Setup Time Reduction in the Water For Injection Sampling Process in the Pharmaceutical Industry

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Abstract

This work consists in the development of a new WFI sampling route that will bring several important benefits to the pharmaceutical industry. Reduction in the setup time will improve daily operations in terms of efficiency, budget, and cycle time reduction. A time study was done in this research that improve the WFI sampling time process for more than 50%, which was the current objective. Swimlane, SIPOC were used to illustrate the process. Furthermore, statistical analysis using mini tab were performed along with graphical illustrations. This research work concludes that the proposed setup time for WFI sampling process is more than 50% more efficient than the current one. Thus, improvement of daily operations is achieved in this work.

Project Description

This research will compare and reduce the cycle time process of WFI sampling in a regulated industry. Using tools like 5S, Lean Six Sigma, and Kaizen techniques will help to illustrate and compare more precisely the improved WFI process versus the current WFI sampling process on the site. This study is important since it will benefit this manufacturing company in several areas, economically, manpower expenditure, and cycle time reduction.

Objectives

- Compare and measure improvement for WFI sampling.
- Stablish cycle time improvement of more than 50% of the original sampling setup time expenditure process.
- Demonstrate how 5S concepts improve operations.

Methodology

This project will apply 5S, Swimlane, SIPOC and Lean Six Sigma tools in order to illustrate the results obtained. Quantitative statistical data with a confidence interval of 95% will be analyzed in order to compare the original setup time versus the proposed setup time. The standard deviation of both processes will be study in order to perform our comparisons.

Results and Discussion

Study and analysis of the collected data in the WFI monitoring process will take place. In addition, comparison of the differences between the current WFI monitoring process versus the proposed WFI monitoring process will be considered. Furthermore, measurement of the progress obtained by comparing and analyzing the standard deviation, normal distribution test and P value will be discussed. The comparison will be with a confidence interval of 95%. Three microbiology analyst participated on this research; the monitoring process was performed for two weeks.

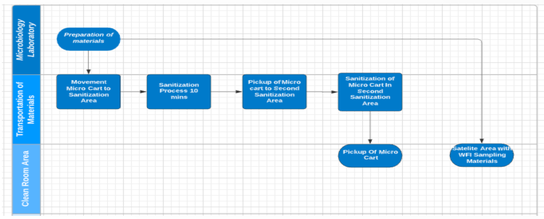

Figure #1 Swimlane Illustration of Process

Results and Discussion

On Figure 1 it is shown the process map using the Swimlane technique. On the left side can be seen the current process step which is Microbiology Laboratory, Transportation of Materials, and Cleanroom area. The arrows show the order on which the task is followed until the end of the process. Note that the new process implemented have only two steps, which is much simple.

Suppliers	Inputs	Processes	Outputs	Customers
Who supplies the process inputs?	What inputs are required?	What are the major steps in the process?	What are the process outputs?	Who receives the outputs?
New product development	Design and process CTQ's	Internal audit	Monthly quality report	Site management
Site quality steering team	External standards	Advanced quality planning	Corrective actions	Marketing leaders
Customer service	Quality control plans	Dock audit	Inspection and traceability records	External auditors
QC equipment suppliers	PFMEA risk factors	Control plan execution		
Warranty information system	Measurement equipment	Quality metrics reporting		
	Internal audit calendar	Continuous improvement		
	Customer complaints & warranty data			

Figure #2: SIPOC TABLE

One of the tools more commonly used for process improvement tasks is SIPOC, that stands for Suppliers, Inputs, Processes, Outputs and Customers. It summarizes the inputs and outputs of one or more processes using a table format as of Figure 2. In this table it is showed the specific departments or areas that may be affected.

Figure 3 One of the two Sanitization Rooms Areas

Figure 4 Satellite Material Area Inside Manufacturing Area

Results and Discussion

Week 1 Day's	Time setup 1 (minutes)	Setup Time 2 (minutes)
Monday	70.11	6.02
Tuesday	72.30	5.40
Wednesday	69.03	4.55
Thursday	75.07	5.10
Friday	68.26	6.20
Saturday	74.15	5.18
Sunday	77.09	4.99

Week 2 Day's	Time setup 1 (minutes)	Setup Time 2 (minutes)
Monday	71.32	5.55
Tuesday	72.11	5.36
Wednesday	70.35	6.08
Thursday	73.23	5.20
Friday	70.54	6.11
Saturday	75.49	5.10
Sunday	76.32	5.02

Figure #5: Data Time Collection for two Weeks

Figure 5 shows the time in minutes of two consecutive weeks. Setup 1 is stated as the original process and Setup 2 is the data collected from the new proposed process.

