New Flow Route for the Delivery of the to be Cleaned Filling Equipment for the Lot-To-Lot Changeover Optimization Using the Lean Manufacturing Methodology

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Abstract

Focused on process improvement and downtime reduction an initiative started to reduce the lot-to-lot changeover for filling areas. A new flow route was added to the SOP to deliver the used filling equipment. This new flow route resulted in a reduction of 33% in movement waste and a 58% benefit of time spent on task for the Syringe Filling Line, and a 43% in movement waste and 67% time spent on task benefit for the Vial Filling Line. These results yielded a positive impact in time reduction for both filling lines.

Objectives

The objectives for this project are to successfully implement a new shorter flow route for the delivery of the to be cleaned equipment from the filling rooms to the wet component preparation room for the improvement of motion and transportation during the lot-to-lot changeover. Reduction of the ergonomic risk in the handling of the equipment during the transportation. Reduction of the transportation and motion waste by a 30% during the lot-to-lot changeover.

Introduction

The commercial demand in the filling areas has been on increase on the last years. The high commercial demand produced a demand to reduce downtime on the changeovers between batches, called lot-to-lot changeovers. Changeover can be defined as a change from using one system, machine, method, etc. to another [1], in this case the change that occurs is one filling batch to another filling batch. The to be cleaned equipment is the equipment used during the filling batch that needs to be delivered to component preparation for it to be cleaned. The equipment is transported inside of a Rapid Transfer Port (RTP), this is a device used to securely transfer materials from one place to another while preventing the contamination of the product. There are two stablished flow routes in Vial Filling, and one flow route in Syringe Filling for the used equipment delivery. The stablished equipment routes make the operators move the equipment from classified Grade 8, <100 CFUs, to Control Not Classified (CNC), an area with HVAC system designed to reduce airborne contaminants below the level of the ambient environment [2]. Moving the equipment from one area to another makes the task a two-operator job, because an operator from CNC must pick up the equipment and finish delivering it. This means less operators performing the changeover in the filling rooms and more equipment handling. This project looks to implement a new flow route for the filling equipment from the filling areas to wet component preparation staff.

Methodology

The first step to achieve the objectives for this project was to analyze the equipment delivery process and the stablished flow routes. The SOP has a different route for the delivery of used filters from the filling equipment. The filters are delivered to wet component preparation area by using a wall Pass-Thru that connects a Grade 8 corridor to Grade 9 Wet Component Prep Area.

This route was chosen as the proposed flow route (PFR) for the filling equipment because it reduces the handling of the equipment and the staff needed to perform the task of delivery. Using this Pass-Thru for the delivery of the filling equipment, and filters, allows for additional flexibility in the lot-to-lot changeover.

To ensure the selected route is the best flow route for the delivery of the equipment, a spaghetti diagram will be created to measure the steps and time used for each stablished route.

The measurements of volume inside the Pass-Thru and the equipment dimensions are going to be taken to calculate if it is possible to place the equipment inside the Pass-Thru without any safety issue.

An ergonomic evaluation by the EHS department of the Pass-Thru height, and filling equipment weight and handling will be conducted and a comparability with the ergonomic guideline design (Figure 1) will be performed.

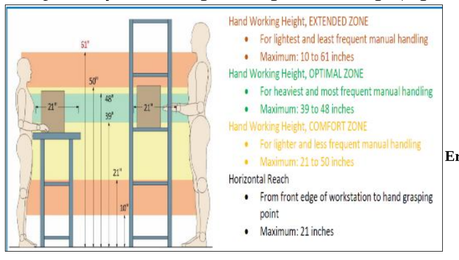

Figure 1
Ergonomic Guideline Design

The last step for this project is the review, update and approval of the equipment and material flow route SOP, in conjunction with PQA, to add the new flow route for the to be cleaned filling equipment. This step helps ensures compliance with the established regulations by the pharmaceutical and regulatory agencies.

Results and Discussion

This section summarizes the results obtained from the methodology section to ensure the Proposed Flow Route (PFR) is the optimized flow route. The PFR is the flow route to deliver the used filters by using a wall Pass-Thru.

