

Sterilization Area Downtime Reduction

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Abstract

With plans of increasing production, the sterilization area of a pharmaceutical plant has to maximize its operating performance and reduce its downtime. The major offenders of downtime are the micro test cycles, maintenance and the operators' efficiency. Nevertheless, the data revealed that many of the downtime reported recently is due to lack of production. It was also identified that most of the downtime caused by micro can be eliminated by doing the tests on Mondays and in the mornings, taking advantage of the new production schedule of two 10-hours shifts. In terms of maintenance, as with the micro tests, the mornings have to be used, and new technicians must be hired to perform more maintenance during the weekends. From the operating performance of the personnel, it was identified that the fastest way of unloading and loading the vessels is by working in pairs. All these will reduce the sterilization downtime, but will only count if production stabilizes and increase.

Introduction

In the sterilization area, there are 17 vessels to sterilize the products manufactured in all the 5 manufacturing lines of the facility. These vessels have a standard time for the operators to load and unload them. The time that exceeds this standard is considered downtime. In addition, every time the vessels are taken out for maintenance or have to run an empty cycle to complete the microbiology tests, is time the vessel is not used for production and is also considered downtime. Therefore, beside the load and unload standard time, every time that there is production available and the vessels are not in use, is considered downtime. Figure 1 shows the process flow of the sterilization area, with the operators movement of trucks. There is a high demand for the company's product, therefore the company has decided to increase production. To comply with the planned production, the sterilization area has to improve its efficiency.

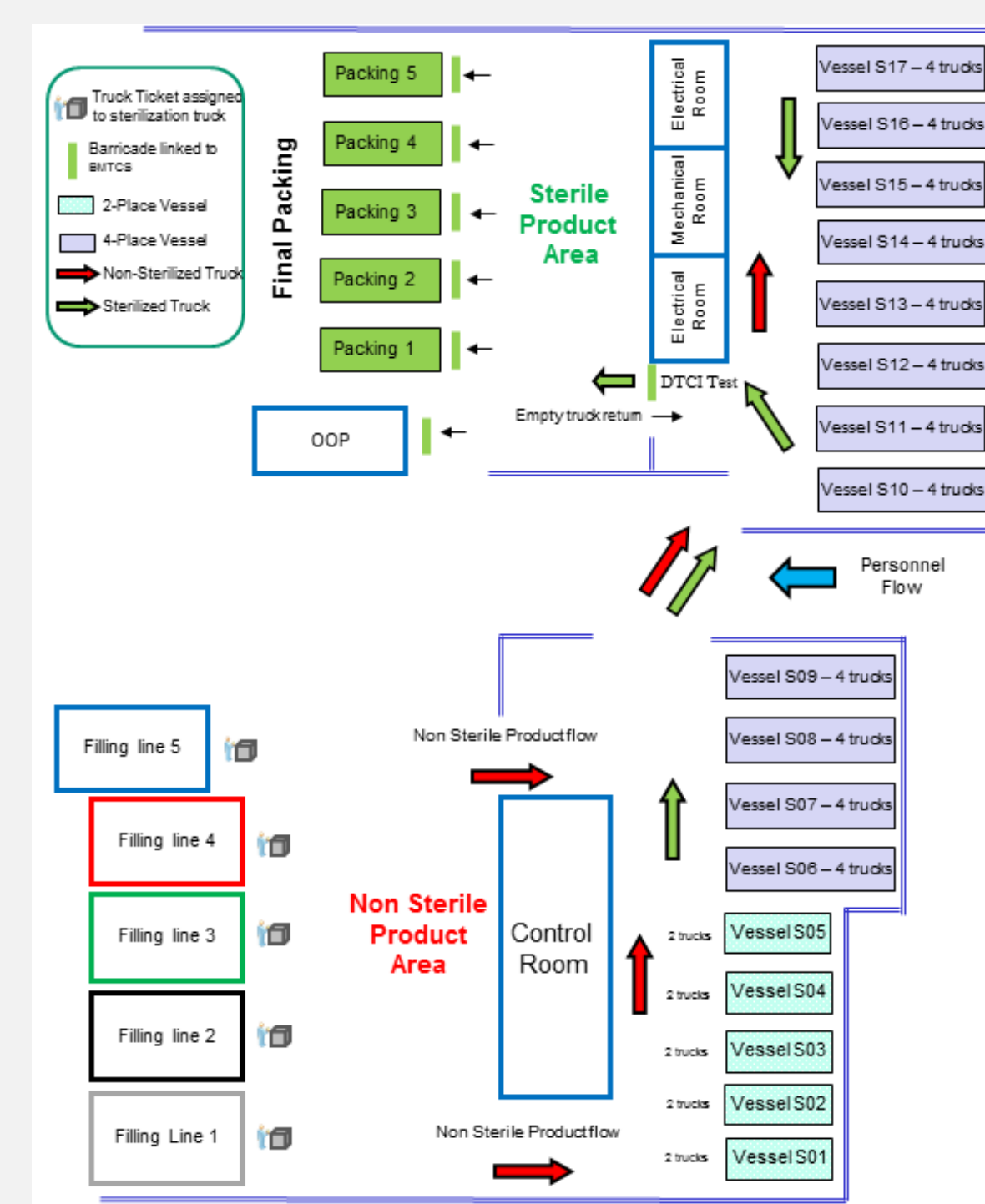


Figure 1. Sterilization Area Process Flow

Objectives

This project has three main objectives:

