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, sampling system, reduce errors, and efficiency.

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. 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.

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.

Table 1: DMAVD Methodology		Timel
(D) DEFINE	Information acquisition to learn how to apply the DMADV	May 1 – May 8
(M) MEASURE	Measure the information for the Research Period	May 9 – May 15
(A) ANALYZE	Continue to analyze the information	May 16 – May 22
(D) DESIGN	Design of the Sample Notification	May 23 – May 29
(V) VERIFY	Implementation of the Sample Notification	May 30 – May 31

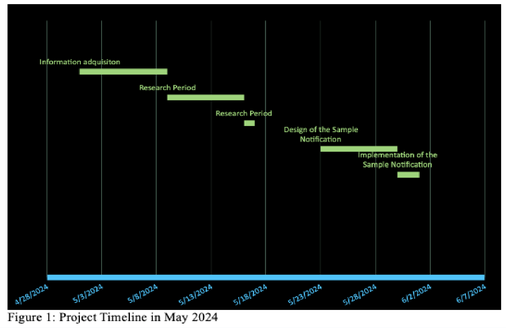

Figure 1: Project Timeline in May 2024

Results and Discussion

DEFINE PHASE

Table: 2 Project Chart Summary	
Description	Reliance 680PG Pharmaceutical Grade Washer Sample Management in Pharmaceutical Industry
Time	May 2024
Goal	Provide a notification when is time to take a sample and automatically stop the equipment in the correct step.
Benefits	**Associate Manufacturing** – Easy sample collecting error free. **Financial** - Reduce reprocessing. **Career Development** - New cross-functional role.
Support	Associate Manufacturing and users with access to equipment.
Members	Graduate student, Associate Manufacturing and users with access to equipment.

MEASURE PHASE

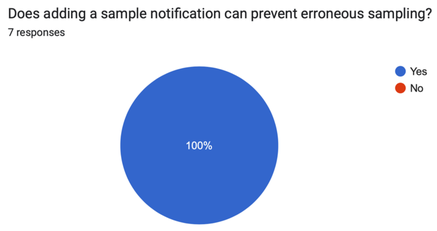

Figure 2: Does adding a sample notification can prevent erroneous sampling?

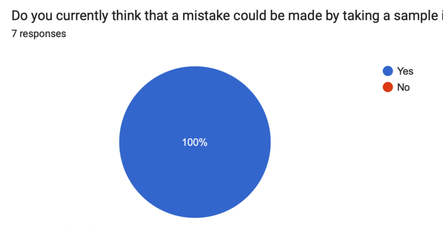

Figure 3: Do you currently think that a mistake could be made by taking a sample in a different phase?

ANALYZE PHASE

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.

DESIGN PHASE

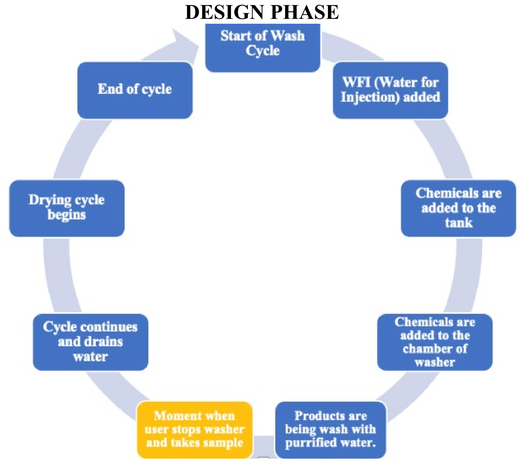

Figure 4: Actual wash cycle.

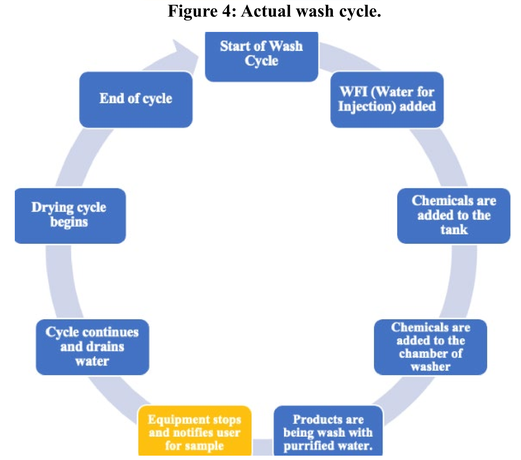

Figure 5: Future implementation cycle

Figure 6: Reliance 680PG Pharmaceutical Grade Washer future take sample display.

VERIFY PHASE

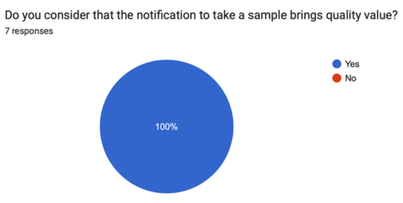

Figure 7: Do you consider that the notification to take a sample brings quality value? The 100% of the Manufacturing Associates responded that the notification brings quality value

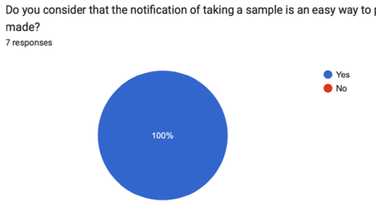

Figure 8: Do you consider that the notification of taking a sample is an easy way to prevent errors from being made? The 100% of the Manufacturing Associates responded that is an easy way to prevent errors during sample taking process.

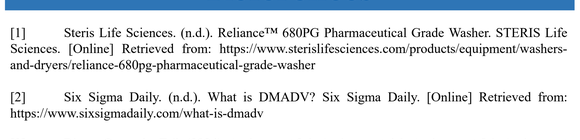

Figure 10: Additional feedback you want to provide? Only one Associate Manufacturing gave their feedback, affirming that the notification would help to have the wash samples taken correctly and even avoid reprocessing washes

Conclusions

This project showcases the collaborative effort and user-centric approach in improving sampling processes by transitioning to automated prompts. Visual representations demonstrate seamless integration into workflows, enhancing sampling accuracy. The focus on benchmarking success and data-driven insights aims to validate the system's efficacy for wider adoption. Ultimately, this project paves the way for improved quality control, operational efficiency, and reliability in pharmaceutical manufacturing.

The upgrade presented brings multiple benefits for the Associate Manufacturing and users plus benefit to the company. The success of this upgrade an its use is currently being studied for consideration and implementation in the pharmaceutical company I work for and is intended to provide ease to the employees and savings to the company.

Acknowledgements

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