



Author: Carilin Ortiz de Jesús

Advisor: Dr. José A. Morales

Master in Manufacturing Competitiveness

Abstract

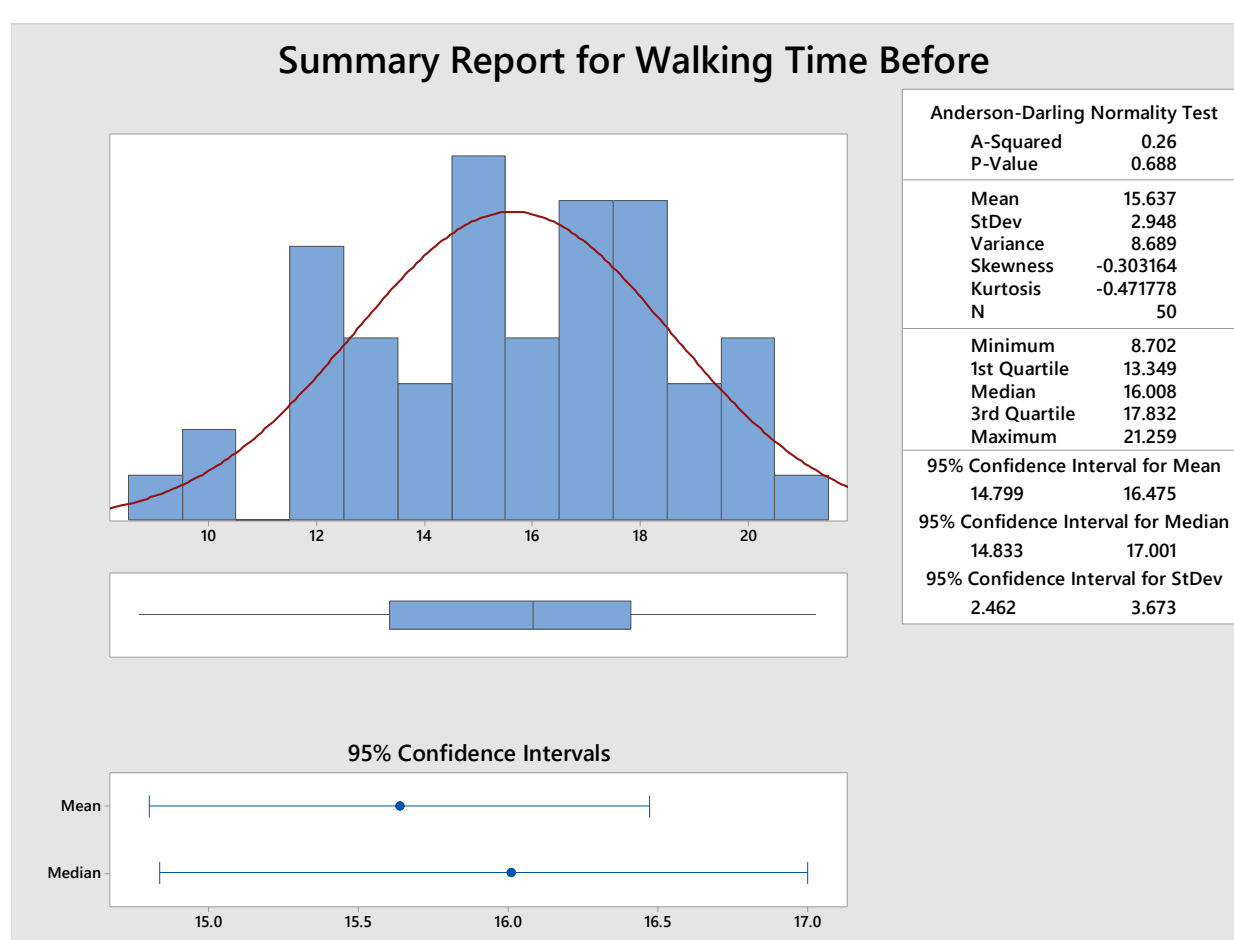
During certain tasks in the Manufacturing Area of pharmaceutical biologics process, nitrile gloves used as Personal Protective Equipment tended to break. Process downtime and skin exposure occurs until the associates replace the gloves in the gowning areas far from point of use. Evaluating the time needed for distances walk and gowning change per occurrence, downtime due to glove breakage was determined. Lack of access close to point of use was evaluated, glove stations were identified and installed strategically throughout the MFG Area reducing the distances, time and quantity to be replaced once a glove breakage occurs. A total downtime reduction of 17.4 minutes in average was able to be improved per any given broken glove occurrence.

