Diagnosis and improvement of production system performance, in a Lean and Lean 4.0 logic, applied to a case study

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Abstract: This master thesis aims to contribute to the evolution of the Lean Manufacturing to Lean 4.0, through the conscious use of traditional Lean tools supported by digitization. The dissertation is based on a case study done in a biopharmaceutical production company. The study began with the realization of a diagnosis to a production flow, with the consequent identification of it's problems and their main levels of cause. Subsequently, several countermeasures were formulated to address the problems encountered and an action plan was drawn up to solve them. The company where the case study was carried out has a high incidence of manual records, without real-time data collection. In this category of companies, the fear of large investments is a reality, so this dissertation aims to demonstrate that, through low-cost sensing and rapid implementation, it is possible to use the potential of digitization and communication and information technologies. For chronological reasons, the sensors were developed not in order to reinforce the diagnosis already made, but as support to the standardization of the improvements implemented using traditional Lean tools. The layout of a possible analytical dashboard was developed to support the control of the standardization of improvements. Finally, a methodology was formulated to assist companies in the evolution from Lean to Lean 4.0, which encompasses the entire process, from the realization of the diagnosis to the consolidation of standardization.

Keywords: Lean Manufacturing, Sensors, Dashboard, Methodology, Standardization.

1 Introduction

The success of the Lean Manufacturing concept during the 90s is due to it's high effectiveness in reducing process complexity and focusing only on value-added activities. However, it is true that the Lean application, in its traditional form, may not be sufficient in response to the growing demand, the shorter delivery times, and the need for personalised products, that is, increasingly targeted at each type of customer (mass customization) [1].

Industry 4.0 (i4.0) then emerges as the transition from a paradigm of a centralized production to its decentralization, through communication between objects, people, machines and resources. Inherent to the fourth industrial revolution arise three concepts: The Internet of Things (IoT), which establishes the connection between all operators and communication with customers, Cyber Physical Systems (CPS) which, together with the concept of IoT, allow the identification of components, storage and data processing, and Smart Factory [2].This latter concept results from the union of the two terms mentioned above, and consists of an intelligent manufacturing unit, capable of analysing its current state, its history and its operational objectives, and of optimizing processes in real time, with constant supervision by operators, which also nicknamed "smart" because they can have faster and informed decisions [3].

With the increase in the complexity of the analysis of data from the sensorization of the processes, it is essential to filter and to process them to obtain relevant information. The concept of digitization emerges as a concept capable of managing all important information through the use of digital technologies, sharing it with all levels of the organization [4].

This dissertation aims to contribute to the conscious evolution of Lean to Lean 4.0, in particular by proposing a methodology for the use of digital technologies to support the standardization (ensuring regular compliance with established procedures) of implemented improvements, resulting from the application of traditional continuous improvement and Lean methods.

2 Research Evidence – Lean Manufacturing and Industry 4.0

The Lean concept – meaning "fat-free", "slender" production – advocates the elimination of all types of waste, that is, all activities that do not add value to the final product, continuously improving quality and promoting the systematic reduction of associated operating costs. In this industrial environment, where production is intrinsically linked to demand, competitive pressure is directed towards the realization of small production lots, in order to produce only the quantity needed to satisfy the customer. The goal, in addition to production at minimal cost, is to reduce delivery times, involve all levels of the organization, and the ability to respond to possible market changes [5].

2.1 Continuous improvement - Kaizen

While perfection in the business context is impossible to achieve, the goal of all employees, from top management to operator, must always be based on the daily and continuous effort to achieve small progress, without major investments, in terms of efficiency and the functioning of the organization. The Japanese use the term Kaizen to describe the culture of continuous improvement applied to the production system: this term describes the systematic attitude of wanting to do better, with less effort, less time spent, fewer resources, less risk to employees and greater value and reliability, ensuring a greater capacity to value the market, through common sense, creativity and commitment of all levels of the organization [5].

2.2 PDCA & SDCA Cycles

In order to ensure the effectiveness and continuity of the implementation of the continuous improvement approach, an iterative method called the Deming Cycle or PDCA Cycle is often used. In fact, this culture of constant search for problem solving is the basis for the development of a more critical and competitive spirit, with subsequent innovations by organizations [6].

