Reducing Downtime Due to Glove Breakage in Manufacturing Areas

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Abstract *— Lean manufacturing was developed for maximizing resource utilization through the minimization of waste. During certain tasks in the Manufacturing Area, gloves tended to break. I propose that we need to reduce the walk distance by installing glove stations in different parts of the factory. This could reduce the time of unnecessary skin exposure and prevention of the product to be compromised. Gowning rooms should be equipped with glove stations for easy replacement if gloves are broken during or after the gowning process. Gloves need to be replaced quickly in case an employee needs to enter for an urgent task.*

Key Terms *— Lean Manufacturing, Manufacturing Area, Time Reduction, Waste Reduction.*

PROBLEM STATEMENT

During certain tasks in the manufacturing area, gloves tend to break. As part of the Personnel Protective Equipment (PEE) and the aseptic techniques, associates need to wear gloves at all times, and those gloves need to be in perfect conditions, so the skin is not exposed and the product is not compromised. If gloves break, the associate needs to replace them immediately, but new gloves used to be available only in the gowning rooms. This manufacturing area has three floors and many rooms, so the gowning rooms were too far to carry out the replacement. Inside the manufacturing area there are some sterile gloves that are only used to collect samples and to perform process inoculation. Some associates tend to use these sterile gloves so they would not have to walk all the way to the gowning room to replace the broken ones. This project proposes that the walking distance should be reduced by installing glove stations in strategic areas, which would bring cost reduction because they would not use the sterile gloves, which are more expensive and have a specific use; reducing the time the skin is unnecessarily exposed; and prevention from the product to be compromised or even contaminated since this is a bulk manufacturing area with mammalian cell processes.

RESEARCH DESCRIPTION

- To reduce and avoid skin exposure in manufacturing areas due to broken gloves.
- To avoid downtime due to walking to the gowning rooms to replace broken gloves.
- To avoid delays in case an employee needs to enter quickly to support any urgent task.

RESEARCH OBJECTIVES

- Install glove stations in the clean side of the gowning rooms for easy replacement if gloves are broken during or after gowning process.
- In order to reduce time waste in 90% in the manufacturing areas from walking the far distance to the gowning rooms, evaluate the installation of glove stations for tasks in which gloves are frequently broken and skin is exposed until finding a replacement in the gowning rooms.

RESEARCH CONTRIBUTIONS

- **Time reduction:** The associate will not have to walk a long distance to replace their gloves and come back to perform the task or process they were doing.
- **Cost reduction:** By installing the glove stations, the associates will not have to use the sterile gloves that are more expensive and are designed to be used in sterile processes such as sampling collection and inoculation processes.

- **Quality (Safety/Prevention):** Having access to replace the broken gloves leads to a rapid change of gloves, which results in minimal skin exposure for the safety of the employee and the integrity of the product (Contamination Prevention).

LITERATURE REVIEW

Lean manufacturing, lean production, or often simply Lean is a production practice that considers the expenditure of resources for any goal other than the creation of value to be wasteful and thus a target for elimination [1].

The concept of lean manufacturing was developed to maximize resource utilization through waste minimization. Later on, lean manufacturing was formulated in response to the fluctuating and competitive business environment. In operational work processes, value-adding (VA) and waste (W) can be measured in terms of parts of cycle time. Ideally, according to the Lean Manufacturing (LM) theory, all activities in a cycle of a process can be classified either as VA or W, and be summed up to 100% of the cycle time [2].

We met with management to formally present our productivity and safety proposal, in which we sought to create additional glove stations in the manufacturing areas with the purpose of reducing and preventing unnecessary skin exposure whenever gloves broke within the clean area. We also aimed to reduce the time they were exposed and the walking distance to the gowning room to replace the broken gloves with new ones, to avoid the manufacturing associates had to de-gown to make this replacement and gown again to go back to the manufacturing area since the gowning room is divided in half and the glove station is at the entrance of the gowning room. Another aim was to reduce cost, since the gloves that were more readily accessible in the manufacturing area were sterile gloves, which are designed for the execution of specific processes in which the aseptic techniques are greater, such as the inoculations of product cells or the collection of culture samples. For the other tasks, these sterile gloves are not required, and they carry a higher cost, so if they are used for everything, it will lead to more company expenses.