Introduction

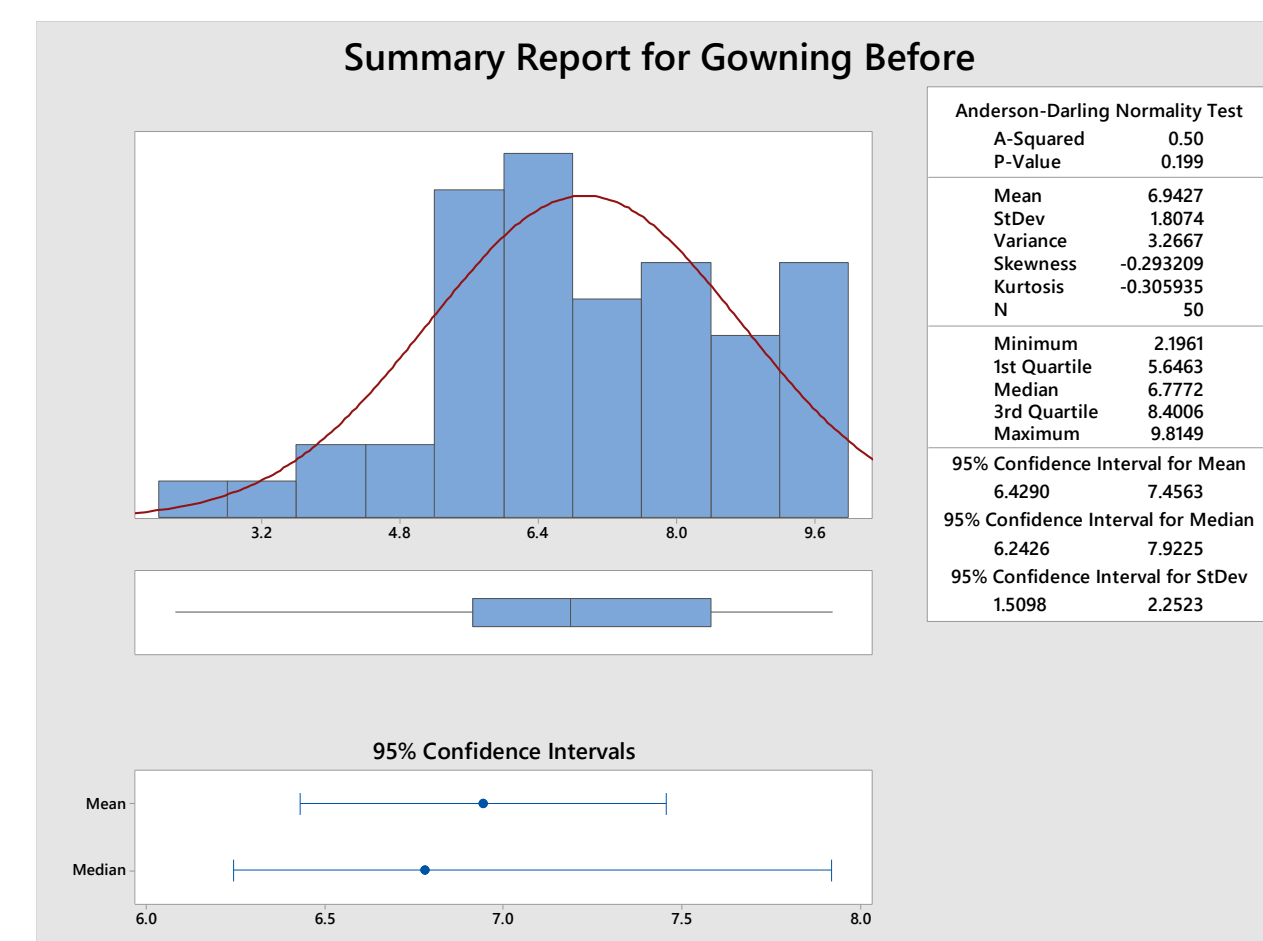
Glove breakage is inherent to the MFG operations for multiple reasons. Gloves need to be replaced immediately after breakage to avoid product contamination and skin exposure. Original point of PPE change was designated on gowning rooms that are located at entrances of MFG area, which are far from point of use rooms and suites at other end or different floor levels of the building. In order to enter the gowning rooms to changes broken gloves, associates needed to pass outside the designated clean area, therefore complete gowning needed to be replaced adding time besides walking to and from the gowning room.