This cycle consists of four distinct actions, which represent the different stages of the cycle:

• **Plan:** Consists of the collection and analysis of data for the mapping of the current state. On the basis of this analysis, an action plan is drawn up to improve the process;

• **Do:** Implements the action plan, as defined in the previous stage;

• **Check:** Evaluates the implementation referred, that is, whether the results of the implementation contributed to the improvement of the process;

• **Adjust/Act:** The last step is a decision-making process. If, in fact, the results are in line with the desired improvement, it is necessary to standardize and stabilize this solution, replicating it to other areas of the organization. If the results are not as expected, it is perpetual to restart the cycle.

To ensure that all learning remains rooted in the company's culture, it is important that the improvements implemented are standardized. This idea is present in the logic of the SDCA cycle, whose line of reasoning is similar to the PDCA cycle, but whose objective is in the standardization of the process and not in the planning with a view to its improvement. Most authors argue that the SDCA approach should be implemented before and after the implementation of the PDCA cycle. Firstly, it is considered important since the stability of the processes helps in the implementation of possible improvements. Subsequently, it is important to ensure that all improvements are properly standardized and used by all employees of the company [7].

2.3 Types of waste

Waste reduction has become one of the biggest concerns of any Lean environment [8]. The Toyota Production System shows the existence of three categories ("the three M's") associated with waste itself or practices that are at its origin [9]:

• **Mura:** irregular work rate and uneven distribution of tasks between jobs, with moments of overload or underload, resulting from poor planning (conducted by the production system and not by customer demand);

• **Muri:** overload of equipment and/or operators, requiring more physical effort on the part of the workers, for long periods of time;

• **Muda:** any activity without added value to the customer, which is thereby the waste, *per se* (overproduction, waiting, transportation, over processing, movement, inventory and making defective parts).

2.4 Lean Tools

The concept behind the **5S** method is to be sure that only in a clean, organised and safe work environment can it be sustainably developed an effective, more productive, waste-free work, with a continuous potential for improvement. This method is based on the organization of the workstation, by removing all materials that are not necessary to the process, set in order, for a quick identification of the necessary tools, cleaning the local, increasing the satisfaction of workers, standardization, through the development of procedures and standards and, finally, in the self-discipline of each one, with a view to compliance with the improvements implemented in the most efficient way possible [5].

The **5-Whys** tool is based on the following reasoning: in a first phase, clearly identify the problem that is intended to solve, then ask the "why?", in order to find the last level of cause for the occurrence of the problem under study, and so on, until a cause is reached to which a reason for its occurrence cannot be attributed – the root cause. It is then, at that last level of cause, that the team will have to act accordingly [9].

The **Spaghetti Diagram** is based on continuous lines that reflect the movement of the operator or materials throughout the process. Its visual representation allows easy identification of redundancies, that is, tasks that do not add value to the final product, according to the customer's perspective, and possible improvements with a view to increasing the efficiency of the process [10].

The **Yamazumi Chart** is used to describe the various activities that make up a process. The Japanese term Yamazumi means “stack up”. Thus, each chart bar contains a series of overlapping activities, which are categorized as follows: added value, non-added value and waste (in this thesis considered as an improvable task). This type of chart is used to visually identify the impact of non-added and/or improvable value tasks.

Poka-yoke is a technique used to prevent the occurrence of human failures and, consecutively, manufacturing defects. Through visual or sound signals, the operator is alerted to the existence of an anomaly and can act immediately accordingly.

2.5 Industry 4.0 – Design Principles

The term Industry 4.0 has become one of the most discussed concepts at both academic and industrial levels. As this is a subject often addressed, there are several definitions in the literature for the concept in question [2].

As an emerging concept, which has not yet been normalized, it becomes complicated, from the company's point of view, to understand and implement scenarios arising from this industrial revolution. Thus, there is a need to define principles that structure this concept, its components, and its applicability [2]. These principles, according to the literature, are called **design principles** [11]. The use of these four principles (interconnection, decentralized decisions, information transparency and technical assistance) makes it possible to identify and describe the possible scenarios for implementing i4.0 technologies and how best to implement them, assist in identifying potential improvements resulting from their application and, at the same time, help clarify the concept itself [2].