The proposal was accepted by the manufacturing area management, and we proceeded to evaluate the different areas or suites, together with the facility's staff, to identify the best locations for the new glove stations. A presentation was made to communicate the purpose, benefits, details of the locations, and profit of the project. A memo was also generated addressed to the work order of the glove stations installation, approved by the project leaders, a representative of the maintenance area, a validation representative, and a quality assurance representative, in which the installation of 15 additional glove stations in the Upstream and Downstream areas was proposed. Also, the memo contained the locations of the rooms with a diagram of the place where it would be installed, an evaluation of where the gloves would be installed clarifying that it did not affect or interfere with the environmental monitoring of the room or suite and that it did not require changes to the environmental monitoring qualifications drawings of the room.

This installation or change did not affect the current validated state of the rooms. The rooms where these additional glove stations were to be installed were Upstream (Media Prep Area, Cell Culture Suite, Cell Culture Lab Area, Harvest Area, Component Prep Area, Inoculation Room Area) and Downstream (Buffer Prep Area, Bulk Filtration Area, BDS Area, Purification Area, Component Prep Area, ATL Lab Area).

METHODOLOGY

For this problem, we use both methods: quantitative and qualitative. The quantitative method was used to identify patterns and make categories. The qualitative method was used in interviews. These interviews allow us to gain more information from the associates who work in the different areas of manufacturing, and they give their perspective on where these stations should be located. They also help us in finding in which task

the rupture of the gloves was a more common occurrence.

The surveys were conducted in the manufacturing areas in all shifts (first, second, and third). We randomly selected five associates from each shift for a total of 15 associates interviewed; there are around 17 associates per shift. The interviews were conducted at their work area and lasted approximately 15 minutes for each staff member. The answers were recorded by note-taking. We described the problem observed to each associate and then proceed to ask them the following questions:

- How often do your gloves break?
- What are the tasks during which gloves break more frequently?
- What do you do to replace the broken gloves?
- Do you have accessible gloves near your work area?
- What would you recommend to solve this problem?
- Where would you place a glove station for replacement?

Identifying patterns and making categories quantitively helps us through the analysis and to generate the correct questions for the interviews in the qualitative method. These interviews allowed us to gain more information from the associates who work in the different areas of manufacturing, and who gave their perspectives on where these stations should be located. They also helped us in finding in which task the rupture of gloves was a more common occurrence.

After finishing the interviews, we proceeded to categorize the answers and analyze them to gain a deeper understanding of the associates and the specific place these glove stations were needed to reduce the walk distance. These answers also strengthened our hypothesis that more glove stations should be installed in different points of the manufacturing areas.

From the interviews, we categorized and identified the different tasks during which gloves tend to break more frequently in the manufacturing area (figures 1 and 2).

These tasks were the following:

- Working with filters
- Vacuum test (Component Prep Area)
- Gowning (Shoe cover replacement, zippers)
- Transfer panel connections
- Clamp installations
- Crimping process to collect samples
- Climbing vertical ladders
- Mechanical interventions
- Valves troubleshooting

