Continuous Improvement of the Compact Granulation System

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Abstract

The present dissertation is a continuous improvement and optimization of the Compact Granulation System, CGS, of Diosna. Thus, its main objective is to reduce setup time by defining and consolidating the operational procedure to adopt in a line change. A setup is the time that elapses since the equipment finishes the production of a given product and begins the production of another, and this includes the washing of the equipment.

In Generis SA, this equipment is usually called Diosna because the company that manufactures this equipment has that associated name.

This project has two components that are interconnected, the manual work performed by the operator and the cleaning program, Clean-In-Place (CIP), integrated in the equipment itself. The need to improve both the human and technical aspects of this work has made it very interesting.

The realization of this project implied a detailed analysis of the operative mode performed during the setup and also a study of the CIP program, allowing to reduce the setup time from 11 h 30 min to 8 h, representing a reduction of 30%. This reduction affected both the manual work performed by the operator and the CIP program. For the manual tasks, these have undergone some improvements based on the application of SMED methodology, Single Minute Exchange of Die. As for the CIP program, this was optimized, since some errors were detected and solved, reducing therefore the washing time from 4 h 20 min to 2 h 50 min.

After defining the operational procedure, the effectiveness of the CIP program was studied, as well as the cleaning of some pieces of equipment and new alternative cleaning methods were proposed.

The established objectives were fulfilled, however, some actions are still pending, since their conclusion was not possible during the internship.

The aim of this study is the continuous improvement, to achieve small and incremental changes in the processes, therefore it will continue because there are still many aspects that can be developed and improved.

Keywords: SMED, Lean, granulation, cleaning, CIP, WIP

1. Introduction

1.1. From Craft Production to Lean Thinking

Lean manufacturing emerged from a continuous improvement in automobile industry. Everything started with craft production, in which the production was very rudimentary. With this method, it was not possible to produce two cars exactly alike because the techniques always varied from one another [1].

Beyond this, the high price that did not fall with the increase in production, the lack of systematic road tests that did not provide quality and confidence, and the fact that companies did not have the resources to develop technologies that could make their cars more reliable were also huge disadvantages [1].

In this way, Henry Ford, came up with a new method to overcome these problems, the mass production.

The interchangeability of parts and ease of fitting them would be the main innovations of this system, which will allow to improve quality and to reduce costs [1].

Ford later concluded that each worker should perform a single task, repeating it from vehicle to vehicle, which would lead to highly trained workers at the tasks assigned to them, increasing productivity [1].

This distribution of tasks led to the creation of different jobs, industrial engineers, workers, hygienists, quality technicians, among others, which allowed each worker to concentrate on his work, optimizing it to the maximum [1].

This allowed fewer workers and the price per vehicle produced decreased with the increase in production.

However, after the Second World War, an automobile industry crisis settled down. Workers were dissatisfied, competition between industries was high and there was a huge increase in the demands of the consumer market, in terms of not only quality but also variety and efficiency [1].

Meanwhile in Japan, a new method of production has emerged and when Eiji Toyoda e Taiichi Ohno came to visit Ford's industry they concluded that the biggest problem observed was the existence of many wastes, in terms of effort, materials and time. This led them to create for Toyota's automotive industry the Lean Manufacturing system [1].

Taiichi Ohno, Toyota's chief production engineer, started by creating teams, each with a leader rather than a foreman, who would assume the same tasks as the other elements, but who also had the extra function of coordinating the team. The team goal was to work together to execute the tasks as efficiently as possible [1].

Continuous improvement, or *Kaizen* in Japanese, was part of this new method, where each worker should try to suggest improvements in the process. Along with that, Ohno, also deployed a problem-solving method called "The 5 Why's," in which, each worker was taught to systematically detect every error, questioning why, so that this error did not occur again [1].

1.2. Lean Principles

The principles of the Lean philosophy have been designed to specify the value in order to align all the activities of a given product along a value stream and to make it flow smoothly until reaching the customer, always aiming at the pursuit of perfection, a continuous improvement [2].

