Reliance 680PG Pharmaceutical Grade Washer Sample Management in Pharmaceutical Industry

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Abstract *— This research project focuses on the optimization of the equipment washing sample collection in the pharmaceutical industry when using from the company RELIANCE the model 680PG Pharmaceutical Grade Washer. This aims to introduce a new automated sampling system upgrade to reduce errors, improve the sample collection and to add accuracy during washing cycles, and enhance the quality control standards. By applying the DMADV methodology, the study seeks to enhance operational efficiency, refine processes, and boost the product quality. The project aims to streamline a sampling procedure, to improve timing for sample collection, and to promote precision, efficiency, and the reliability in pharmaceutical manufacturing. It also addresses error reduction, quality control enhancement, and providing tools for maintaining the focus and efficiency. Through systematic process for enhancement and quality assurance, the research aims to establish a new standard in the pharmaceutical manufacturing industry, ensuring a regulatory compliance and operational excellence.*

Key Terms *— DMADV method, Efficiency, Sampling system, Reduce errors.*

PROBLEM STATEMENT

In this chapter, we will discuss the situation in the pharmaceutical industry where I currently work, specifically with the collection of equipment washing samples we want to improve. Currently, the RELIANCE equipment, model 680PG Pharmaceutical Grade Washer, is used to clean multiple pieces of equipment [1]. During the different washing cycles, samples are taken to see if residues of something unknown are still shown. Although the equipment works based on autonomous recipes, the sampling phase is done manually in a specific step since the equipment does not have a phase where it automatically notifies the user that they must collect a sample. This execution represents a significant margin of error where the user working with this equipment can take the sample by mistake in an incorrect washing phase. This leads us to the fact that this system should be automated more so that it is the same that indicates the exact moment of taking the sample to the user; this would contribute to a reduction in human error and an increase in quality. [3]

Research Description

Approximately 70 bulk batches of different products are manufactured during the year. As previously described, multiple washes are carried out between them using RELIANCE equipment, model 680PG Pharmaceutical Grade Washer. This initiative is to automate it so that when the user must collect samples, the equipment issues a notice indicating that it is time to collect and make it at the right time. This process is investigated using the DMADV methodology during these batches since it would help us improve existing processes [2][3].

Research Objectives

Implement an automated sampling system within the RELIANCE equipment, model 680PG Pharmaceutical Grade Washer, to improve the accuracy of sample collection during equipment washing cycles. Reduce human error by developing a notification system that prompts users to collect samples correctly during washing. Enhance quality control by collecting samples at the precise phase, minimizing the risk of inaccurate or mistaken sample collection. Increase operational efficiency by streamlining the sampling process through automation, ultimately improving overall equipment performance and product quality in the pharmaceutical industry.[3]

Research Contributions

Part of what can be obtained using the DMADV methodology is that it helps improve existing processes, reduce human error, increase quality, and provide more tools to users to keep them focused. The DMADV methodology is a structured approach in Six Sigma that is used to enhance processes in pharmaceutical manufacturing. By following it, organizations can refine operations, reduce errors, improve quality standards, and provide resources to help achieve goals effectively.[2][3]

LITERATURE REVIEW

Automating the sampling process in the pharmaceutical industry is vital due to the critical nature of accurate data collection in ensuring product quality and safety. By introducing automated notifications within equipment like the "Reliance 680PG Pharmaceutical Grade Washer", the potential for human error during sample collection is significantly reduced. This error reduction translates to more reliable data, essential for compliance with stringent regulations governing the pharmaceutical sector. Moreover, automating the sampling phase minimizes the risk of incorrect sampling and enhances overall operational efficiency. With automated alerts prompting users at the precise moment when samples should be collected, there is a streamlined workflow that can lead to increased productivity and cost savings. Additionally, by standardizing the sampling process through automation, pharmaceutical companies can ensure consistency in their quality control practices, ultimately boosting the quality of their products and maintaining high manufacturing standards [3].

Automating this aspect of equipment operation contributes to a proactive approach to quality assurance. By shifting towards automated sampling, pharmaceutical companies can preemptively address potential issues and deviations, leading to early detection of anomalies and prompt corrective actions. This proactive stance improves product quality and helps maintain a strong reputation in the industry by demonstrating a commitment to excellence and regulatory compliance. In essence, the automation of the sampling process in pharmaceutical equipment like the "Reliance 680PG Pharmaceutical Grade Washer" is crucial for fostering a culture of precision, efficiency, and reliability in pharmaceutical manufacturing, ultimately contributing to enhanced product quality, regulatory compliance, and overall operational excellence [3].