- Minimize the impact to production due to vessels maintenance
- Reduce downtime due to empty cycles for Microbiology tests
- Decrease downtime during loading and unloading

Downtime in the Two-Place Vessels

Figure 2 presents the normal distribution of the time between cycles. This time was calculated by subtracting the time of the previous cycle completion to the time when the cycle started. From Figure 2 it can be appreciated that there have been many times reporting a downtime higher than the established time of 15 minutes, with the median value calculated was 39.73.

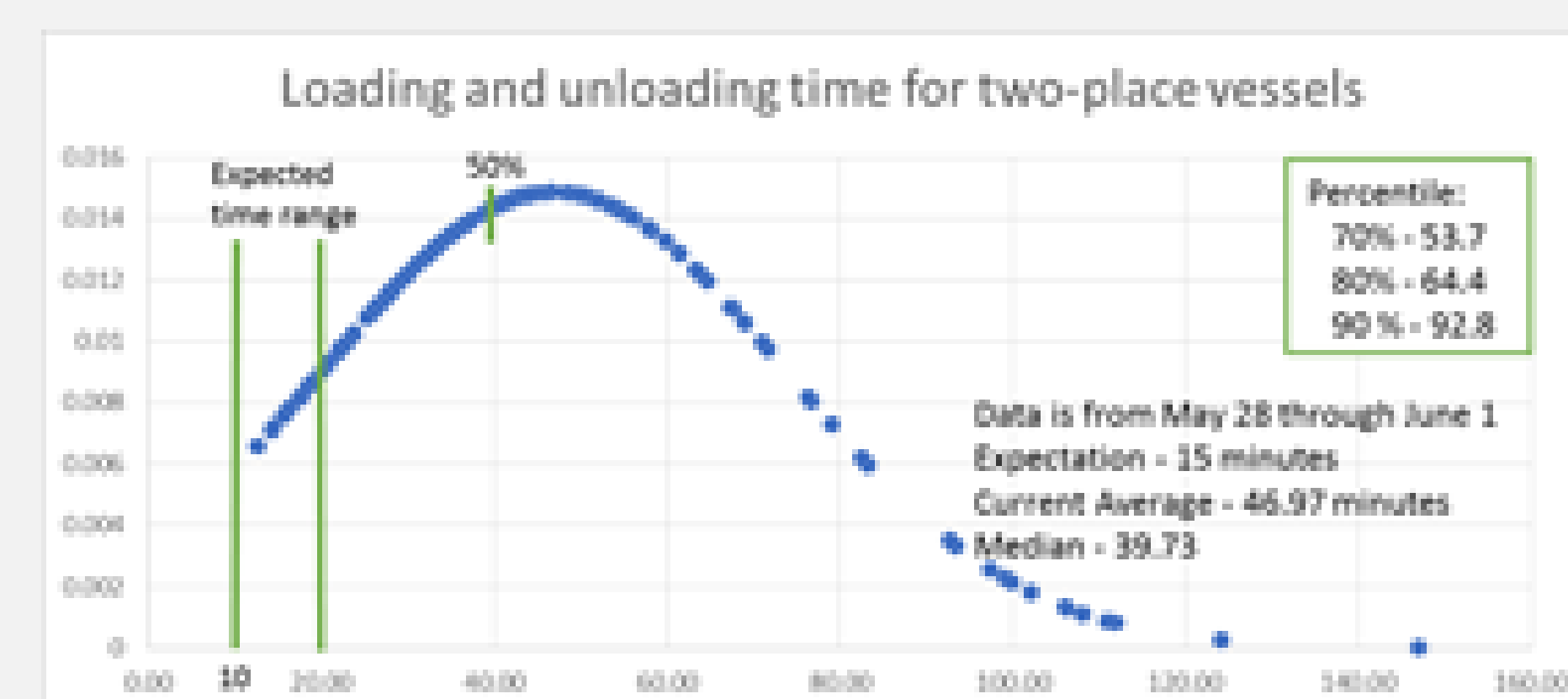


Figure 2. Downtime in the two-place vessels

Findings - There were empty cycles run for Micro tests but mostly, there were cycles run to test materials for receiving inspection.