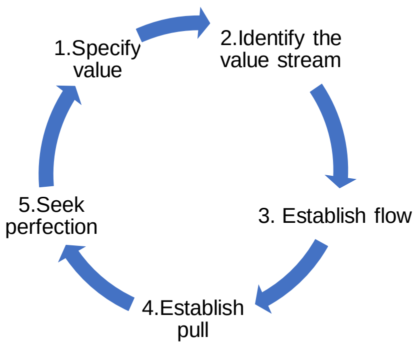


Figure 1 – Lean principles

The critical starting point for Lean thinking is **value**. The value can only be defined by the end customer and is only significant when expressed in terms of a good or service that meets customer needs [2].

The **value flow** is the set of all the specific actions required to produce a given product (a good or a service). Specifically, the value stream analysis will show the existence of three types of steps that occur along the value chain: (1) those that effectively create value; (2) those that do not add value but are unavoidable; (3) those that in fact represent a waste and that should be eliminated from the process [2].

After specifying the value and have wasteful steps eliminated, the next step is to create a continuous production **flow** that allows a faster and more effective response to market needs [2].

The **pull** system consists of a production strategy used to reduce waste in the production process. All the resources of the company are used to produce the goods that will be immediately sold, that is, enough goods to satisfy the demand of the customers [2].

The last principle focuses on the ideal of continuous improvement, striving for **perfection** by implementing new methods for value creation and waste elimination. The most important stimulus for this is transparency, so that everyone can easily observe and identify what can be improved [2].

1.3. The 8 Wastes of Lean

One of the primary goals of the Lean manufacturing approach is the reduction of any material, effort and cost that does not ultimately add value. In this way, there are eight types of waste that can be easily identified [3]:

1. **Overproduction:** producing items we cannot immediately use ou sell;
2. **Waiting Time:** waiting for materials, information, for downstream operations;
3. **Transporting**: moving items needlessly;
4. **Inventory:** more materials or more information than necessary;
5. **Processing waste**: unnecessary steps that don't add value;
6. **Unnecessary movement**: searching for tools, parts, instruction;
7. **Defective Outputs**: errors, failures, forcing to reprocess in order to correct;
8. **Wasted employee creativity**: loss of opportunity for improvement by not listening to the employees.

2. SMED

Along with the appearance of Lean production, Shigeo Shingo, was developing a setup reduction methodology, SMED, Single *Minute Exchange of Die* [4].

This method focuses on the ability to perform a given task and start another in the shortest possible time, increasing the flexibility of the process [4].

This methodology was carried out during Shingo's visit to Toyota's facilities, where he was able to reduce setup time from 4 hours to 90 minutes [4].

SMED was applied to all Toyota facilities and has continued to evolve as one of the main elements of this company [4].

The application of this methodology is based on the distinction between internal and external task [4].

An internal task is characterized by operations that only occur when the machine is stopped. An external task is the one that can be perform while the machine is running [4].

Figure 2 shows the four steps used to apply this methodology.

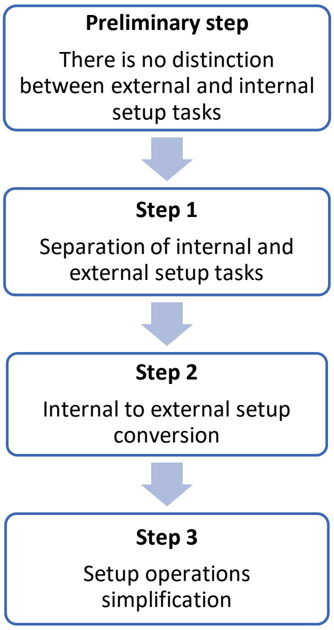


Figure 2- Sequential steps of the SMED methodology

3. Compact Granulation System, CGS

Diosna's Compact Granulation System is a closed system for the production of pharmaceutical granules. In this compact granulation unit occurs various stages of mixing, granulating and drying process. Thus, this unit consists of a series of three equipments, the mixer / granulator P, a fluidized bed dryer and a dry granulated Frewitt, also called a calibrator [5].