2.6 Digitization

With the increase in the complexity and quantity of data acquired associated with production systems, it is important to know how to filter the relevant information, as well as know how to convert and use it [4]. Then, the concept of digitization emerges as a representative concept of a new organizational level, capable of filtering and managing all important information through the use of digital technologies [12] sharing it attractively and explicitly by all employees, with consequent reduction of the time spent in these analyses and increasing the frequency of updates of the state of the process [13].

2.7 Dashboard – Digitization Support Tool

The dashboard, understood as a graphical interface with a single digital screen, is intended for monitoring, visualization, and quick understanding of the manufacturing unit or a given production line, through process performance indicators, allowing the passage of information in real time through all hierarchical levels of the company, from the shop floor to the

top management, providing a more efficient and agile production system [14].

3 Case study

The first part of this dissertation consisted of conducting a case study in a company dedicated to the production of biopharmaceuticals, in which production areas were selected in order to first diagnose their flow, then identify their problems, and, finally, develop and implement their solutions.

This first phase, which comprises the beginning of the diagnosis until the beginning of the implementation of the improvements, lasted about 2 months and involved a significant effort, raising the question of whether it would be possible to make the diagnosis in an automatic way, obtaining real-time values measured by sensors, and consecutively making the diagnosis more robust and credible, without being based only on a finite number of observations. This is something already recurrent in companies with some level of industrial automation, contrary to what happens in the company under study, where there is a high incidence of manual labour, without automatic data collection, and where the uncertainty of the return generated by large investments is significant.

After diagnosis based on observations and timings, the root causes for the problems found were identified, and solutions were developed based on Lean principles and tools. This was followed by the implementation of these solutions by internal teams with the support of external auditors. In a traditional approach, the standardization phase of procedures would be followed to ensure the change of habits and the consistent application of procedures (this phase was no longer accompanied by the author of this dissertation).

3.1 Description of the production and cleaning systems under study

In the present work, a diagnosis was made to the production flow, and its cleaning, of two rooms of the facility, X and Y. Room X is intended for weighing raw materials (Figure 1, left) and Y (Figure 1, right) for the preparation of materials and solutions necessary for the production of parts.

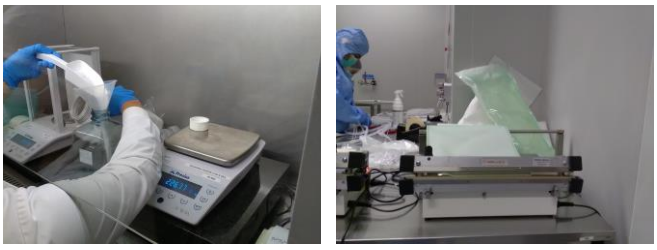

Figure 1 - Raw material weighing (left) and component assembly (right)

Due to the high similarity of the problems identified in the two rooms, both in production and cleaning, and in order not to make this analysis unnecessarily extensive, it was decided to describe only one of the rooms. Y was selected because it is a classified room and due to its high size and importance for the final product.

Before starting the production flow in room Y, one of the operators must go to the shelf containing all the production support documents and collect the corresponding production to be carried out. The warehouse phase follows, where the necessary components for the process are collected, which are placed in a double bag properly disinfected. After the warehouse, operators are allowed to enter the room to start the activity.

To enter the room, it is necessary to comply with a strict dress-up procedure. In the case of room Y, there are masks, gloves, shoes and protective suits to ensure that the operator does not contaminate the process.

The production flow in Y begins with the opening of the room. The preparation of the process consists, in a first phase, in the labelling of all equipment that will be used during the activity, using white operating labels, without using labels that say clean or for cleaning, since they are used only after the process, or shortly after cleaning the equipment. At the same time, the other operator must fill out the logbook of the room, a book containing mandatory filling fields intended for the start-up of the process, ensuring the existence of a history of use of the equipment.

To start the assembly process of the parts it is necessary to remove the double bag containing the components of an airlock. This compartment is an air chamber that allows for the entry and exit of people and materials, prepared in such a way as to prevent or minimize the mixing of different gases.