Spaghetti Diagram

To ensure that the PFR is the optimized route, a spaghetti diagram was created (Figure 2). It revealed that the stablished flow routes by the SOP have more equipment handling than the proposed flow routes, each green and red dot represents the start and end movement of the filling equipment. This means that the stablished flow routes need at least two operators to deliver the used filling equipment while the PFR only need one operator to complete the task. A PFR had to be design for each filling line, the spaghetti diagram helped recognize the necessity of creating a PFR for the Syringe Filling Line and another for the Vial Filling Line.

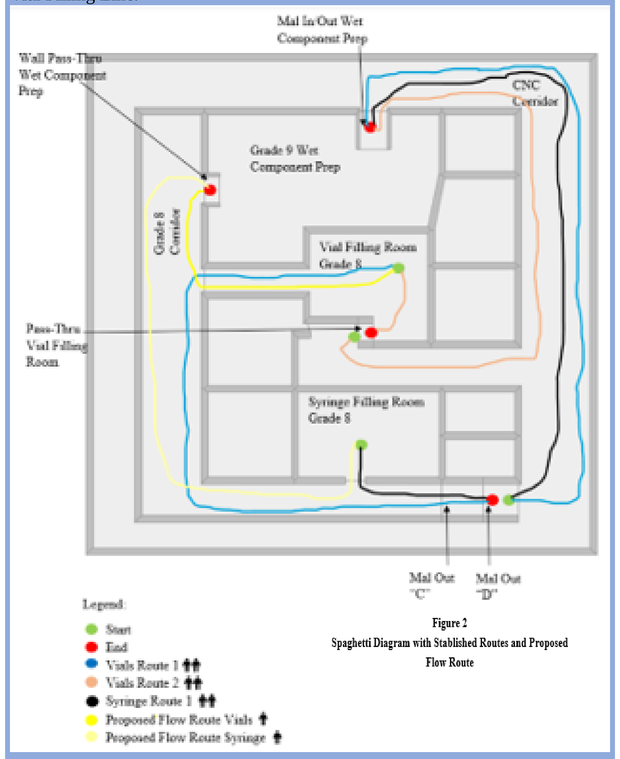

Figure 2
Spaghetti Diagram with Stablished Routes and Proposed Flow Route

Steps Taken, Time Spent, and Benefit

The time and quantity of steps were tabulated for each stablished route and the PFR for Syringe Filling Line (PFRS) and Vial Filling Line (PFRV) (Table 1).

Equipment Flow Route	Quantify of Steps	Time Spent (min.)
Stablished Vial Route 1	579	17
Stablished Vial Route 2	338	12
PFRV	192	4
Stablished Syringe Route 1	451	12
PFRS	300	5

Table 1
Steps Qty and Time Spent for the Stablished Routes and the PFRs

In Figures 3 and 4 the difference between the quantity of steps and time of each route can be appreciated. The PFR for both filling lines provide a greater benefit to the lot-to-lot changeover with four 4 minutes and 192 steps for the Vial Line and five 5 minutes and 300 steps for the Syringe Line.

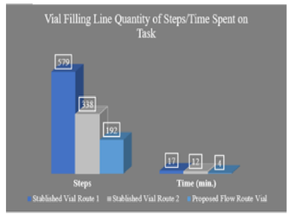

Figure 3
Vial Filling Line Quantity of Steps/Time Spent on Task

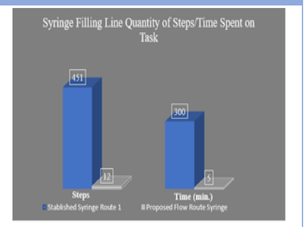

Figure 4
Syringe Filling Line Quantity of Steps/Time Spent on Task

Using the data from Table 1 the benefit obtained comparing the stablished routes with the PFR in time spent and steps taken while performing the task for both filling lines was calculated (Table 2). The obtained time benefit for Vial Filling Route 1 was 67%, for Route 2 was 4%, and for the Syringe Filling Route was 33%. The obtained benefit from the steps taken in the Vial Filling Route 1 was 67%, Route 2 was 43%, and Syringe Filling Route was 33%. These are significant benefits that makes a difference when performing the lot-to-lot changeover.