This equipment also has an integrated and automated washing system, the Wash-in-Place, WIP.

A key feature of the CGS is the connection between the mixer and the fluidized bed dryer that is ideally suited to ensure a good product transfer [5].

The outlet and the inlet of both parts of the mixer and the dryer are installed closely together to allow automatic transfer of the product from the mixer / granulator to the fluidized bed dryer. This covered transfer distance is considerably smaller than in conventional Mixer-Dryer combinations, which minimizes the surfaces in contact with the product, providing a better performance. This type of transfer also allows the more adhesive granules, difficult to transport by a pneumatic conveying system, to be transferred to the dryer easily and quickly [5].

Figure 3 shows the compact granulation system divided by zones. Each zone as a color associated, which makes it easier to perform the machine assembly.

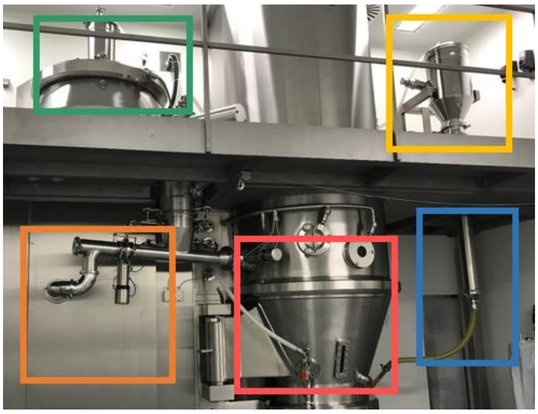
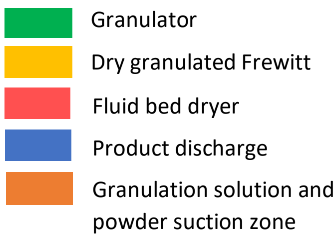


Figure 3– Compact granulation system divided by zones



3.1. CGS Line Cleaning

This granulation line is equipped with a Wash-in-Place (WIP) cleaning system consisting of an automatic cleaning performed by spray nozzles that are distributed throughout the equipment.

The WIP system includes several washing recipes with 26 steps, divided into cleaning, draining and blowing phases.

The cleaning phase consists of 13 steps in which the sequential water / detergent inlet is activated in each of the cleaning nozzles [5].

However, the washing recipes included in the program only correspond to the activation of the cleaning nozzles by pneumatic valves and the time that they remain open, not allowing to trigger the supply of water or detergent [5].

In this way, the washing equipment also requires the use of another program, the Clean-in-Place, CIP. CIP is an interface that makes the connection between the WIP and the technical area, which is the place that provides the water and detergent, stored in tanks, required for the washing [6].

4. SMED methodology applied to DIOSNA

The SMED methodology became important in this project due to the enormous size of this unit and also due to the huge number of pieces that need to be assembled and disassembled in each setup.

Besides the problems mentioned before, this equipment was new in the company and it was the first one with an automated cleaning system.

These problems along with the lack of experience and little knowledge about the cleaning program lead to setups with more than 11h.

4.1. SMED Application Step 1

The first step of the SMED methodology is the division of internal and external tasks, respectively, tasks performed with the machine stopped and tasks performed with the machine in operation, producing or in CIP mode. In this way, step 1 began by numbering all the tasks performed in the setup and identifying the internal and external tasks, as represented in the Table 1.

Table 1- Division of external and internal tasks

Task	Intern	Extern
Equipment parts disassembly	✔	✔
CIP parts assembly	✔	✔
Sleeves removal	✔	
Filters disassembly		✔
Parts washing		✔
Room cleaning		✔
Filters assembly		✔
CIP parts disassembly/Assembly to start production	✔	✔

- **Equipment parts disassembly and CIP parts assembly**

This is the first step to start the change of line. Diosna has a large number of parts that are exclusive to the production phase, and therefore need to be dismantled before washing the equipment. To start the washing program, it is necessary to assemble the parts for the CIP. This task of disassembly and assembly can be considered both external and internal.