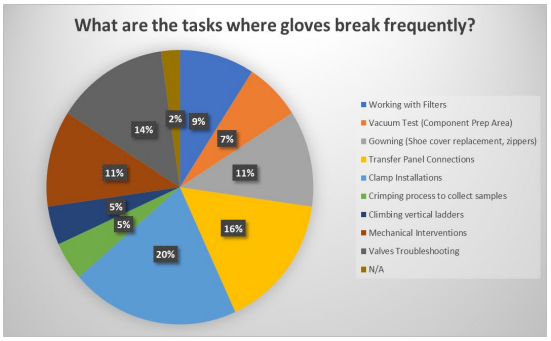

Figure 1
Tasks During Which Gloves Break More Frequently

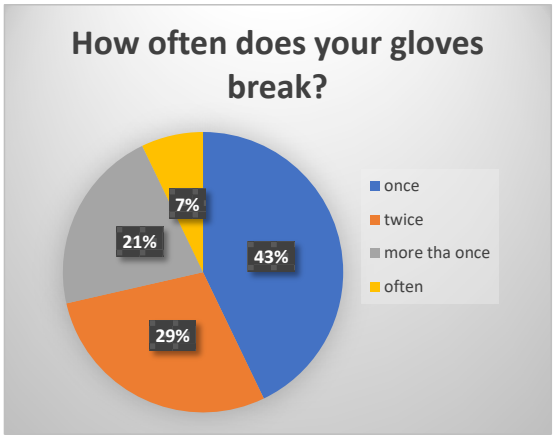

Figure 2
Frequency of Gloves Breaking

Any unimportant action that generates unnecessary results is referred to as waste. Lean manufacturing works on the methodology to eliminate waste, as it reduces industrial output and effect on industrial performance [3]. In order to assess the current state of the downtime due to glove breakage and associated PPE change, the process was stratified into two different

measurements: 1) the walking time to and from the Gowning area was timed, and 2) the actual PPE change time in the Gowning from the dirty area and back to the clean area. The team collected 50 observations, the data of which were summarized in figure 3. Depending on how far the room was when the gloves broke, different distances/time is needed to walk to the gowning area and back to the manufacturing room. In average, 15 minutes are consumed on a full lap, ranging from 8 to 21 minutes.

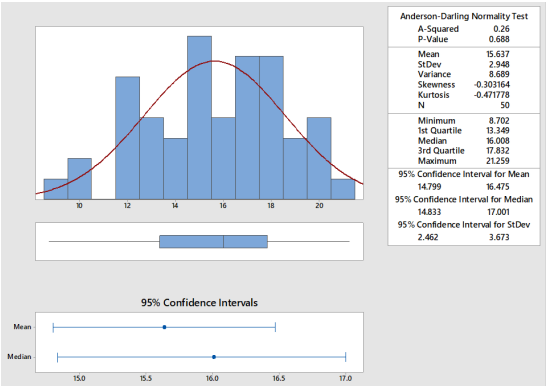

Figure 3
Summary of Walking Time Report Before Glove Stations were Installed

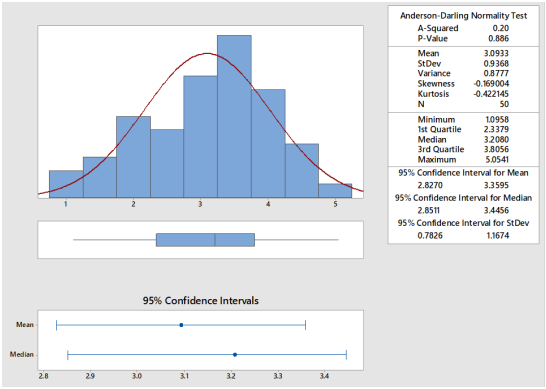

Figure 4
Summary of Walking Time Report After Glove Stations were Installed

As part of the project implementation, multiple glove stations (15) were installed at strategic locations throughout the manufacturing areas, in order to minimize the need to walk all the way to the gowning room. The average distance to any given manufacturing suite and the new glove stations was dramatically reduced, as well as the time needed to change PPE once glove breakage occurred. Also, nitrile glove availability was ensured, avoiding the need to use sterile gloves, which are more expensive and required for specific processes. 50 observations were collected in order to compare the transport time needed. On average the walking time was above 3 minutes, ranging from 1 to 5 minutes (figure 4).

Current glove changes required manufacturing associated with de-gown and re-gown, given that they needed to exit the clean area. This meant replacing not only the gloves but the full gown. There are various factors that affect gowning times once the process is initiated. For each trip lap monitored, the gowning time was measured: an average of 7 minutes were employed in this activity, ranging from 2.19 to 9.8 minutes (figure 5).