STERIS Corporation's Pharmaceutical Grade Washers are designed to clean critical components in the pharmaceutical industry. The washers are built to ensure high-quality cleaning performance, compliance with industry standards, and reduced utility consumption. They offer features like monitoring critical parameters, various sizes for different applications, and support services for installation, validation, and ongoing operational assistance. The washers' cleaning performance is uncompromised, incorporating features like monitoring chamber spray arm rotation to ensure thorough cleaning of load items and monitoring Total Organic Carbon (TOC) in final rinse water for consistent cleaning results [3][4].

METHODOLOGY

The deployment of the DMADV methodology was instrumental in overseeing Reliance equipment's design and implementation process, including the model 680PG Pharmaceutical Grade Washer and the notification to collect a sample. DMADV, standing for Define, Measure, Analyze, Design, and Validate, is vital to Six Sigma's toolkit, ensuring a structured approach to project execution.

The DMADV methodology, also known as Define, Measure, Analyze, Design, Verify, is a structured approach used in Six Sigma to create new processes or products with a focus on quality. It involves defining the project goals and customer requirements, measuring and analyzing process options, designing new processes, and verifying the design to ensure it meets the desired quality levels before implementation. The DMADV methodology is typically used when an organization aims to develop a new product or process from scratch or when a significant redesign is needed to improve existing processes. It is employed when there is a need for a structured approach to ensure that the result meets or exceeds customer expectations and quality standards. This methodology helps in creating processes that are efficient, reliable, and capable of consistently delivering high-quality outcomes [2][3].

- **Define phase:** At the project's onset, the critical focus is clearly outlining the goals for enhancing or revamping the existing system. This initial stage encompasses pinpointing the areas of concern, devising a strategy, defining the project's boundaries, assessing available resources, and setting a timeline. Collaboration with the team is vital to distinctly define the project while aligning all plans and all goals with the organization's broader vision [2][3].
- **Measure phase:** At this phase, the proposed process of the Reliance equipment's design and implementation process, with the model 680PG Pharmaceutical Grade Washer adding the notification to collect a sample, is analyzed, and studied to determine whether there are better ways to achieve the desired results. Areas or systems that need adjustment or improvement in developing and implementing the template for the screen are identified by contacting the Reliance company directly and other budlings from the pharmaceutical manufacturing site that use the same equipment to get feedback. One budling has this system notification implemented. It is necessary to create a prototype setting at this phase to see how it works and to study it on my budling. This step aims to develop strategies to incorporate those and improve the process. For this project, I personally approached the employees who use this equipment to find out how the implementation of this notification would benefit them [2][3].
- **Analyze phase:** In this phase, we are involved in a detailed analysis and improvement process to design and implement a setting on the equipment. We aim to identify, collect data, and analyze to compare it with the specified requirements for adjustment and improvement. In this case, to see if a prototype for testing in our building will help refine strategies and enhance the overall process with a hands-on approach [2][3].
- **Design phase:** With what we learned in the analysis phase, the Reliance Pharmaceutical Grade Washer must create new recipes, adding the collect sample notification on the step corresponding to the pharmaceutical company's SOP. A representative from Reliance can do this design in conjunction with automation and engineering employees [2][3].
- **Verify phase:** When cleaning miscellaneous parts used for different processes, we want to verify and integrate a new feature that meets and exceeds the quality standards on a pharmaceutical site. Including the new recipes created to see if they work as they should and notify the user when it is needed to collect samples. This ongoing work on the site is being studied to be implemented [2][3].
- **Plan for Investigation:** Refer to the timeline in Figure 1 that is from (May 1, 2024, to May 31, 2024). Sample notification will be completed within a month. A period of one week from May 1 to May 8 was established for Information acquisition to learn how to apply the DMADV methodology to the project. During this week, we searched how the users know when it is time to take a sample if needed; a survey was made using Google Docs to know from the users of the equipment if it is beneficial to have a notification to sample. From May 9 to May 15, we begin to analyze the information for the Research Period. May 16 to May 22 Continuation of the Research Period we continue to analyze the information, add more

sources, expand the search with engineer and automation employees from the site where the equipment is used, and create new recipes with the notification for testing. May 23 to May 29 for the Design of the Sample Notification, a week for testing the system with the new implementations to see that all works and to see how users work with it. May 30 to May 31, the Implementation of the Sample Notification [3].