Background

Distances walked to and from the MFG rooms is one of the two downtimes derived from current lack of strategic access to gowning changing points. 15.6 minutes in average are expend on this activity.



Entering the Gowning room clean area is exited, hence complete PPE needs to be replaced (not only the gloves) 6.94 Minutes are spend in average every time de-gowning and gowning is needed. This time is added to downtime of transportation to and from point of use.



Problem

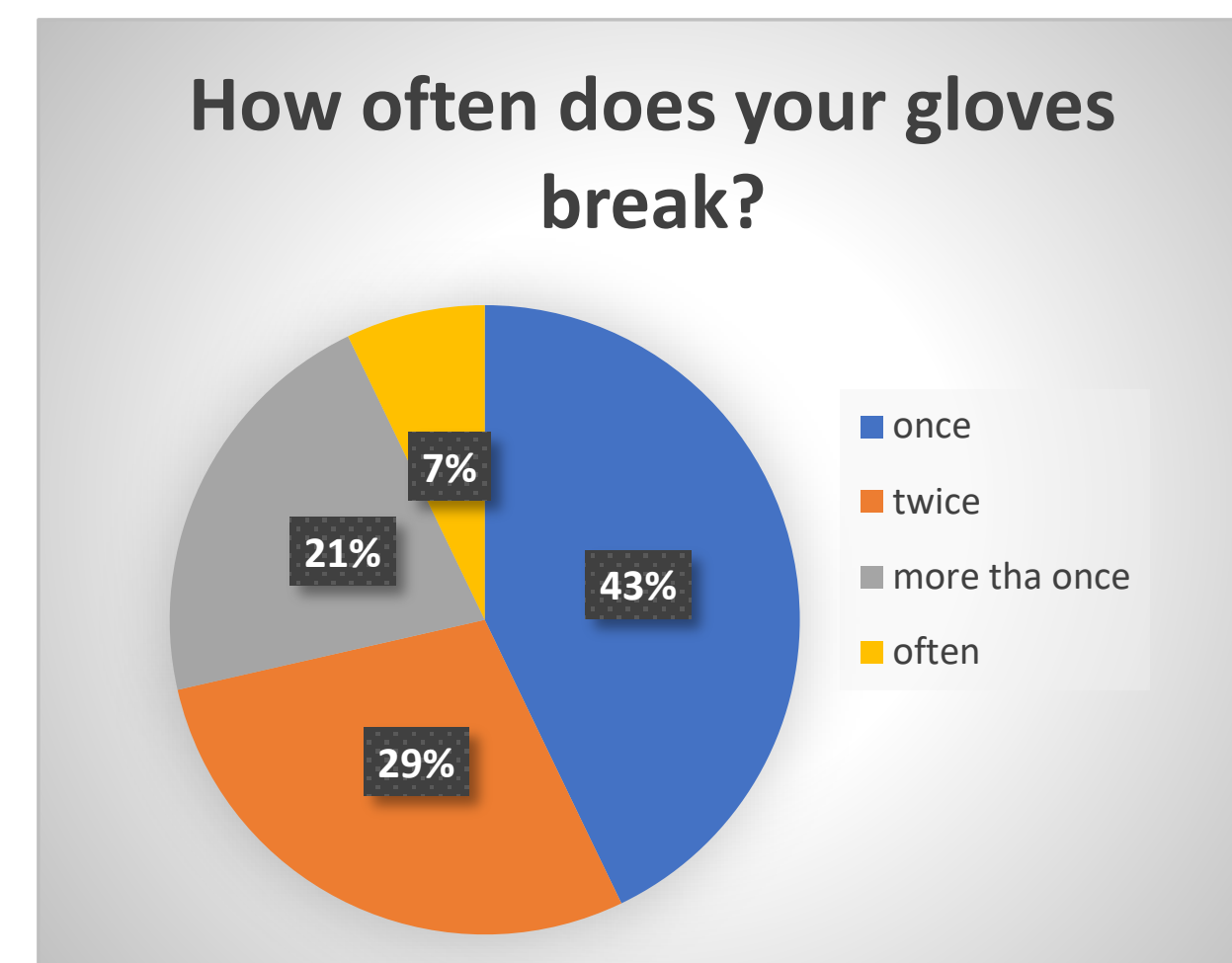
As part of the PPE and aseptic techniques, associates need to always wear gloves, and those gloves need to be in perfect conditions, so skin is not expose and product is not compromised. If gloves are broken, the associate needs to replace them immediately, the new gloves were only available in the gowning rooms. This MFG area has three floors and many rooms, so the gowning rooms were far to perform the replacement. Some associates tend to use sterile gloves which are available in the clean area instead of the nitrile gloves, so they did not have to walk all the way to the gowning room to replace the broken one.

