

Sterilization Area Downtime Reduction

*Irene Morales
Engineering Management Program
Hector J. Cruzado, PhD, PE
Graduate School
Polytechnic University of Puerto Rico*

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.*

Key Terms — *Coordination, Maintenance, Operating Performance, Vessels*

INTRODUCTION

The goal of every manufacturing area should be to operate at its highest efficiency. This report discusses several methods to help achieve this in the sterilization area of the pharmaceutical plant studied.

Background

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.

Company's Production Plan

There is a high demand for the company's product. This has created backorders in most of them and the company has decided to increase production. The first change was to modify the shifts from 8 hours to two shifts of 10 hours. The second change is that now most of the lines work on Saturday for at least one shift. Furthermore, the plan is to have full production during the weekends, Saturday and Sunday, two shifts.

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

LITERATURE REVIEW

To achieve a downtime reduction in the Sterilization Area, the DMAIC methodology will be used. DMAIC stands for define, measure, analyze, improve and control. This methodology will help to organize and give structure to the project activities. DMAIC is considered "the glue which holds together the individual tools and facilitates solving real problems effectively" [1].

For the evaluation of the downtime, it is important to define how this downtime is going to be measured, understand the process and present it

in a way that could be easily appreciated for management decisions. “If you do not fully understand the condition of the workplace, you will not notice problems and will not be able to make improvements. Visual control management is a method for making workplace problems stand out” [2].

A thorough evaluation has to be performed in terms of the operators’ efficiency. The operating performance must be measured and their methods studied to develop the best technique to unload and load the vessels. Always keeping in mind that “convincing people to change something that has historically worked for them requires special skill” [3].

DATA GATHERING

Downtime in the Two-Place Vessels

The data of the downtime reported in the two-place vessels was evaluated, first of all as a whole and then dividing the values per shift. Figure 1 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. This is the time where the vessel is supposed to be unloaded and loaded and as per the standard it should be 15 minutes. Figure 1 presents the expected time range to perform the task, the average, the median and the percentile at 70, 80 and 90 percent.

From Figure 1 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. With these values and knowing the dates and times of each cycle, all the dates of the graph were evaluated to define what caused the downtime. With this evaluation it was observed that there were the empty cycles run for Micro tests but mostly, there were cycles run to test materials for receiving inspection. Receiving inspection test cycles cannot be avoided or coordinated in advance. These are for material that is required for production and are generally performed as soon as they are received

because are immediately needed for production. It was also identified that during the first shift and primarily on Monday there are several periods of downtime due to lack of production.

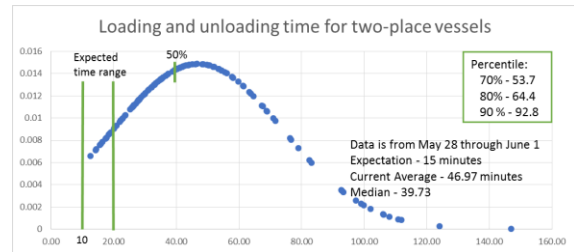


Figure 1
Downtime in the two-place vessels

Downtime in the Four-Place Vessels

Figure 2 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. The time when the cycle started minus the time when the previous cycle was completed, is the downtime. Figure 2 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. The data from these vessels also showed the empty cycles for the micro tests and the periods with lack of production during the first shift, especially on Mondays. These are the values that appear more to the right and affect the average and the median value used to evaluate the area’s performance. In addition, some of the highest values are due to maintenance being performed, a cycle run for a preventive maintenance, a calibration, etc. these also affect the performance.

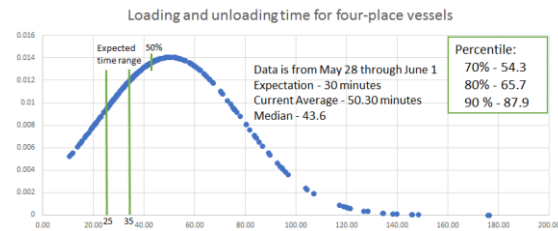


Figure 2
Downtime in the four-place vessels

Downtime per Shift

When the downtime data was divided by shift, the data of the four-place vessels was used. The two-place vessels data was not included in the evaluation because it was too affected by the Receiving Inspection cycles. 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, as in the previous graphs these values are of the time between cycle start and previous cycle completion. This is the shift less affected by the periods with 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.

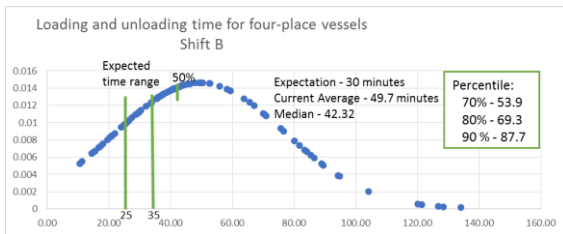


Figure 3
Downtime in second shift

ANALYSIS OF BIGGEST DOWNTIME OFFENDERS

With the data gathered, it was identified that the major offenders in terms of downtime for the vessels are the cycles run for receiving inspection, the empty cycles run for Micro tests, the lack of production and the operating performance.

Downtime due to Production

Once the downtime data is calculated, the points with the higher values were evaluated and one by one, the time at which the vessel started was searched to confirm the area had enough production to continue the sterilization process. If at the moment of loading the vessel there is not enough trucks to complete a load, the vessel cannot be filled. This offender was not expected, it is with the evaluation of each high point that it was identified that during the last month the manufacturing area

has reported a lot of downtime, which in return creates downtime in the sterilization area. For this type of downtime, there is nothing that the sterilization area can do to reduce or avoid it. The only action with this kind of downtime is to take advantage of it and use the available time for Micro test and maintenance.

Downtime due to Micro Tests

The Microbiology Laboratory takes two samples from each of the 17 vessels. The main problem identified is that there was only one resource qualified to perform this test, therefore the vessel had to be removed from production to run the empty cycle as soon as the technician was available. From all the data evaluated, periods of time without production were found on most of the days. Based on this, a good coordination has to be made to complete all the testing at the beginning of first shift, when production has not started and there are generally no trucks.

Downtime due to 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 per the evaluation performed, the biggest downtime offenders were lack of production, microbiology tests and the operators' performance for the task of unloading and loading the vessel. 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

During the last month the 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.

REFERENCES

- [1] Robin, G., "Six Sigma Quality Improvement with Minitab", 2ed, New Jersey, Wiley, 2011
- [2] Ozeki, K., et al, "Handbook of quality tools; the Japanese approach", 1ed, Cambridge, MA, Productivity Press, Inc, 1990
- [3] Dougherty, D., et al, "Human Resource Strategy A Behavioral Perspective for the General Manager", 1ed, New York, McGraw-Hill Higher Education, 2002