Parts Washer Filling Load Optimization

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Abstract

Parts washers are used in new manufacturing and remanufacturing processes; they are designed to clean, degrease and dry bulk loads of small or large parts in preparation for assembly, inspection, surface treatment, packaging and distribution. Part washer used to cleaning process of the filling configuration load at Parenteral Vial Area of the Biopharmaceutical located at Puerto Rico was evaluated for the amount the components in the load. During evaluation was determine that the components stablish for the load were few to the demand of the lots manufacturing for product. An evaluation was performed and the methodology DMAIC was choose to analysis the problem found in the filling configuration load in the part washer. The analysis was developed and the conclusion was reached to add additional components in the fill load to meet the manufacturing batch quantities per product. This change will generate a significant savings to the industry of $ 167,859.

Introduction

A global biopharmaceutical company focused on helping to address the unmet medical needs of patients with serious diseases. This biopharmaceutical has an opportunity for improvement in the Part washer Configuration filling load, located at Parenteral Vial Area (PVA).
Parts washer are currently qualified for use in the cleaning process of direct/ non-direct product contact parts, related to the A, B and C Drug Product manufacturing process. Each manufacturing lot of Drug Product requires several cleaning processes in the part washer to filling configuration load cycle. The research consists of reducing the number of cycles per lot by adding more components in the filling configuration load.

Background

Based on the current validated configuration load, various cleaning cycles might be required for processing filling components/parts in support to the manufacturing process of A, B, and C. As present condition, Five (5) parts washer filling load cycle runs have to be performed every A manufacturing lot, and three (3) cycles runs every B manufacturing lot.

A (product) filling lot requires nine (9) long tweezers, and B (product) requires six (6). Current filling configuration load for cleaning process has two (2) long tweezers only. Ten (10) additional Long tweezers will be validated for a total of twelve (12) Long tweezers in Filling Configuration load, therefore one (1) parts washer filling load cycle run will be performed to A manufacturing lot.

Problem

The purpose for this research is to include additional amount of non-product components to the Filling Part configuration load, in order to complete the required components for lots manufacturing, reducing multiple cleaning cycle performed. The proposed amount of additional components to be included in the validate configuration loads are summarized below table.

Table 1. Filling Configuration load

Before		After	
Maximum amount of component			
Component	Quantity	Component	Quantity
Long Tweezer	2	Long tweezer	12

Problem

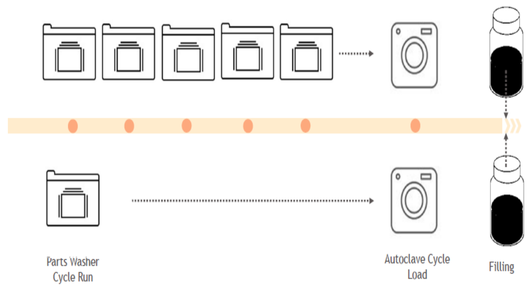

Figure 1 current vs proposed filling load configuration flow

Methodology

As part of Parts Washer Filling Load Optimization Project methodology includes Standard Operating Procedures (SOP) revision and cleaning verification study (Confirmation run). For this change no modification to the validated cleaning process, recipe and no changes to the drug product manufacturing process. This implementation will have no impact to the validated state of manufacturing process.
An evaluation was made and it was determined to use the DMAIC methodology for the development of analysis and results.
The DMAIC methodology is composed of the following steps:
• Define: Objective or scope of the Project.
• Measure: Having established some metrics to follow that help us to know the situation in which as maximum amount components in the configuration just be two components that are causing manufacturing time problems, we want to solve it, we must measure these parameters and establish a follow-up that allows us to analyze the situation later.
• Analyze: With the data that we have collected we will do an analysis of them, to try to find out the reasons why something is failing and we will apply the strategy of adding the components as a corrective action to be able to correct the problem and improve the cleaning process in manufacturing.
• Improve: All analyzes developed will be applied to improve the problem and solve it.
• Control: In the final project phase after completing all the improvements, the implementation will take place.

Results and Discussion

Define
Project Charter shows our preliminary understanding of roles and responsibilities, the objective of the project, and will be give the authority to do our job. See the table 5.
Measure
Current Filling Configuration load will be compared with New Filling Configuration load determine the improvement between two loads. Filling Configuration load are used in the part washer to cleaning process and then this part are used to complete required components for lots manufacturing. See the table 6. To Pareto diagram see table 7 and figure 2.
Analyze
The analysis of the load was based in that two (2) long tweezers only in the filling configuration load for cycle, was evaluated and identified as the primary root cause. The cause and effect Diagram shows the analysis. See figure 3.
Improve
The improvement plan include additional amount components to the Current parts Filling Configuration load, in order to complete the required components for lots manufacturing, reducing multiple cleaning cycles performed. As part of Analysis will be perform a cost analysis to compare the cost with Current Configuration load. See the figure 4 and table 8.

Results and Discussion

Control
As part of the implementation of project a cleaning verification study (confirmation run) was performed including the 10 long tweezer additional using the same recipe of the current filling configuration load in the part washer machine.