Methodology

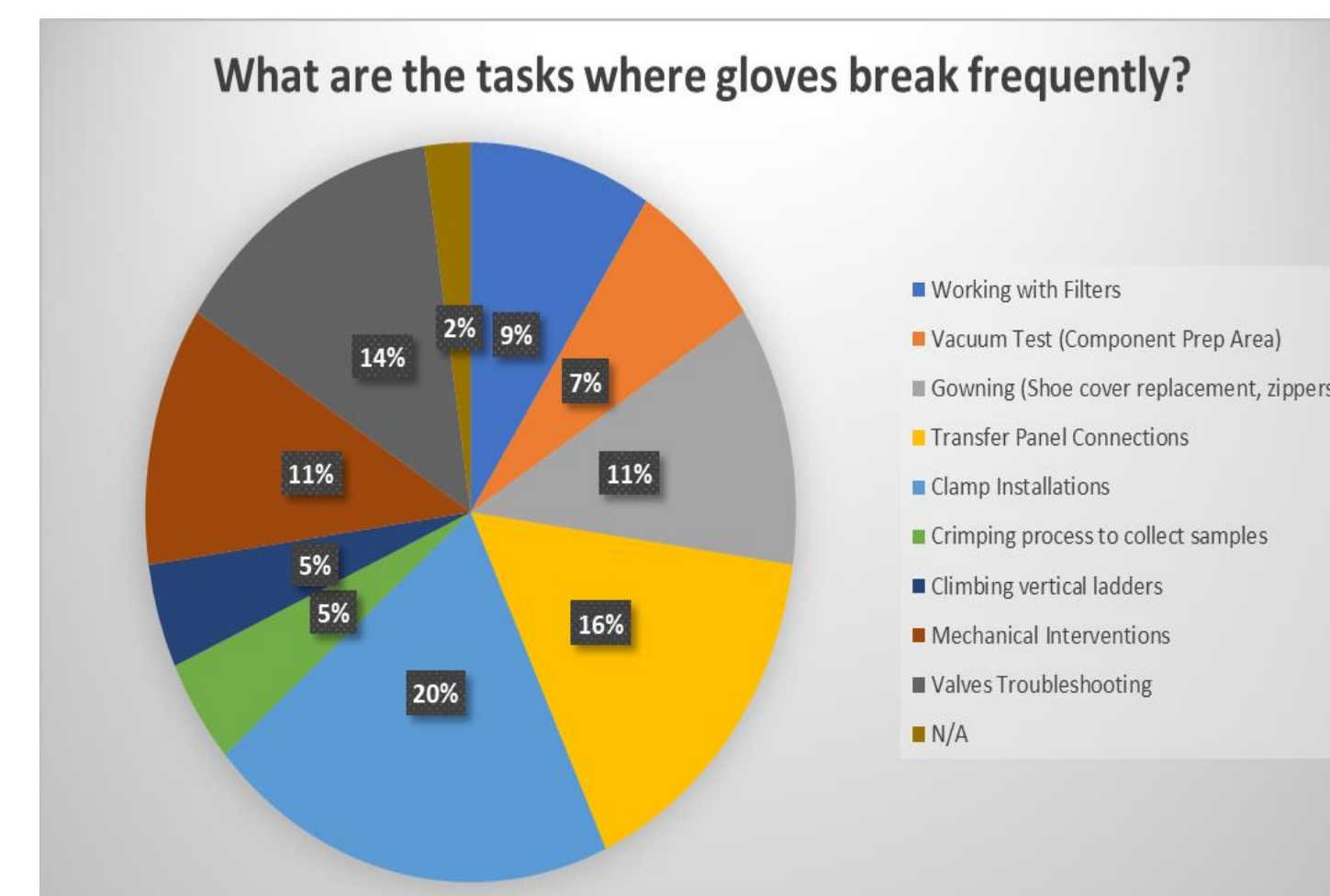
For this project we use both methods: the quantitative and the qualitative. The quantitative method was used to identify patterns and make categories. The qualitative method was use in interviews. These interviews allow us to gain more information from the associates that work in the different areas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