Downtime in the Four-Place Vessels

Figure 3 presents the normal distribution of the time between sterilization cycles for the four-place vessels. The time between cycles was calculated in the same way as the two-place vessels. Figure 3 shows a similar situation to the two-place vessels, a positively skewed distribution, with downtimes higher than the 30 minutes established and a median value of 43.6.

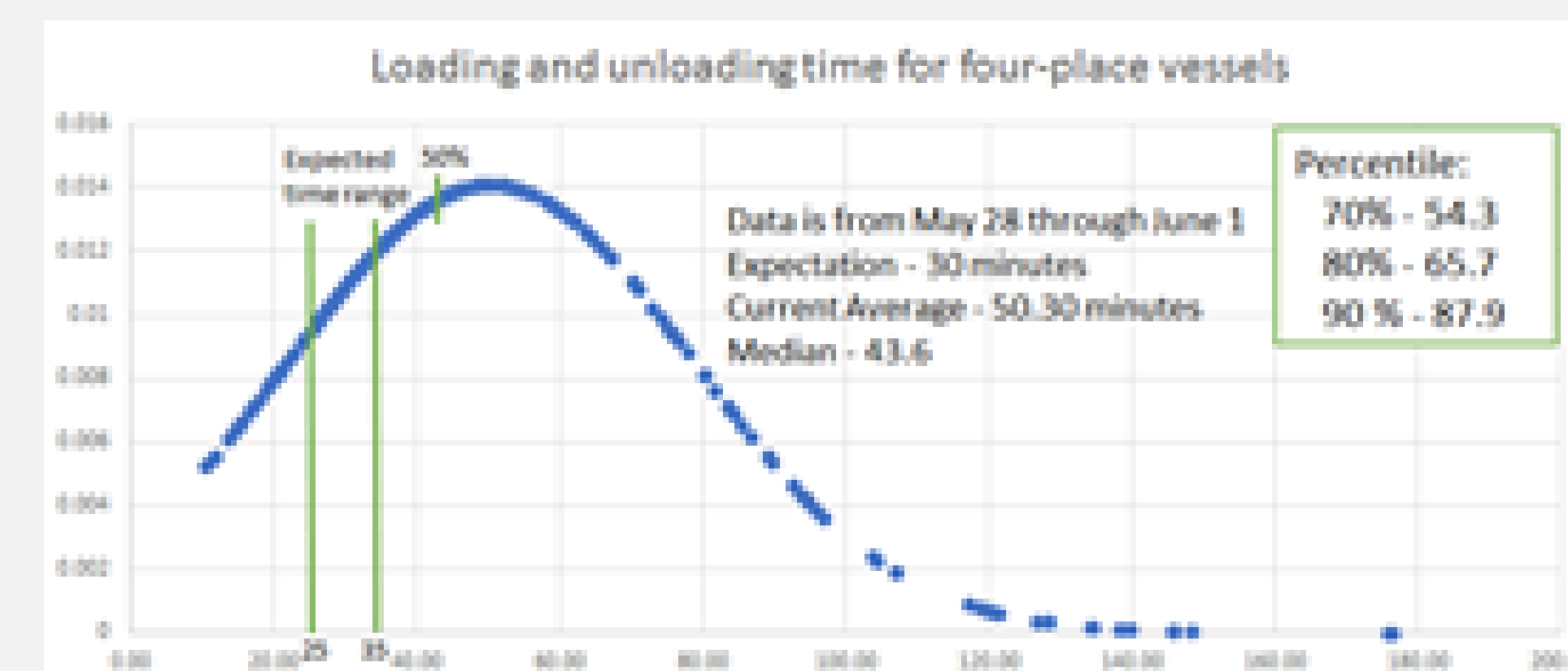


Figure 3. Downtime in the four-place vessels

Findings - There were empty cycles run for Micro tests, time Out of Service due to maintenance and periods with lack of production during first shift, especially on Mondays.

Downtime per Shift

With the evaluation of the three shifts, it was observed that the second shift has the best median value, with 42.32 minutes. Figure 3 shows the data from the second shift.