After removing all components from the double bag, they are placed without storage criteria, inside the room. The PG instructions are then analysed, and assembly is carried out. At the same time, the packaging phase takes place: it is necessary to connect the machine intended for purpose, to test whether it is operational and then to pack each part finished twice by the other operator.

After double packaging, an identification label of the part is placed on the paper part of the package and yellow adhesive tape on the plastic part which corroborates the efficiency of the autoclave cycle (if, at the end of the cycle, the yellow label has a black stripe, it means that the autoclaving was successful). The autoclave cycle allows to sterilize all packaged parts to be delivered to the warehouse and then to the customer. Each cycle has a previously defined number of packed and lasts about 3 hours.

At the end of the procedure it is necessary that all equipment present in the room, whether or not it has been used, has an operating label filled with the name of the case concerned and with a red label indicating that the equipment is unclean. This allows the cleaning operator to know immediately all the equipment that will need cleaning. It is also essential for the operator to attach a red label to the operating label on the door of the room, thus indicating that the room has been used for a process and that it must be cleaned.

When all autoclave cycles in the document are finished, all sterile packages are placed in a double bag, which is signed and dated. The bag is placed in an airlock access to a room where the parts will be packed in crystal sleeve, consisting of a material more resistant to mechanical shocks, preventing the parts from being damaged. Finally, after being wrapped in crystal mango, the pieces are put back in the double bag, and are delivered to the warehouse, where they are stored according to the project to which they belong (it should be noted that the same production document, currently, can contain several projects/customers).

In the cleaning process it is strictly necessary that the cleaning operator paste, on all equipment present and on the door of the room, a green label on the top of the red one, respective

to the previous production, which proves that the equipment has been disinfected.

Before leaving the room, the cleaning operator must register in the logbooks of the room and in that of each equipment that a cleaning occurred, signing and dating the respective registration.

The changeover, as it is designated in the company, is a document that is filled in at three different times. First, it is filled by the operators when the activity ends. In a second phase, by the cleaning operator after finishing his function, serving as proof that the cleaning of the room was in fact carried out and labelled. Finally, it is the responsibility of all operators to check how effective was the cleaning, whenever they are available and as soon as possible. If problems associated with cleaning are detected, if for example, the lack of a green label proving that the equipment has been cleaned, it is necessary to ensure that the cleaning operator is notified in time and does not compromise the next process.

4 Diagnosis

4.1 Production process

The diagnosis made allowed to understand the details regarding the production in the room Y, as well as to identify problems and delays in production, through observations and notes made to various processes, always with critical spirit before all the steps contained in the procedure. In order to make the diagnosis of the production, it was defined that the element of the study would be the part itself, so that the follow-up was carried out from the beginning of its assembly, until it is doubly packed. The tasks performed throughout the production process of the part were characterized (added value, not added and improvable) and timed. Thus, it is possible to define which areas have room for improvement or, at its limit, move towards the elimination of tasks that do not increase the value of the product, with a view to reducing waste and consecutively increasing the efficiency of the production flow.

After 10 observations made to the assembly of parts, the results are presented in the following figure and table:

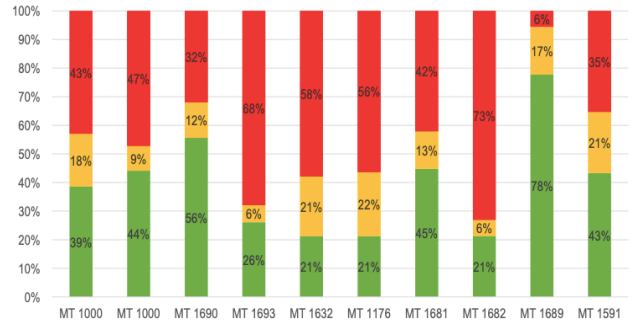

Figure 2 - Analysis carried out to the assembly process

Table 1 - Average percentages of non-added value, improvable and added in a total of 10 observations

Total number of observations	Average of total % of tasks with non-added value (%)	Average % of improvable tasks (%)	Average % of tasks with added value (%)
10	46%	15%	39%

There is an average of 39% of added value, compared with the entire process time. This average classification allows to conclude that less than half of the process duration is spent on creating value for the final product.