The surveys were conducted in the manufacturing areas in all shifts (first, second and third). We randomly select 5 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. The answers were recorded by note taking. We describe the problem observed to each associate and then proceed to ask them the following questions:

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



After finishing with the interviews, we proceed to categorize the answer and analyzed them to gain a deeper understanding of the associates and the specific place these glove stations were needed to reduce the distance walk. This answers also strengthened our hypothesis of that more glove stations should be installed in strategic points of the manufacturing areas. From the interviews we categorize and identify the different tasks that gloves tend to break frequently in the manufacturing area.

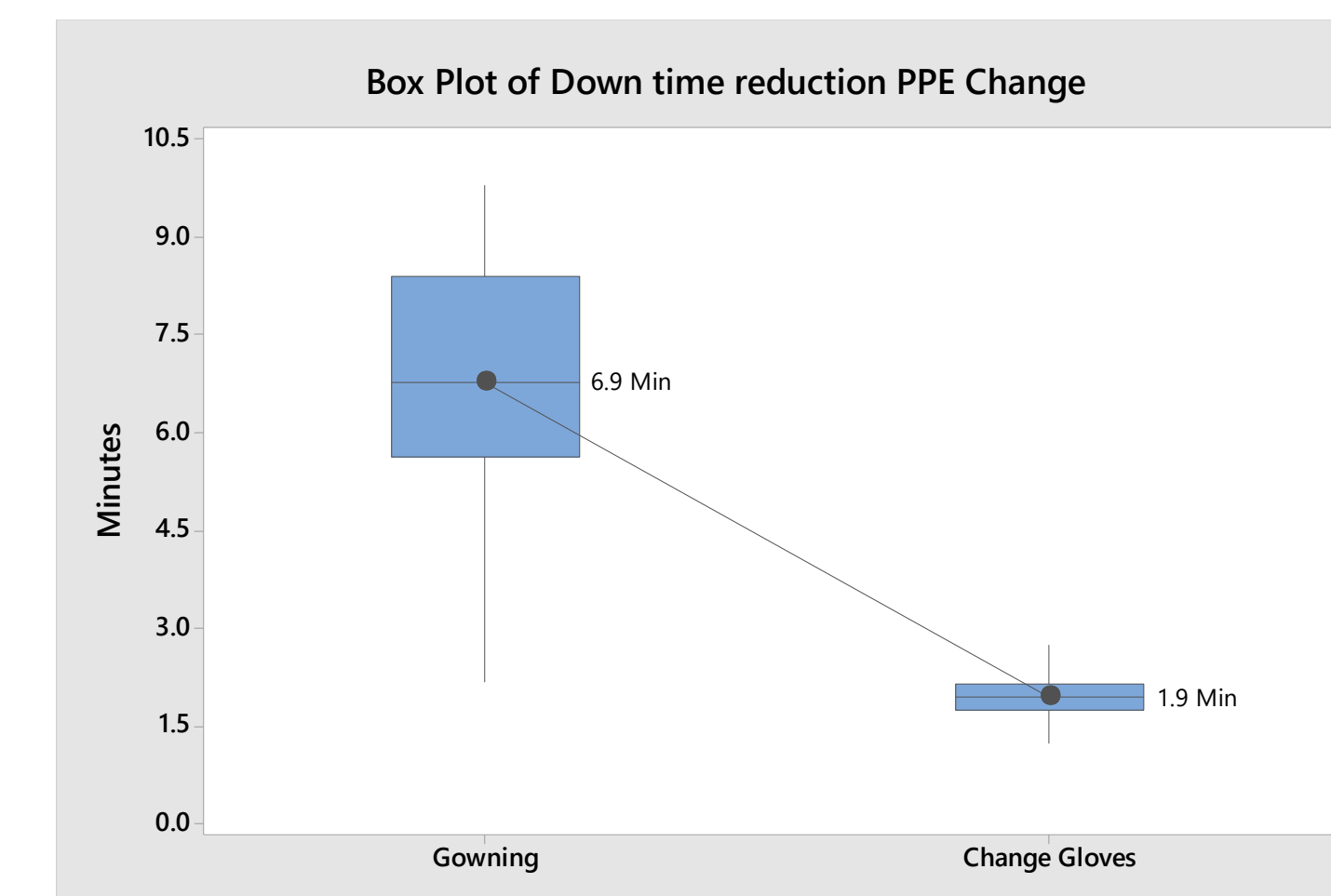


In order to assess the current state of the down time due to gloves breakage and associated PPE change, the process was stratified into two different measurements; first time lapsed walking to and from the gowning area and second the actual PPE change time inside the gowning, passing from the dirty area to the clean area again. The team collected 50 observations, depending on how far the room when the glove breakage happens different distances/time is needed to walk to the gowning and back to the manufacturing room.