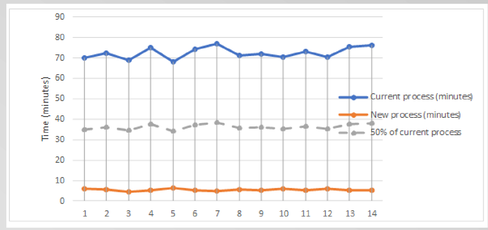

Figure 6 Graphical Comparison Between the Current Process and the New Process with the 50% Reduction Graphical Line

Assuming a Normal Distribution of Times in Both Processes

Current process (minutes)		*New process (minutes)*	
Mean	72.52643	Mean	5.418571
Standard Error	0.742102	Standard Error	0.134931
Median	72.205	Median	5.28
Mode	#N/A	Mode	5.1
Standard Deviation	2.776693	Standard Deviation	0.504866
Sample Variance	7.710025	Sample Variance	0.25489
Kurtosis	-1.11921	Kurtosis	-0.86815
Skewness	0.177103	Skewness	0.300374
Range	8.83	Range	1.65
Minimum	68.26	Minimum	4.55
Maximum	77.09	Maximum	6.2
Sum	1015.37	Sum	75.86
Count	14	Count	14

Hypothesis

$H_0: \sigma_1 = \sigma_2$

$H_a: \sigma_1 \neq \sigma_2$

Significance level is $\alpha = 0.05$

Test Statistic

$$F = \frac{s_1^2}{s_2^2} = \frac{7.710025}{0.25489} \approx 30.248445$$

P value for the test statistic,

$ValorP = 1.46 \times 10^{-7}$

Figure #7: Results From Statistical Analysis

Results and Discussion

Figure 7 shows there is enough evidence to establish a difference between the standard deviation of both procedures. Obviously, the deviation from the new process is significantly less than the current one.

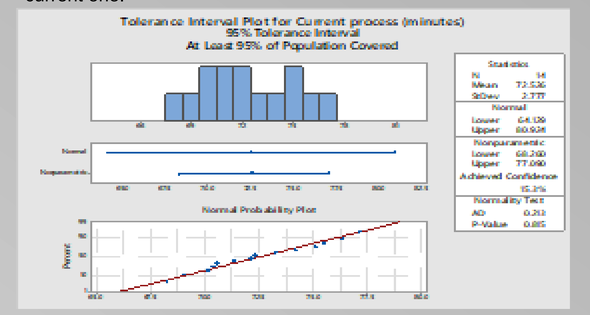

Figure #8 Normality Test Data For the Current Process

Figure 8 shows the normal distribution, and all the values were aligned quite close to the line. The P value found is 0.815, which determined that there is not enough evidence that the distribution is not normal.

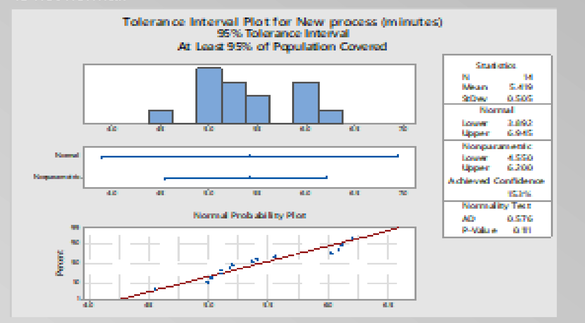

Figure #9 Normality Data Test For the New Process

Figure 9, shows the new procedure, the data is less aligned, but still appeared to be close to the line. The P value found is 0.111, so it is less than the current process. There is not enough evidence either to say that the data do not follow a normal distribution.

Conclusion

During this research and according to the results obtained, development and successful demonstration of improvement has been showed. Innovation and efficiency in the WFI sampling process had been stated. The most important finding during this research is the unexpected results of a progress of more than 50% of efficiency in the task. Establishing the 5S structure in the sampling process really helped the results. The contributions that the research brings are reduced the downtime in the WFI sampling process, increased productivity by eliminating waste and established positive economic impact to the pharmaceutical industry by reducing the process length.

References

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P.Hines & D. Taylor, (2000) *Going Lean*. Cardiff, UK: Lean Enterprise Research Centre Cardiff Business School, 3-43, 2000.