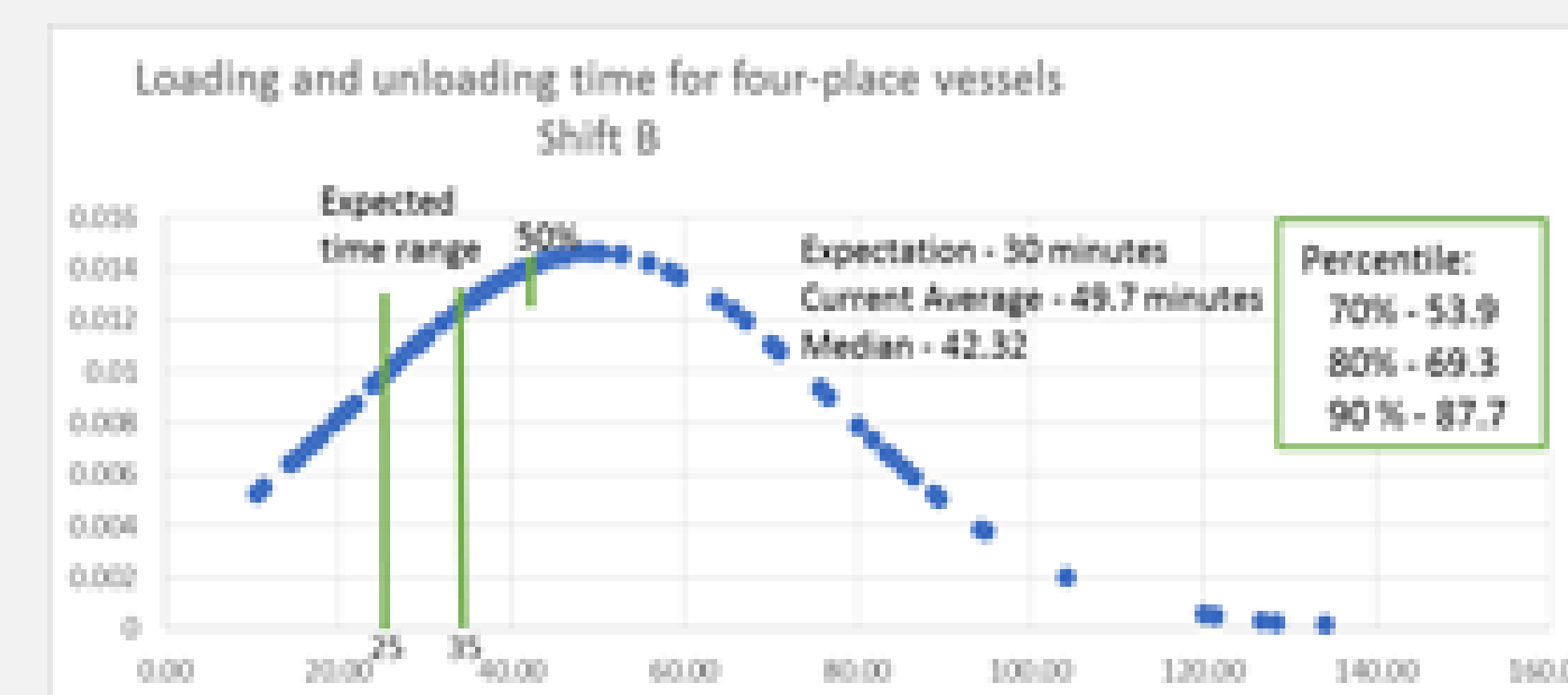


Figure 4. Downtime in second shift

Findings - Second shift is less affected by lack of production. Another important aspect of this shift is that has more employees in the area and when needed, the operators help each other to unload and load the vessels.

Biggest Downtime Offenders

The major offenders in terms of downtime, are the cycles run for receiving inspection, the empty cycles run for Micro tests, the lack of production and the operating performance.

- Production - For this type of downtime, there is nothing that the sterilization area can do to reduce or avoid it.
- Micro Tests - Two samples from each vessel must be taken for micro tests weekly. The main problem identified is that there was only one resource qualified to perform this test and it is sometimes required to remove the vessel from service to run an empty cycle.
- Operators Performance - The process of unloading and loading the vessels was evaluated and different techniques were considered to reduce the amount of time the operator invests in the task.

Ideas for Improvement and Control

As mentioned previously, in terms of the lack of production, there is nothing the sterilization area can do. It is an issue of the manufacturing areas and cannot be reduced or avoid by the sterilization area. For the opportunity areas identified with the microbiology tests and the operators' performance, the following ideas were developed for the improvement of the area's performance and the increase in the operators' efficiency:

- Microbiology Test: Train second resource for the vessel test. Establish schedule to test all vessels during the beginning of shift A and taking advantage of Monday.
- Operator Performance: Instead of assigning vessel to one operator, assign more vessels to two operators. They will load and unload together and one can be responsible of the vessel in case the other goes out.

Conclusion

Manufacturing area has had several issues with production, which has resulted in downtime in the Sterilization Area. This is not a controllable downtime but it was a downtime that significantly impacted the data evaluated. With the evaluation it was concluded that the empty cycles run for the microbiological tests affect the downtime metrics and that to avoid this, an additional resource has to be trained in the process and a schedule should be made to perform the tests during the mornings and taking advantage of the Mondays. The operators' performance was also evaluated and a method was developed to divide the vessels between two operators. This way both employees are responsible of ensuring the vessel is unloaded and loaded in the corresponding time.