Optimizing Syringes Tubs Scanning in the Aseptic Filling Area through a Portable Screen Mobile Scanning System

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Abstract

This research is a comprehensive study of the optimization of the syringe tubs scanning process in aseptic filling area and using the mobile scanning system to reduce lead-time and improve efficiency. Integration of DMAIC methodology as a structured procedure allows for a thorough analysis of scanning procedure during the filling process in March 2024, based on the data collected from the batches filled. The analysis includes the study of the lead times, which displays significant variation across batches, that leads to clear inefficiencies within the pre-implementation of the process The implementation of the mobile scanning system results in a significant reduction of lead-times. This demonstrates the effectiveness of optimization efforts when it comes to getting the right materials and making the best use of our resources. Standardization, automation, and the implementation of systems are crucial strategies that are needed to support these advancements and make them more productive, efficient, and profitable.

Introduction

The Aseptic Filling is such a critical role in the pharmaceutical industry due to the high importance of keeping parenteral products completely sterile, of high quality, and of high efficacy. The optimization of the syringe tubs scanning in the aseptic filling area is of the essence to make the operations smoother, have fewer mistakes, and attain the highest production rate. This research concentrates on designing a syringe tubs mobile scanning system with DMAIC principles (Define, Measure, Analyze, Improve, and Control) to be used for scanning syringe tubs in aseptic filling area. Regarding this, the main intent is to reduce the chances of mistakes, increasing precision, and improving efficiency. Ultimately, this study will be a guarantee of patients getting safe and high-quality parenteral drugs. Furthermore, there are a number of advantages such as potential cost savings and better regulatory compliance.

Background

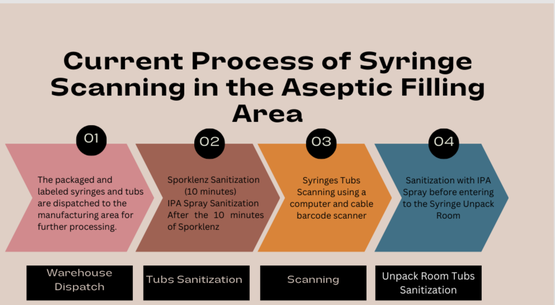
In recent years, the adoption of pre-filled syringe tubs in manufacturing has increased due to their productivity, safety, and convenience benefits. These tubs, preassembled with components such as a barrel, piston, plunger rod, needle, and needle shield, reduce manual assembly and contamination risks, thus enhancing process efficiency and lowering costs. Prefilled syringe tubs simplify filling and weighing operations, offering precise dosing and ease of use, making them ideal for healthcare. Sanitizing these tubs with Sporklenz solution and 70% IPA spray is crucial for maintaining product safety and quality. Additionally, integrating Manufacturing Execution Systems (MES) with mobile scanning devices improves inventory management, accuracy, and efficiency. MES systems, aligned with Lean principles, support continuous process improvement and effective decision-making. In multiproduct manufacturing environments, particularly in pharmaceuticals, efficient changeover processes, including syringe tub scanning, ensure compliance with specifications and regulations, minimizing delays and maintaining product quality.

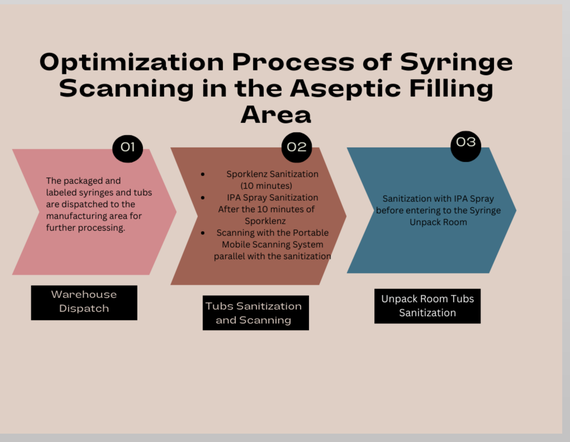
Problem

The pharmaceutical industry's aseptic filling process involves receiving syringe tubs from the warehouse, requiring accurate scanning to track inventory and syringe movement. However, the current manual scanning method with handheld devices is inefficient, leading to operational delays and potential production disruptions.

Methodology

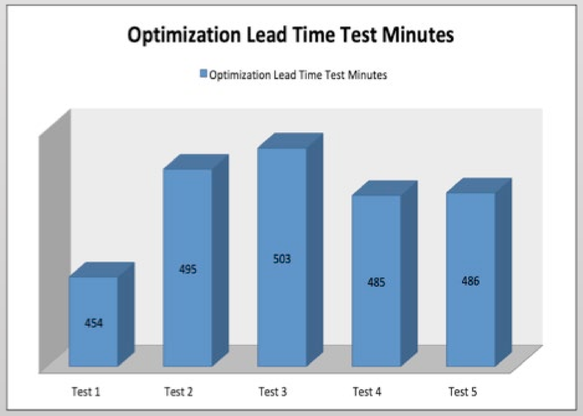
The research will use both quantitative and qualitative methodologies to achieve its objectives. Qualitative methods include in-depth interviews with key stakeholders such as operators, quality control personnel, and managers in the aseptic filling area, as well as direct observation of operations to understand existing processes and identify critical points for optimization. Quantitative methods involve collecting statistical data on the efficiency and effectiveness of the previous syringe tubs scanning process compared to the new portable screen mobile scanning technology. Data will be gathered through observations, time tracking, and error reporting, with statistical analysis quantifying improvements in scanner accuracy and speed. The DMAIC methodology will guide the research, with phases including Define, Measure, Analyze, Improve, and Control, to systematically address and improve the syringe tubs scanning process. Key steps involve process mapping, identifying inefficiencies, implementing new scanning technology, training employees, and establishing controls to sustain improvements.