- **Sleeves removal**

The filter sleeves are removed from the fluid bed dryer and this step must always be considered an internal task, this is because the washing program has a programmed pause, specifically to remove the filters. This is necessary because if the filters remain inside the dryer, during the washing program, the cleaning is not successful.

- **Equipment manual cleaning**

This step is directly connected to the previous one, since the operator takes advantage of the programmed pause to do a manual cleaning of the equipment, in order to wash some zones that CIP does not have access. In addition, the operator also removes the excess of product from the granulator and dryer with pressurized water, which is essential for proper cleaning

- **Disassembling the filters**

This step is an external task because it must be performed after the programmed break of the CIP system is finished. Thus, the various parts of the filters are disassembled.

- **Parts cleaning**

Most parts that are removed from the equipment are washed in the cleaning room. However, the smaller parts such as clamps and rubbers are washed by the operator in the room itself. This task is performed while the CIP program is running, being considered an external task.

- **Room cleaning**

The full room must be cleaned, including airlock, when a line change occurs, which means the equipment is going to produce a different product. This operation is performed by the hygienists and can be done as soon as the operator finishes the manual washing of the equipment. In this way, it can be performed while the machine is washing. The hygienist should start by washing the airlock and then the room.

- **Filters assembly**

Assembling the filters is also an external task and can be performed as soon as the airlock is clean. In this way, even if the room has not yet been cleaned, the filters can be mounted in the airlock to save time.

- **CIP parts disassembly/ Assembly to star production**

This step, as the first one referred, may be started while the washing program is still running. This is because, the cleaning program has a final stage of drying that takes place in the granulator and in the fluid bed dryer. Once the drying in the granulator is complete, this zone of the equipment can be prepared to production.

4.2. SMED application step 2

This step aims to redefine the setup operations in order to analyze whether the separation between internal and external tasks is definitive.

Thus, after further analysis it is concluded that the step of disassembling the machine and assembling the CIP parts could be optimized because some tasks that were defined as internal can be done while the machine is running.

In short, when the operator is preparing the equipment to star CIP, there are some parts, that are cleaned externally. For example, the orange zone is not cleaned by the automated cleaning program, and because of that should only be dismantled after the start of the CIP.

In this way, there are other parts that follow the example mentioned before. These allows the operator to save about 13 min.

4.3. SMED application step 3

This step is intended to simplify all the aspects of the setup operation and also to optimize the various tasks.

- **Disassembly/ CIP parts assembly**

The time of this task was reduced from 45 min to 30 min, by doing what was mentioned in section 7.3 and also because the operator started to assembly the CIP parts with an optimized way.

- **Room cleaning**

The manual cleaning of floor 1 done by the operator causes a large accumulation of water on this floor, since it is not possible to have a drain.

Then, the hygienist, responsible for the room cleaning, spends a lot of time, collecting this water by depositing it in a bucket. This water collection takes about 30-35 min and involves collecting the water and emptying the bucket, when it is already full, into the floor 0 drain.

In this way, a vacuum cleaner was acquired to facilitate this task and reduce the time wasted, from 35 min to 5 min.

- **Machine assembly to start production**

Due to the huge amount of clamps and sealing rubbers, the first step to be taken in order to start the equipment assembly is to make the separation of these parts by color in the existing bench in the room.

This step allows the operator to do the assembly in a much more efficient way because he doesn't have to waste time looking for the right part. This saves about 5 minutes.

In addition, the operator started to transport the clamps belonging to the yellow and green zones located on the top floor inside of a box. Before, the operator could not transport all the clamps at one time to the top floor. The existence of this box allows the operator to save about 5 min, which makes it more efficient.

Another optimization that allow us to reduce five more minutes is related with the assembling and disassembling of the dryer's filters. Initially, this task was done manually, which was very inefficient. Now a screwdriver is used to enhance this step.

- **CIP**

After a detailed analysis of the cleaning program, there were some errors that were increasing the washing time. These errors were solved allowing a reduction of 90 min.