The improved tasks - yellow in Figure 2 - represent about 15% of the process (Table 1). It is worth to note the lengthy interpretation of the assembly and the successive movement of the operator between the workbench and the storage cart to seek, as well as to identify, the bag of components necessary for assembly, due to the lack of a properly suitable and sectioned place to store them.

The red part presented in Figure 2 is related to the tasks of non-added value, which represent about 46% compared of the entire process (Table 1). The waiting time resulting from the interruption of the assembly reflect a large part of this percentage (39%) and occur due to several reasons: need of the auxiliary operator in another assembly / packaging and doubts that arise in the course of the process. It can, less frequently, be also due to, sometimes also due to exits from the room due to lack of material inherent in the assembly or deterioration of gowning accessories. The operator's demand for some necessary missing component/record represents about 4% of the percentage initially mentioned and is due to the lack of organization of the registers, labels and inside of drawers.

4.2 Cleaning process

As with production, a diagnosis of Y's cleaning flow was also made, due to the extreme importance and impact that cleaning has on the quality of the final product. A methodology of analysis similar to that described for the production flow was used to the cleaning process, as shown in Figure 3.

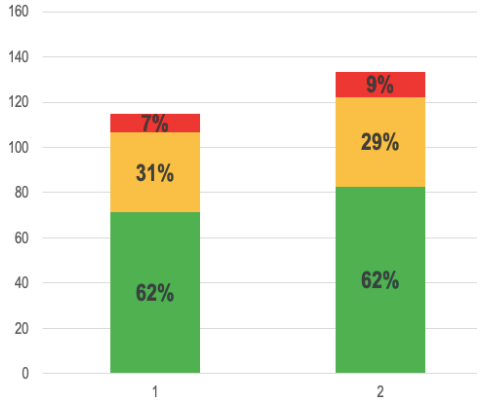

Figure 3 - Analysis performed on the room cleaning process

According to the previous figure, 2 observations of the cleaning process were made. It is concluded, immediately, that the cleanings are quite coherent with each other, and that the procedure is mostly fulfilled, since the cleaning operations observed were carried out by different operators. The most significant percentage lies in value-added tasks, an average of 62%, characterized by activities that are in fact included in the procedure and are carried out in the correct order.

The Spaghetti Diagram was also used, a lean tool widely used that allows the identification, in a fast and visual way, of all movements made by the operator inside the room under study.

The color red corresponds to tasks of non-added value, yellow to the improvable ones and, finally, green represents those of

added value. It should be noted that each line in Figure 4 represents a single movement done by an operator.

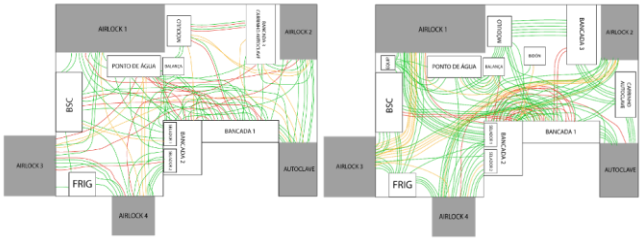

Figure 4 – First (left) and second (right) observations

Both situations demonstrate that the cleaning flow is undefined, that is, that they do not follow a coherent order of cleaning and that, above all, they do not comply with the correct order established in the procedure. There are many activities without added value corresponding to the passage of disinfectant or water more than once on the same surface and referring to a series of unnecessary movements to different areas of the plant.

5 Solutions

In addition to the diagnosis made to the present case study, methods of resolution were applied to the problems identified in the previous phase, in the light of Lean thinking. Each of the challenges encountered was assigned a team responsible for its resolution, composed of members of the various departments of the company.

5.1 Quick-Win (QW) & A3 Problem Solving (A3)

Generally, the QW methodology is fast resolving, with an ideal duration of one week, and is characterized by a low effort to find a solution, but with a high impact for the company. However, many of the QWs that will be presented in this dissertation are of a more complex nature, so their implementation will take much longer than usual.