Table 2
Benefit Obtained Comparing Time Spent and Steps Taken

Filling Equipment Flow Route	Time Benefit%	Steps Benefit%
Vial Filling Route 1	76%	67%
Vial Filling Route 2	67%	43%
Syringe Filling Route 1	58%	33%

Safety

Security was considered for the new delivery point. The measurement from the interior of the Wall Pass-Thru and the filling equipment dimensions were taken (Table 3). Using these measurements, a sketch was made with the calculated area, and it shows that at least four 4 RTP can fit inside the Wall Pass-Thu without any safety issues (Figure 5).

Table 3
Measurement from Interior of Wall Pass-Thru and Filling Equipment Dimensions

Interior Wall Pass-Thru	
Long	32" ¼"
Width	27"
High	27"
Rapid Transfer Port (RTP) Dimension	
Diameter	12" ¾"
Height	21" ½"
Height with Valve	23"
Diameter with Handle	19"

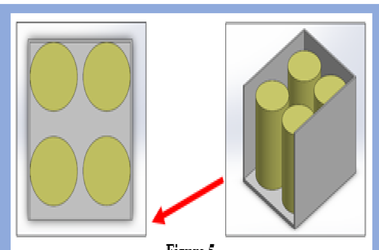

Figure 5
Sketch of Filling Equipment Inside of Wall Pass-Thru

Standard Operating Procedure (SOP)

The last step is the reviewal, update and approval of the SOP. The PFRs were added as alternative delivery routes to the equipment and material flow route SOP. The stablished flow routes were kept as backup in case the PFRs are not available. The SOP was reviewed and approved by the SOP owner and Plant Quality Assurance (PQA).

Once the revised version of the SOP became effective an official notification was sent to the affected areas with the new delivery instructions for the to-be-clean filling equipment.

Table 4
Risk Priority Score (RPS) Levels

Score Level	Risk
0 - 9	Low
10 - 30	Moderate
> 30	High

The administrative ergonomic controls recommended by the EHS department were implemented. The Job Hazard Analysis (JHA) for the Vial and Syringe Filling Lines, and Component Preparation were revised and updated with the activity of Rapid Transfer Port (RTP) handling.

The administrative control added to the activity was to follow the Good Ergonomic Practices; which are to be aware of awkward postures, maintain neutral postures, use tools to minimize material handling, keep materials close to the body, and to move feet instead of torso to avoid twisting. Rotation of tasks to reduce time exposure to heavy lifting was already in placed on the manufacturing floor but as a precaution it was also included on the JHA as an administrative control.

Ergonomic Evaluation

The ergonomic assessment by the EHS department for the handling of the RTPs at the Wall Pass-Thru was conducted to analyze and risk rank manual handling activities. The task was evaluated using the Humantech System. The Wall Pass-Thru has a height from floor to base of 39", which is inside the optimal working zone on Figure 1. The overall Risk Priority Score (RPS) of the task was 20.8, presenting a Moderate Risk (Table 4), due to identified potential ergonomic risk factors of bent wrist, twisted back, overhead reach, horizontal reach, awkward neck, and heavy lifting. The RPS was reduced to 8.9 with the implementation of recommended administrative ergonomic controls.

Conclusion

Using Lean Manufacturing methodology helped made the development of this project a more standardize process, as well as helped increase the manufacturing capacity by lowering the time spent on this task in the lot-to-lot changeover, a 58% benefit on the Syringe Filling Line and a 67% benefit on the Vial Filling Line, reduce transportation and motion wastes on both filling lines, 33% on the Syringe Line and 43% on the Vial Line. Therefore, increasing the productivity of the line.

References

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[4] N. Torres, "Process Optimization by the Application of Lean Manufacturing Principles." Polytechnic University of Puerto Rico, 2020. PUERTO RICO CLOUD REPOSITORY (PRCR): POLYTECHNIC UNIVERSITY OF PUERTO RICO, hdl.handle.net/20.500.12475/1050.

[5] J. Henry, "Introduction" in *Achieving Lean Changeover Putting SMED to Work*. 1st ed. New York: Taylor & Francis Group, 2013, ch 1, pp. 21-22.