The time reduced by doing all these optimizations is presented in Table 2.

Table 2-Time reduction resulting from the optimizations mentioned before

	Inicial Time	Current Time	Reduction (min)
Disassembly/CIP parts assembly	45 min	30 min	15
Room cleaning	2h30	2h	30
Machine assembly to start production	2h45	2h30	15
CIP	4h20	2h50	90
			TOTAL: 2,5 h

4.4. Results

The diagrams present in this section represent the distribution of tasks performed during the setup and their evolution throughout this project.

Figure 4 shows the initial state of the setup before the improvements made in this project, corresponding to a total of 11 h 30 min.

Figure 5 represents the setup obtained after the optimizations described on Table 2.

However, in addition to the improvements presented it's still possible to reduce the setup time by overlapping tasks.

As mentioned before, the granulation system consists of three interconnected equipments, the granulator, the fluidized bed dryer and the calibrator. When the granulation is finished, the granulator pauses and the product that comes from it is transported to the dryer. While the product is drying, the operator has time available to begin the dismantling of the parts of the granulator, as well as the assembly of the necessary parts for the washing, because the production has already finished in this area. This originates a reduction of 15 min.

Disassembling the filter holder and cleaning some parts in the room is something that can also be done while the washing program of the equipment is in operation, saving about 30 minutes. Then, after this task is completed, the room is available to be cleaned by the hygienist, even with the cleaning program still running, since this action is not affected. On the other hand, the first area of the room that needs to be cleaned is the airlock, this allows the assembly phase of the filter holder to be carried out inside the airlock while the rest of the room is still being cleaned. Thus, the total setup time would be 6 hours as can be seen in Figure 6.

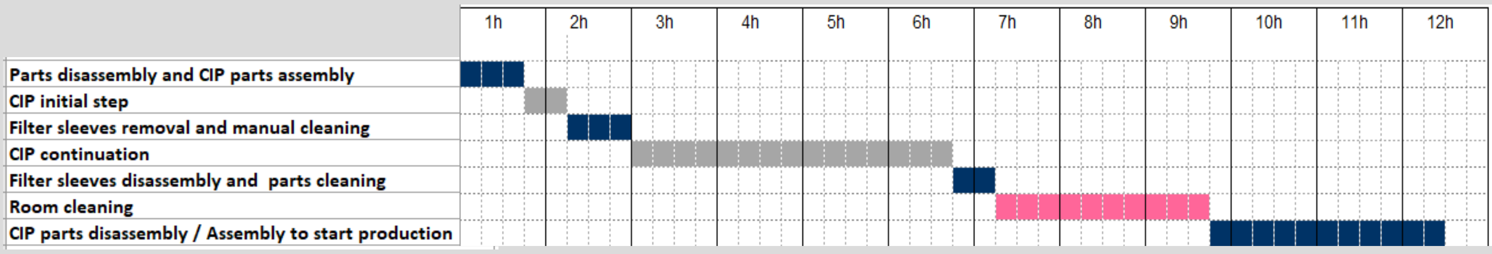


Figure 4- Setup tasks distribution diagram before the beginning of this project.

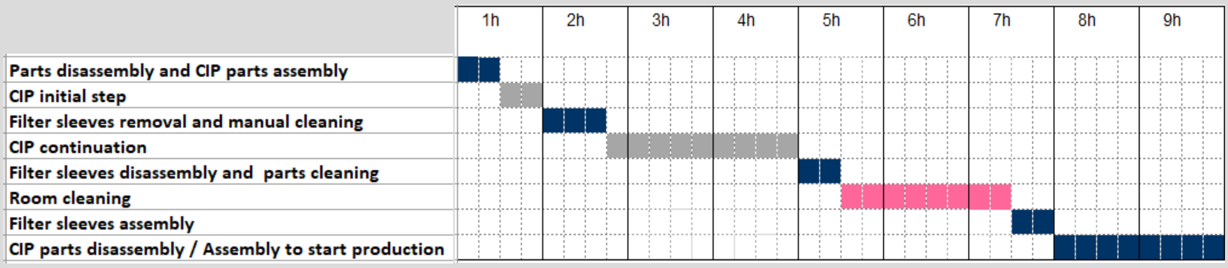


Figure 5- Setup tasks distribution diagram obtained with the time reductions shown in Table 2