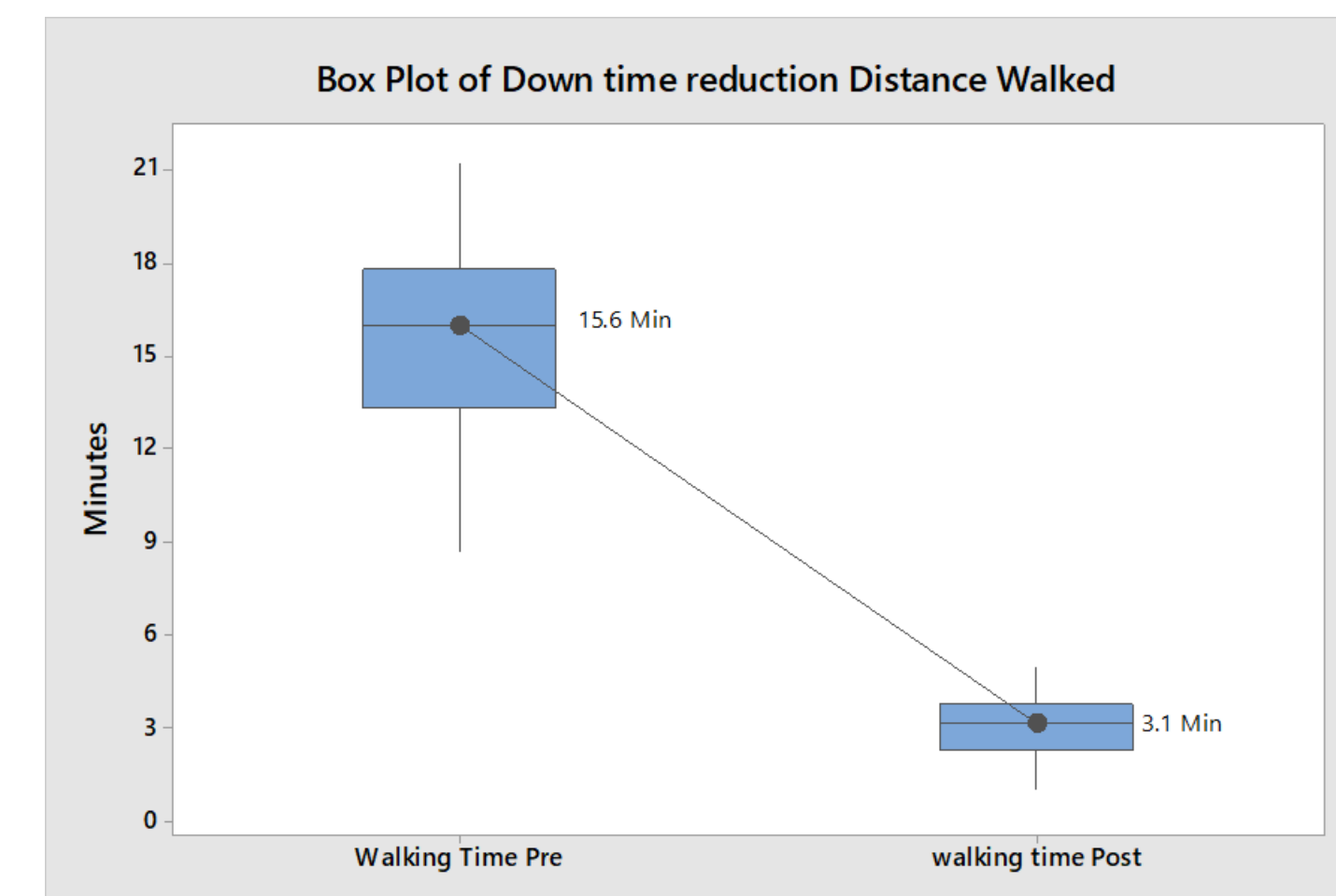
Results and Discussion

As part of project implementation, multiple glove stations (17) were installed at strategic locations throughout the manufacturing areas, in order to minimize the need to walk to the gowning room. Average distance to any given manufacturing room and the new installed glove stations was drastically reduced, therefore the process downtime due to PPE change once glove breakage occurs. Also ensures that Nitrile gloves are readily available avoiding the need to use sterile gloves which are more expensive and required for specifics processes.

With the new glove stations available within the clean area of the manufacturing shopfloor, the need to de-gown has been eliminated completely, in turn only broken gloves need to be discarded and replaced. A mean time reduction of 4.9 minutes for PPE change has been achieved.



A Box Plot of the lap times walked to and from the MFG rooms to the changing points compares the two data sets visually, process means pre and post implementation of glove stations are graphed. Shortening the distance for any give MGF suite to the closest glove station (17 stations) shows an average reduction in transportation time of 12.5 minutes.



In order to assess if the mean time for the walking and PPE change activities has improved significantly, Two- sample T-Test was employed in order to compare the sample mean times and assess whether these are equal statistically. Results for Two Sample T-test for walking time yield a difference of 12.5 minutes, 95% CI for means do not contain zero, P-value of 0.00 rejecting the Null hypothesis that samples mean difference were zero.

Two-Sample T-Test and CI: Walking Time Pre, walking time Post

Method