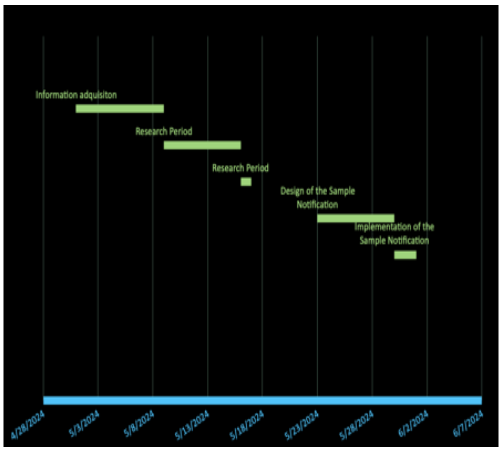

Figure 1
Project Timeline in May 2024

Results and Discussion

In this Chapter we are going to present the analysis of the results and discussion of the problem established on Chapter # 1 and how the design and implementation of the notification system that prompts users to collect samples correctly during washing [3].

Define

We will be defining the goals of this project using DMADV methodology for the design of the notification system that prompts users to collect samples correctly during washing. As per Chapter #1, this idea of creating this alarm focuses on optimizing the equipment to improve accuracy, reduce human error, enhance quality control, and increase operational efficiency whiting the pharmaceutical manufacturing using the DMADV to revolutionize the sampling process and elevate product quality standards [2][3].

Measure

We interviewed 7 Manufacturing Associates that have access to the “Reliance 680PG Pharmaceutical Grade Washer”. We wanted to know their thought about adding a sample notification and to know what they think about their current sampling. We created a Google Form to survey and analyze the responses that were anonymously. The two questions where in a basis of Yes and No. (1) If they think sample notification can prevent erroneous sampling, (2) currently think that a mistake could be made by taking a sample. In the following Figure 2 and Figure 3, we can analyze the answers:[3]

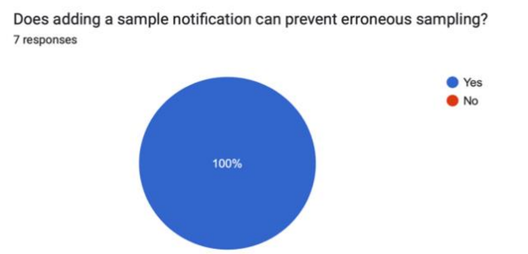

Figure 2
Does adding a Sample Notification can Prevent Erroneous Sampling?

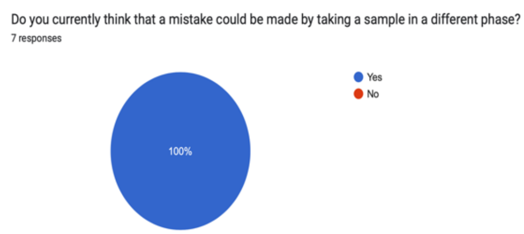

Figure 3
Do you Currently think that a Mistake could be Made by taking a Sample in a Different Phase?

Analyze

Figure 2 is presenting a question about whether adding a sample notification can prevent erroneous sampling. The options "Yes," "No," and "100%” were “Yes” suggesting that respondents agree that adding a notification can really prevent erroneous sampling. In Figure 3 likewise the options "Yes," "No," and "100%” were “Yes” suggesting that respondents agree that currently a mistake could be made without the notification. Analyzing this was found that this implementation would give the users of the equipment the ease that with every wash they are going to sample at the right time every moment [3][5][6].

Design

In the Design section, we will be explaining the development of the Sample Notification on "Reliance 680PG Pharmaceutical Grade Washer". We used Microsoft Word to design the cycle templates from the actual cycle and future cycle of wash and the future display for taking sample of the equipment. Refer to Figure 4 for the actual wash cycle with a yellow step where the user manually stops the equipment without notification following the pertinent SOP. Figure 5 presents the future wash cycle with a yellow step where the equipment will automatically stop and notify the user if required to take sample of the cycle. Figure 6 shows the future screen display to confirm if sample is taken if not only confirm [3].