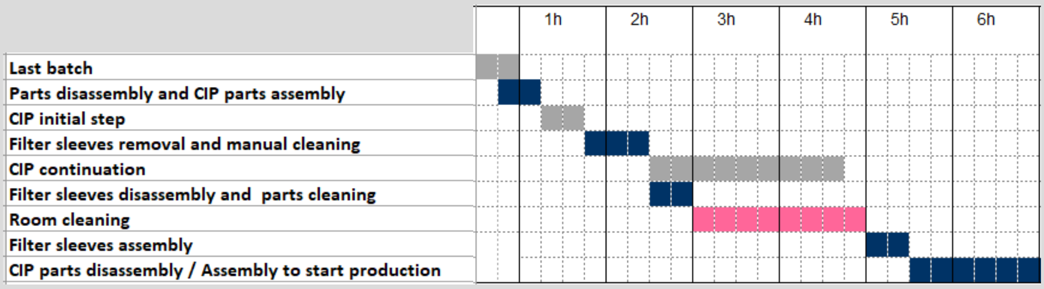


Figure 6- Theoretical setup tasks distribution diagram with steps overlapping

However, it is not possible to apply the diagram of Figure 6, because the room is almost never cleaned exactly in the right time. This happens because the hygienist, responsible for the room cleaning, is cleaning another room. In this way, the setup time increases, because the waiting time for the room to be cleaned is usually about 2h. Figure 7 shows a more realistic diagram. However, it's still difficult to obtain this setup time, which lead to the conclusion that the company should hire another hygienist in order to reduce the waiting time.

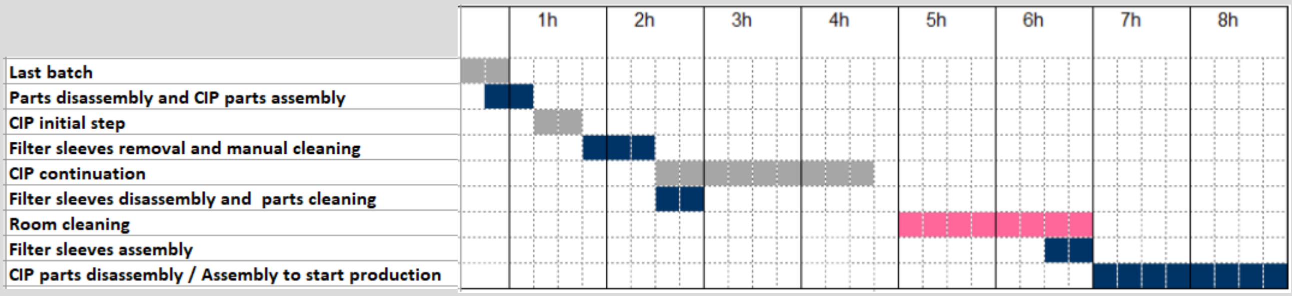


Figure 7- Setup tasks distribution that is possible to put in practice

5. Study of the CIP / WIP program cleaning effectiveness

The zone of the equipment that proved to be the most critical in the washing step was the plate where the filter sleeves fit.

As already mentioned, after the initial rinse, the filters sleeves are removed from the dryer because their presence don't allow the correct cleaning.

However, at the end of each cleaning, both the walls next to the filter plate and the dish itself have stains and remains from the product, which reveals inefficient cleaning in those areas, as can be seen in Figure 8.

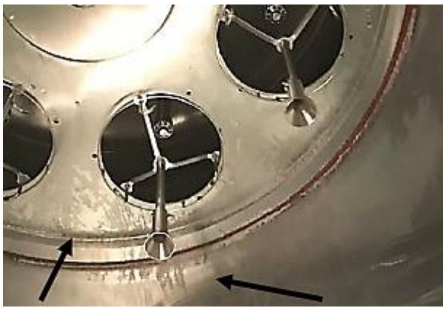


Figure 8- Dirt that remains in the filter plate.