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 $H_a: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
28.68	58	0.000

Results and Discussion (Cont.)

Results for Two Sample T-test for gowning & Glove change times yield a difference of 4.9 minutes, 95% CI for means do not contain zero, P-value of 0.00 rejecting the Null hypothesis that samples mean difference were zero..

Two-Sample T-Test and CI: Gowning, Change Gloves

Method

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 $H_a: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
19.14	51	0.000

Conclusions

After evaluating the process improvement, it can be concluded that the Glove Stations project proof to address a major reduction on waste transportation and PPE change times for the required activities whenever a broken glove occurs in the manufacturing process. A total downtime reduction of 17.4 minutes in average was able to be improved per any given broken glove occurrence by eliminating the need to de-gown and gown again and significantly reducing the walking distance/time in order to execute said PPE Change.

After these results explained to Manufacturing Managers, they approved a budget to buy the 17 new 3-slot Glove Dispenser (REY1693) and proceed to install them in the different areas. This dispenser was made from 304Brushes Stainless steel which is allowed inside manufacturing areas. Is also all welded construction and is easy to clean.

Future Work

The next step is to expand the strategic allocation of glove stations to additional manufacturing buildings comprising Upstream, Downstream, Formulation and Packaging areas where downtime due to glove breakage is currently impacting.

Acknowledgements

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