Table 5: Project Charter

PROJECT CHARTER	
PROBLEM STATEMENT	BUSINESS CASE
Present Condition Five (5) parts washer filling configuration load cycle runs have to be performed every A manufacturing lot, and three (3) cycles runs every B manufacturing lot. A (product) filling lot requires nine (9) long tweezers, and B (product) requires six (6). Current filling configuration load for cleaning process has two (2) long tweezers only.	The change will provide several benefits to Parenteral Vial Area, such reduced cost of utilities, equipment and labor. In addition, it will reduce the preparation processing time and generation of documentation; therefore, it will reduce the personnel workload and increase the time utilization. The consequences of not doing this project would be that the industry will lose money and time when the runs last a longer time due to the number of cycles it has for each filling confirmation load for each lot.
GOAL STATEMENT	TIMELINE
Obtain at least ten (10) additional Long tweezers for a total of twelve (12) Long tweezers in Filling Configuration load	Phase / Planned Completion Data Define 09-01-20 Measure 09-09-20 Analyze 09-17-20 Improve 09-22-20 Control 10-02-20
SCOPE	TEAM MEMBERS
Scope • Validate ten (10) long tweezers in filling configuration load for a total of twelve (12) long tweezers to obtain one (1) parts washer filling load cycle run to a (product) manufacturing lot. • Evaluation and assessment of new configuration load. Cleaning verification study (confirmation run) • SOP standard operating procedure revision Out of scope Unexpected situations encountered during the development of the project that impacted the deadlines.	Team Members Sr. Process Validation Scientist Engineering SME (Subject Matter Expert) Quality Assurance QA Manufacturing Supervisor or designee

Table 6 Loads Comparison

Current Filling Configuration load	New Filling Configuration load
For Filling configuration load has two (2) long tweezers for cycle run. For A (product) filling lot require nine (9) long tweezers = 5 cycles = 7hr 35 min For B (product) filling lot require six (6) long tweezers = 3 cycles=4hr 41 min Filling load part washer time= 1hr 47 min	For filling configuration load Ten (10) additional long tweezer are included. For a total of twenty long tweezers for cycle run. For A (product) filling lot require (9) long tweezers = 1 cycles=1hr 47 min For B (product) filling lot require six (6) long tweezers = 1 cycles=1hr 47 min Filling load part washer time= 1hr 47 min

Table 7 Data Collection Plan to perform Pareto Diagram

Loads	Run cycle time (hr)
Current Filling load (5cycles)	8
New Filling load (1 cycle)	2

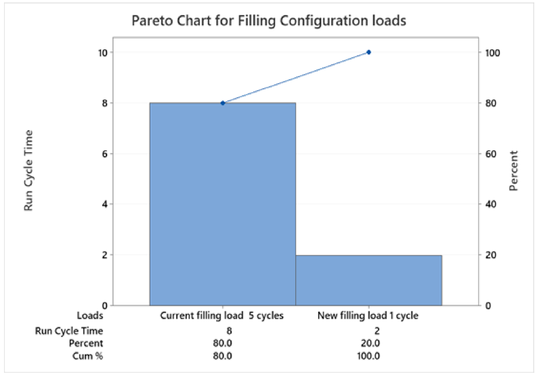

Figure 2 Pareto Diagram

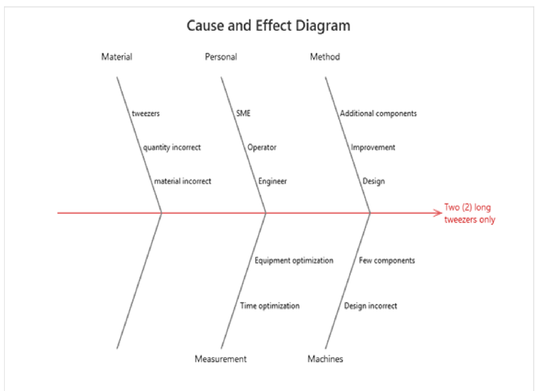

Figure 3 Cause and Effect Diagram

Results and Discussion

Figure 4 Benefits of optimizing parts washer filling load

TOTAL COST ($/YEAR)	Current Cost	Propose Cost
	$100,711	$37,422
	$40,723	$9,293
	$94,764	$21,624
Total	$236,198	$68,339
Diff.	$167,859	

Table 8 Costs Analysis

Conclusions

- As part of analysis of the Project, the Six Sigma DMAIC methodology was chosen for the development and improvement of the problem detected in the Parenteral Vial Area in the Part Washer loads. This methodology helped to determine the root cause of the problem and reach an effective solution by improving the tweezer cleaning process load in the Part Washer.
- Upon detecting the cause of the problem which was two (2) long tweezers only in filling configuration load for each cycle. Ten (10) long tweezers additional were included in the load and a confirmation run was performed to verify of load consistently comply with the requirements stablished.
- The run was completed and the results were satisfactory. The New filling configuration load was implement and release for manufacturing use. All Standard Operating Procedures (SOP's) that were impacted for this project will be revised.
- With the implementation of this project and the improvements obtained in the filling configuration load in the part washer located Parenteral Vial Area, the biopharmaceutical industry will obtain a total annual cost savings of $ 167,859.

Future Work

- Complete revision and approval of Standard Operating Procedures
- Closed Change Control

Acknowledgements

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