After an analysis of the washing process, an attempt was made to identify the causes of ineffective washing in this area of the equipment.

The first cause that could be identified is related to the location of the cleaning nozzles. Figure 9 shows that the dryer has five cleaning nozzles, but only two of them are responsible for cleaning the upper part of the dryer and present some problems.

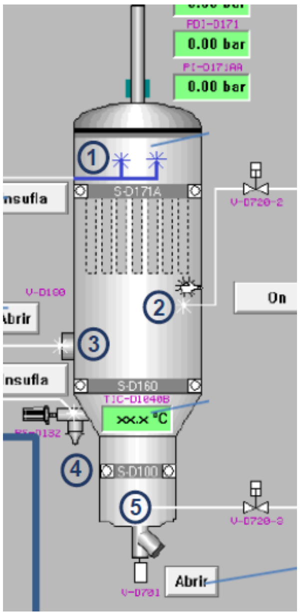


Figure 9- Fluid bed dryer cleaning nozzles

The dirt present in the filter plate, shows that the cleaning nozzle 2, identified in Figure 9 is not located at an height enough to perform the right cleaning.

The dirt that is always trapped in the wall next to the dish can also be justified by the fact that the existing sealing rubbers do not allow water from the nozzle 1 to flow through the walls. This is because one of the conditions that the program requires for starting the wash is the inflation of those rubbers.

These situations were reported to the manufacturers, suggesting that the rubber could be deflated during washing to allow water to pass.

It has also been suggested that the dish may go up and down during washing so that the water sprinkled by the cleaning nozzle 2 reaches the dish effectively.

Regarding the first recommendation made, the manufacturers have stated that it is a viable and easy change option, and it can be done remotely. The second suggestion is still in the process of evaluation by the manufacturers, as it may imply modifications to the equipment.

The dirt in the granulator is the result of product dispersion due to the rotation of the propellers containing product residues at its base.

This situation was also reported to the manufacturers and they realized that some changes in the cleaning recipe could be done. The increase of the propeller rotating speed and the higher amount of water and detergent entering were the main changes.

Given the problems raised in the washing program, Diosna manufacturers will come to Generis to follow up on the WIP program in order to analyze what can be improved.

So, this optimization project will continue because there are still many improvements that can be made and could not be accomplished during the internship.

6. Conclusions

Based on the SMED methodology and Lean thinking it was possible to reach the established objectives. An operational procedure was defined and the setup time was reduced from 11 h 30 min to 8 h, which represents a reduction of 30%.

As mentioned before, the setup time could be smaller than the 8 h, however, it is very difficult to perform setup times of 6 h and 7 h, because there is always some unforeseen situations and simultaneous waiting rooms for cleaning. In this way, this project proved the need to strengthen the number of employees responsible for cleaning the manufacturing zone, which would reduce many delays, and turn out to be a benefit.

In this study, the detailed analysis and an understanding of the CIP program allowed the detection and correction of some errors that were occurring and increasing setup time.

In a second phase of this dissertation, the effectiveness of the CIP program was evaluated and new cleaning methods were proposed for certain pieces of the equipment. There are, however, some pending actions due to difficulties in their implementation.

In the course of this dissertation, the development and implementation of certain actions have not always been able to proceed as required, since this project is part of a manufacturing unit in which there are deadlines and objectives to be fulfilled, like a weekly planning that should not be concerned. On the other hand, some improvements depend on the Engineering and Maintenance Department, which sometimes was very busy attending problems that arise in the operation of manufacturing machines. In addition, some actions proposed in this dissertation are dependent on the response of other companies, such as the monitoring by the manufacturers of Diosna, scheduled for September only.

In short, in an industrial environment, it takes some extra time to reach the desired goals and for a project like this to be fully developed. Thus, despite the significant progress made in these 6 months, there is still much more to develop, which is why the project does not end here.

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