The reasoning used in an A3 reflects lean thinking applied to problem solving. This method should be used when there is no obvious and direct solution to the challenge under study. It involves a significant effort on the part of the allocated team, with a very significant impact on the company at the time of its implementation. Its application lasts an average of 6 to 8 weeks until countermeasures are implemented.

5.2 Countermeasures: Development & Implementation

In the annexes of this dissertation are detailed the action plans used for the efficient implementation of the countermeasures developed to solve the problems encountered.

The most relevant problems found will be highlighted in this summary. The first concerns the incoherence of the nomenclature used in the document for production compared to that used in the software. To remedy the problem, the nomenclature has been fully standardised so that this type of mistake will not be made again in the future.

In addition, the sheet used for the changeover was also not the most appropriate, it was a single document, common to all rooms, which made its filling slow and with a large number of fields unnecessary to many rooms. A new version of the sheet was developed, adapted to each type of room.

A clear waste associated with the production procedure was identified: difficulty in organizing the workspace and planning tasks during the parts production phase. To reduce the time spent in these activities without added value, a logic of storage of the components in the cart was assigned, the layout of the room was redefined in order to comply with the procedure sequentially (Figure 5), in the most efficient way possible.

Figure 5 – New layout for the room Y

Operation labels and logbooks also revealed to have been two significant factors for wasting time on tasks with no added value. New layouts have been proposed for each case, with a view to making filling them simpler for both production operators and cleaning operators.

Besides these, a few boxes were assigned to each autoclave cycle, avoiding any mixtures of finished parts.

In addition to these changes, as provided for by the planning, the drawers present in the room were identified, with a well-defined place for consumables, tools and documents. Figure 6 shows some examples of identifying the materials inside the various drawers.

Figure 6 – Identification of utensils inside the drawers of room Y

Finally, in order to fill in the lack of work between different shifts, an identification card was developed that allows identifying the last piece that was performed by the previous shift. The card is stored inside one of the storage drawers and must be placed by the operator above the last piece made before leaving the room (Figure 7).

Figure 7 – Work pass identification card between shifts

Throughout the diagnosis, it was observed, for both the rooms analyzed, that there are numerous entrances and exits of the room during the process. The objectives and countermeasures proposed for this problem were developed only for the room X, since it was the room where its frequency proved most significant, at the time the diagnosis was made.

Although this dissertation presents only the diagnosis related to recurrent problems in room Y, given the transversally of this problem to all units of the installation, and given that one of

the sensorization ideas proposed in this dissertation is related to the high number of entrances and exits of the room, this challenge was analyzed in detail, even if applied to room X. There was a recurrent lack of materials necessary for weighing and cleaning the room, namely funnels, shovels, spatulas and disinfectant. In addition to these utensils, there was also a shortage of clothing material inside the room, with special emphasis on gloves, which easily tear and which replacement has to be immediate, according to the good practices established by the company. Since operators only notice the lack of a specific material during weighing, the process has to be constantly interrupted by exits from the room to collect the necessary material, which is in the warehouse, resulting in interruptions of the process and a high time spent in this activity that does not add value to the product.

A minimum stock of material required for weighing the raw materials was defined, together with the chief operating officer. The numbers chosen were based on the experience of the operators, since there is no history regarding the existence of materials inside the rooms. The following was the identification of all the boxes present inside the room, concerning the materials used to aid weighing. In order to ensure that the minimum stock previously defined is respected, Kanban cards were used in each of the boxes in order to alert the operator when it is necessary to replenish the stock. When the card becomes visible inside the box, the operator places it in the living room door so that the stock can be quickly replenished by a production operator or, ultimately, immediately before the start of the next process. The two improvements implemented are illustrated in the next figure.