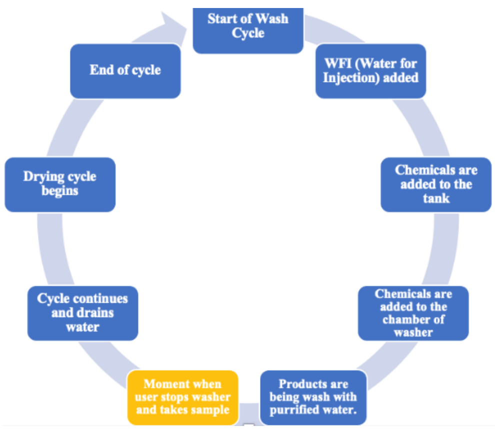

Figure 4
Actual Wash Cycle

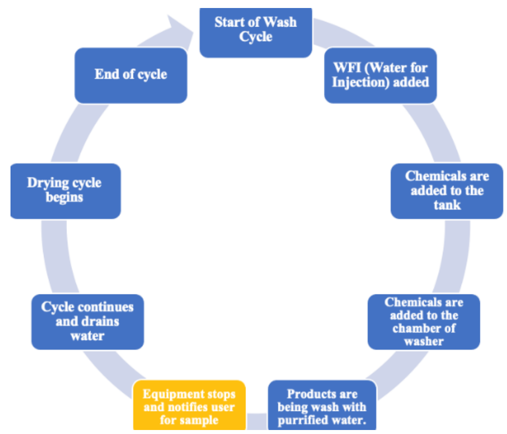

Figure 5
Future Implementation Cycle

Figure 6
Reliance 680PG Pharmaceutical Grade Washer Future Take Sample Display

Verify

In this section we will be discussing how we are going to verify that the design and implementation of the sample notification on the "Reliance 680PG Pharmaceutical Grade Washer" has been successful in other budlings that use the same equipment, meaning that if the system is implemented, we are going to be as successful with this as other budlings on the pharmaceutical manufacturing site. We included a Google Form to survey and analyze the responses that were anonymously [3].

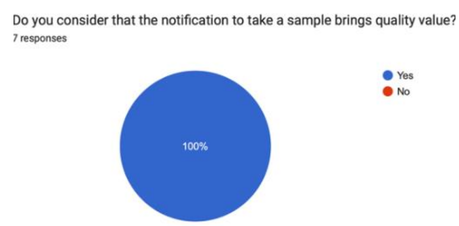

Figure 7
Do you Consider that the Notification to take a Sample brings Quality Value?

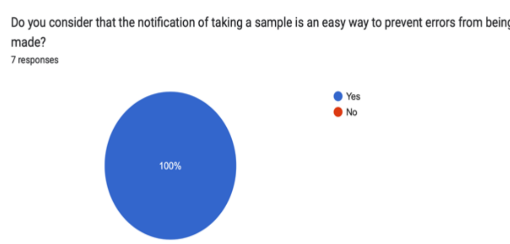

Figure 8
Do you consider that the Notification of taking a Sample is an easy Way to Prevent Errors from Being Made?

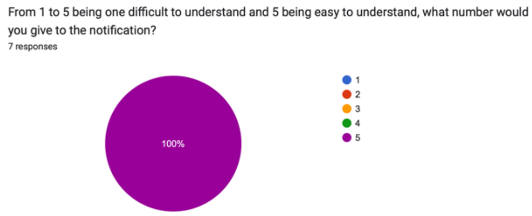

Figure 9
From 1 to 5 being one Difficult to Understand and 5 being easy to Understand, What Number would you Give to the Notification?

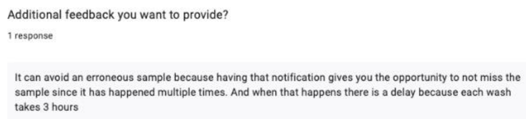

Figure 10
Additional Feedback you want to Provide?

Conclusion

This project has not only shed light on the potential benefits of the sample notification system but has also highlighted the collaborative effort between different parts of an organization to enhance the sampling process. By incorporating feedback from Manufacturing Associates and utilizing tools like Google Forms for data collection and analysis, we can see the feedback provided from Figure 7 to figure 9 where we have that a 100% of the participants assure this will bring quality value, that is an easy way to prevent errors, that is an easy system to understand and on Figure 10 one participant provided personal feedback that this would help on having the samples taken correctly and even avoid reprocessing washes. With this information we can say that the project has taken a user-centric approach to address existing challenges in sampling procedures [3].

The detailed design section illustrates the practical implementation of the sample notification system, emphasizing the transition from manual intervention to automated prompts for sample collection. The visual representations provided in Figures 4, 5, and 6 offer a clear depiction of how the system will integrate seamlessly into the existing workflow, ensuring timely and accurate sampling during the washing cycle [3].

As the project progresses to the verification phase, the focus on benchmarking success across the facility underscores a commitment to standardizing best practices in pharmaceutical manufacturing. By leveraging feedback and data-driven insights, the team aims to validate the efficacy of the sample notification system and ensure its wider adoption within the organization [3][5][6][7].

In essence, this project sets the stage for a transformative shift in sampling protocols, aligning with industry standards for quality control and operational efficiency. The journey towards implementing the sample notification system represents a strategic investment in enhancing product quality standards and advancing the overall reliability of pharmaceutical manufacturing processes [3].

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