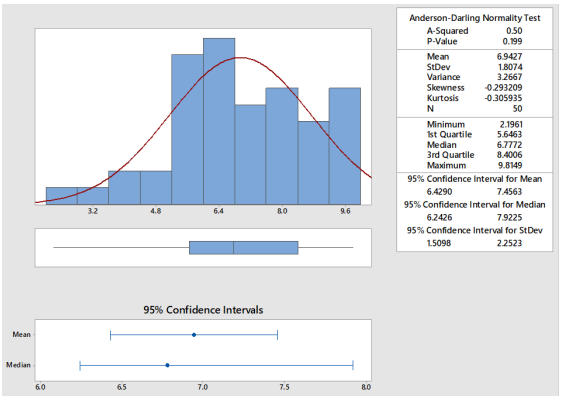

Figure 5
Summary of report for gowning before glove stations were installed

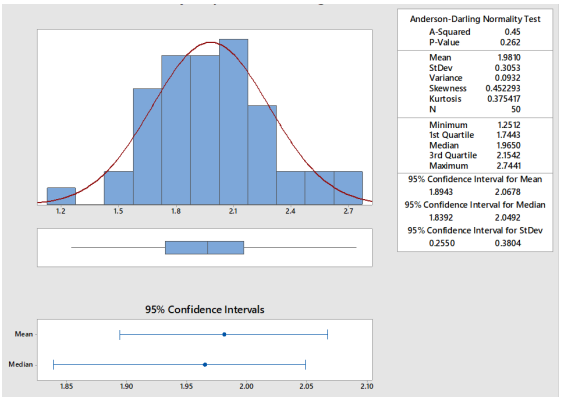

Figure 6
Summary of Glove Change Report After Stations were Installed

After project implementation, the glove stations eliminated the need to walk all the way to the gowning area. In addition, since the associate remained within the clean bounds of the building, their gown was not required to be changed completely; only the broken gloves are discarded appropriately and replaced. This operation was monitored to compare it to the previous process. In average, less than 2 minutes were needed to change gloves, ranging from 1.2 to 2.4 minutes (figure 6).

A box plot of the lap times to walk to and from the manufacturing suites and the changing points compares the two data sets visually, and the means of both process pre and post-implementation of the glove stations are graphed. Shortening the distance from any manufacturing suite to the closest glove station (15 stations) shows an average reduction in transportation time of 12.5 minutes (figure 7).

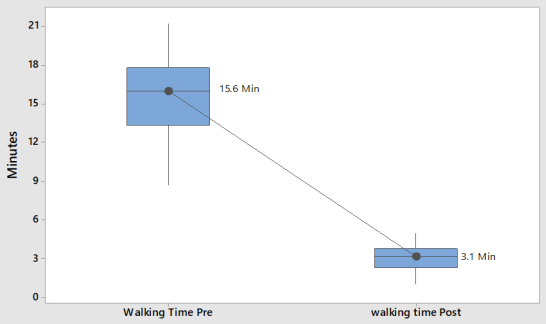

Figure 7
Box Plot of Downtime Reduction of Distance Walked

In order to assess whether the meantime for the walking/transport and PPE change activities has improved significantly, a two-sample T-test was employed in order to compare the sample mean times and assess whether these are statistically equal or not. If these two process times were equal, the difference between walking time pre- and post-implementation should be zero; a 95% confidence interval (CI) should contain zero in it. On the contrary, if the mean difference and a 95% CI do not contain zero, it would be statistical evidence that the process mean times are statistically different from one another.

Results of the two-sample T-test for a walking time yielded a difference of 12.5 minutes; 95% CI for means do not contain zero, P-value of 0.00 rejecting the null hypothesis that the difference in the sample mean was zero (figure 8).