Figure 8 – Kanban cards (left) and box's identification (right)

Operators' familiarization to these implemented improvements was not immediate. With regard to the proposed logic for the storage trolley, the operators said that they often forgot to comply with it. Thus, a general clarification session was held, which established that it would be necessary to paste the sheet directly into the trolley, at the level of the operator's field of view. Regarding the new layout of the room and the boxes for the components of each autoclave cycle, there was a rapid acceptance and compliance with the new measures. The operators showed some resistance to the use of the identification of drawers, and revealed that, for reasons of habit, they continued to spend time in opening and closing the drawers consecutively when searching for a particular utensil. Regarding the passage of information at the time of the shift change, the standardization has also proved to be somewhat complex as it is not possible to stop the cycle and change shifts at any time. To address this problem, a clarification meeting was held with the responsible team, external auditors and a member of the QA department to establish the specific phases where cycles can be suspended.

To verify all these difficulties, several face-to-face evaluations of the system were carried out before and after these mentioned corrections.

6 Standardization

It is important that all the improvements implemented are properly standardized, to ensure that the defined procedure is fulfilled identically by the same performer and between performers. For this, they must be followed by a continuous and daily effort, in order to avoid setbacks to the initial situation, with negative consequences for the company and for the motivation of all employees.

In the present case study, it was possible to verify a certain reluctance on the part of operators when implementing some of the improvements. In fact, in the current reality of the industrial sector, it is still possible to observe a certain resistance, devaluation and misunderstanding regarding the importance of these improvements for the process. This means that, although responsible for monitoring them, they voluntarily do not comply with the procedures associated with standardization, or simply forget to carry them out.

Faced with this difficulty, the need arose to develop a **methodology** that would support the company in the autonomous and automatic control of the improvements implemented, with a view to the stability of standardization. This methodology allows, in a general approach to the process, that any hierarchical level of the organization can quickly audit the solutions implemented, without the need for periodic, time-consuming external audits and associated costs. To ensure the autonomy of these audits, four sensorization proposals have been devised to allow the implemented improvements to be continuously monitored, through real-time measurement of certain critical values for process efficiency.

In addition to this objective, the sensors also allow, in the future, to reinforce the diagnoses made to production flows, by obtaining data in real time, and not based only on a relatively small number of observations made.

6.1 Sensors

Due to the impossibility of implementing these proposals in the company where the diagnosis was made, due to the costs it entails and the time it would be necessary for all proposals to be implemented and tested, a model representative of room Y was developed. In addition to this model, another illustration of a drawer of one of the modules inside the room was developed in order to illustrate the way the various sensors operate.

These models were conceived as an explanatory model for companies with a low (or zero) level of maturity in i4.0, and a low receptibility to these concepts, allowing to illustrate that, through a relatively low investment, several critical aspects of the production flow can be identified efficiently and in real time.

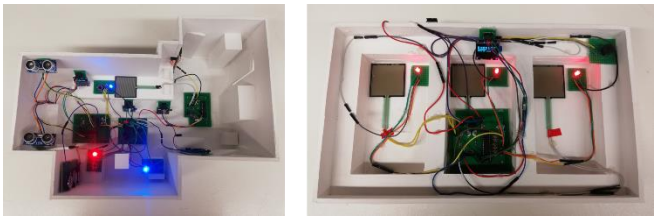

Figure 8 – Finished models, top view

The first proposal is based on the quantification of a part's waiting time, in real time, regarding the total production time. In fact, waiting times account for 39% of the total time spent on assembling and packaging a part.

This time will appear on a small LCD - Liquid Crystal Display - present in the model and theoretically appear, in real time, on a dashboard outside the room. This would allow project managers immediate access to this data so that action can be taken if these times prove to be extremely high. This proposal is based on the design principle of I4.0 called transparency in information, allowing real-time access to data obtained during the process through the dashboard, and at all levels of the organization. On the other hand, the careful analysis of this data drives the search for mechanisms to assist the operator in reducing these waiting times and optimizing the process, so indirectly, this concept can also be based on the design principle called technical assistance. In addition to the two design principles mentioned, this proposed sensorization also allows decentralized decisions, since the operator can decide in real time what to do to overcome the problem of high waiting times.