Results and Discussion

This project aims to optimize the syringe tub scanning operation of the aseptic filling area by introducing a mobile scanning system. The main goal is to increase efficiency and precision by minimizing the workload of the scanning process. The project will include activities of researching and selecting an efficient portable scanning system, designing integration plan, checking and evaluating the system, implementing it and monitoring its performance after the implementation. Key stakeholders such as Aseptic Filling operators, Warehouse staff, Quality Assurance experts, information systems (IT) specialists for system development and management will play important roles in the project. Define phase, a project charter was developed, and research identified inefficiencies in the manual scanning process, such as it being slow, tedious, and error-prone. The Measure phase involved comparing the previous process, which included warehouse dispatch, multiple sanitizations, and scanning steps, to the proposed optimization using a mobile scanner. Analysis showed that before mobile scanning, lead times ranged from 753 to 1019 minutes with an average of 866.2 minutes. Following implementation, five test runs revealed that lead times decreased to between 454 and 503 minutes, indicating substantial efficiency gains and a reduction in errors. The Improve phase focused on deploying the mobile system and standardizing procedures to ensure consistency and reliability. The Control phase involves ongoing monitoring with a comprehensive plan to track key performance indicators (KPIs) like scanning accuracy, cycle time, and error rates. Additionally, continuous training programs and standardized operating procedures (SOPs) are being developed to ensure that operators can perform their tasks accurately and consistently, reinforcing these protocols through regular training sessions to maintain 100% compliance.



Date	Warehouse Dispatch Total Time	Tubs Sanitization Debox Area Total Time (Minutes)	Tubs Sanitization Syringe Unpack Total Time (Minutes)	Total Lead Time (Minutes)
26-Mar-2024	30	309	115	454
27-Mar-2024	31	335	129	495
28-Mar-2024	36	329	138	503
29-Mar-2024	32	326	127	485
30-Mar-2024	29	333	124	486

Conclusions

Adopting the comprehensive DMAIC Methodology analysis for improving the scanning process for syringe tubs that are utilized in the aseptic filling area with lead-time reduction as the primary objective has provided remarkable findings and lessons. In addition, the methodology has proven to be a useful tool in understanding process efficiency and performance within a shorter interval of time, mainly by getting rid of the steps that are not necessary and impacts the company metrics. The lead-time analysis in which the data from batches filled in March 2024 illustrated clearly how the mobile scanning system could ensure improved process efficiency. Before the application of a mobile scanning, the process was in multiple stages, which increase the changeover time. Across the five batches examined it was noted that batch Lead-Time displayed a variation with batch time ranging from 753-1019 minutes, thus underscoring potential bottlenecks and steps through the process can be improved. Following the introduction of mobile scanning technology, five test runs was conducted between March 26 and March 30 for which each run comprised of 1200 tubs. Each test run lead-time was dramatically reduced (average of 454-503 minutes) compared to the pre-implementation time, showing a very appreciable improvement. The contrast between the data before and after the introduction of the mobile scanning technology illustrates the optimization process performance. Moving ahead, operational metrics are to be continuously monitored and the processes are to be continuously rectified in order to minimize variability as well as enhance efficiency.

Future Work

The next steps for furthering this research on optimizing syringe tubs scanning in the aseptic filling area through a portable screen mobile scanning system involve close collaboration with industry experts and stakeholders will be pursued to gather feedback and insights, which will be used to refine and optimize the system's performance.

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References

[1] Sacha, G., Rogers, J. A., & Miller, R. L. (2015). Pre-filled syringes: a review of the history, manufacturing and challenges. Pharmaceutical Development & Technology, 20 (1), 1–11. [Online] Available: https://ezproxy.pupr.edu:2093/10.3109/10837450.2014.982825

[2] Parag V Ingle., Vivekanand Chatap., & Bhatia N.M (2014). Environmental Control of Parenteral Production. Journal of Pharmaceutical Research & Clinical Practice, 4(3), 22-32. [Online] Retrieved from https://www.rroij.com/open-access/environmental-control-for-parenteral-production.pdf

[3] Agalloco, J. P., & Carleton, F. J. (2007). "Validation of Pharmaceutical Processes". CRC Press.

[4] Cottyn, J., Van Landeghem, H., Stockman, K., & Derammelaere, S. (2011). A method to align a manufacturing execution system with Lean objectives. International Journal of Production Research, 49(14), 4397–4413.

[5] Li, Xiaoyan & Liang, Xuedong & Li, Zhi. (2023). "The Strategy of Strengthening Efficiency and Environmental Performance of Product Changeover in the Multiproduct Production System". SAGE Open. 13. 10.1177/21582440231193390.