μ_1: mean of Walking Time Pre

μ_2: mean of walking time Post

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Walking Time Pre	50	15.64	2.95	0.42
walking time Post	50	3.093	0.937	0.13

Estimation for Difference

Difference	95% CI for Difference
12.544	(11.668, 13.419)

Test

Null hypothesis	$H_0: \mu_1 - \mu_2 = 0$
Alternative hypothesis	$H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
28.68	58	0.000

Figure 8
Two-Sample T-Test and CI: Pre and Post Implementation Waking Time

With the new glove stations available within the clean area of the manufacturing shopfloor, the need to de-gown has been eliminated completely. In its place, only broken gloves need to be discarded and replaced. A meantime reduction of 4.9 minutes for PPE change has been achieved (figure 9).

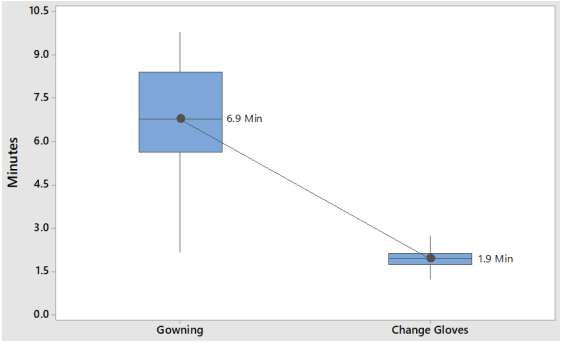

Figure 9
Box Plot of Downtime Reduction of PPE Change

Results for the two-sample T-test for gowning and glove change times yield a difference of 4.9 minutes, 95% CI for means does not contain zero. A P-value of 0.00 rejecting the null hypothesis that samples mean difference were zero (figure 10).

μ_1: mean of Gowning

μ_2: mean of Change Gloves

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Gowning	50	6.94	1.81	0.26
Change Gloves	50	1.981	0.305	0.043

Estimation for Difference

Difference	95% CI for Difference
4.962	(4.441, 5.482)

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$

Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
19.14	51	0.000

Figure 10
Two-Sample T-Test and CI: Gowning and Changing Gloves

After evaluating the improvement of the process, it can be concluded that the implementation of glove stations proves to address a significant reduction in waste transportation and PPE change times for the required activities whenever gloves break in the manufacturing process. An average total downtime reduction of 17.4 minutes was an improvement per any given broken glove occurrence by eliminating the need to de-gown and re-gown and significantly reducing the walking distance/time in order to execute said PPE change.

Figure 11
3-Slot Glove Dispenser (REY1693)

After these results were explained to manufacturing managers, they approved a budget to buy the 15 new 3-slot glove dispensers (REY1693) (figure 11) and proceeded to install them in the different areas. This dispenser was made from 304Brushes stainless steel, which is allowed inside manufacturing areas. It also has an all-welded construction and is easy to clean.

The process of identifying the problem and proving it with the help of the manufacturing staff was easy and fluid. The limitations, or the tough work, came from choosing the points where the new glove stations were to be installed. These rooms have P&ID diagrams that tell us where we can install or place things since these rooms have HEPA filters and are categorized as classified. This action or modification must go through work order and approval and also puts the room out of service, which meant that a new temporary flow diagram needed to be done so that staff could enter the area.

REFERENCES

[1] M. V. Iuga and C. V. Kifor, "Lean manufacturing: The when, the where, the who," *Land Forces Academy Review*, vol. 18, pp. 404-410, 2013 [Online]. Available: https://www.researchgate.net/publication/305373927_Lean_manufacturing_The_when_the_where_the_who.

[2] P. Johansson and C. Osterman, "Conceptions and operational use of value and waste in lean manufacturing – an interpretivist approach," *International Journal of Production Research*, vol. 55, no. 23, pp. 6903-6915, 2017. [Online]. Available: doi.org/10.1080/00207543.2017.1326642.

[3] N. Kumar et al., "Lean manufacturing techniques and its implementation: A review," *Materials Today: Proceedings*, vol. 64, part 3, pp. 1188-1192, 2022 [Online]. Available: doi.org/10.1016/j.matpr.2022.03.481.