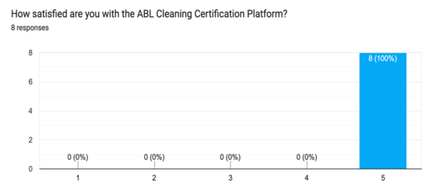

Figure 14: How satisfied are you with the ABL Cleaning Certification Platform?

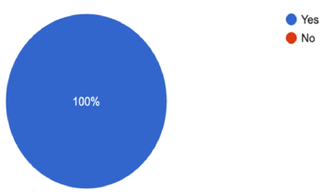

Figure 15: Do you think that the ABL Cleaning Certification Platform can improve the process?

Conclusions

The Manufacturing Execution System (MES) and the Laboratory Information Management System (LIMS) are to be combined into a single digital platform to meet the difficulties a biotechnology manufacturing company faces in its Cleaning Certification procedure. This platform is in keeping with lean manufacturing principles to streamline the Cleaning Certification procedure and improve operational effectiveness. The expected results include increased adherence to FDA standards, faster process, shorter waiting times, and quicker sample testing—all of which will improve the operational environment. This program demonstrates the business' dedication to regulatory compliance, high-quality products, and patient safety.

The project streamlines the Cleaning Certification process by integrating MES and LIMS on a digital platform, improving efficiency, ensuring compliance with FDA requirements, optimizing resources, and streamlining workflow, thereby promoting a more efficient and environmentally sustainable manufacturing process.

Future research may expand digital platforms in biotechnology production, automate tasks, and use artificial intelligence (A.I.) and machine learning (ML) for quality control, revolutionizing the industry and reinforcing high-quality standards.

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