The second proposal arises with the aim of accounting, again in real time, the numerous exits and entrances in the room, which constitute activities that do not create added value for the final product, and which should be reduced or, if possible, totally eliminated. On the LCD associated with this proposal, the hours of entry and exit of the room by the operators will be recorded, and the first time recorded corresponds to the beginning of the process and the last to its end. Thus, in addition to this data it is possible to calculate the duration of each output (activity without any added value for the product) and, in the end, it is possible to obtain the total time of non-added value in inputs and outputs of the room, the total time of the process and, relating these two data, calculate the percentage of non-added value of the set of these activities. Due to the similarity with the previous proposal, the second proposal also relies on the principles of transparency in information, technical assistance and decentralised decisions.

The third concept aims to simulate a sensorization of a traditional Lean tool, the 5S, thus giving rise to a kind of an "e-5S". The objective is to ensure the effectiveness in organizing one of the drawers present in the room, where the various records used during the process are stored. In addition, it allows to alert to the temporary absence of records of the appropriate places (visual signs) or, ultimately, to their lack (problem identified as frequent at the time of diagnosis) and to the need for stock replacement - sound alert. To facilitate the understanding of this concept, a model representative of a drawer was developed, where the locations destined for each type of record were identified: operating labels, logbooks and cleaning labels. The design principles that best characterize this type of sensing are technical assistance, by directly alerting the operator to the high time spent on the registers, allowing the latter to act immediately accordingly, and interconnectivity, by allowing the continuous and real-time passage of information, through the strong connection between the sensors and the collaborators. Transparency in information is also present in this proposal by allowing all levels of the organization to become aware in real time if it is necessary to replenish the stock or if registration times are significantly high.

The last proposal allows for visual identification of all the equipment present inside the room, both those that are cleaned and those that are for cleaning. One of the problems identified during the diagnosis and addressed with the use of this proposal, is the uncertainty in the number of equipment inside the room, ultimately causing production delays, if any equipment has remained unclean. For this proposal, it was decided to perform it only for 3 equipments, since it is considered enough to understand its purpose, avoiding overloading the model unnecessarily. This Poka-yoke solution allows to identify, in a visual and intuitive way, the number of equipments inside the unit and its cleaning status, avoiding forgetfulness and consecutive delays in the next process. This sensor also reflects three design principles. The first is the decentralized decisions, since it allows the cleaning operator to make the decision, without any doubt, to clean the equipment when it is associated with a red LED. The second is technical assistance, allowing the operator to know exactly the number of equipments inside the room. Finally, it reflects the transparency in the information, since the cleaning status of all equipment can be communicated abroad through the dashboard, allowing the cleaning officer to act accordingly, in case there is an anomaly, without compromising, thus, the planning of the following productions.

6.2 Dashboard

An example of a dashboard was developed that contains, in a structured and visually appealing way, several key process indicators. Summarizing, the on-board panel shall contain, in real time, the following data (Figure 9):

• Waiting times per part;

• Number of entrances and exits of the room and their duration;

• Cleaning status of the equipment (if it is clean or for cleaning);

• Number of components already completed, per autoclave cycle;

• Cycle percentage already completed;

• Section where notifications are automatically generated, e.g. lack of stock of manual records (labels).

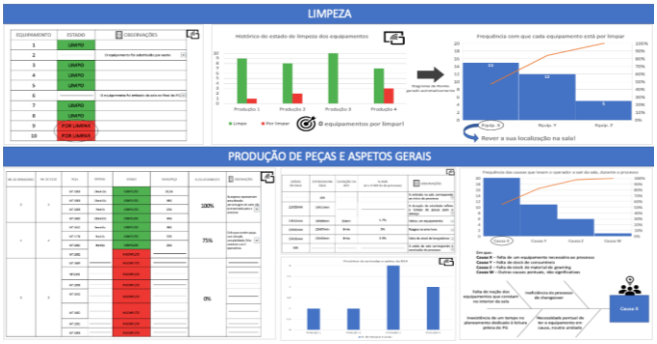

Figure 9 – Dashboard developed to monitor the improvements implemented in room Y

With the use of the information presented in the support dashboard, it is possible to perform internal audits of the improvements implemented in an automatic and continuous way, dispensing of the periodic presence of an internal or external auditor to the company. In the background, the decision is made by the operator in real time, whenever deviations occur to the established target values, through corrective actions, and in the long-term preventive, which ensure the return to stability of the standardization of the procedures. This allows to avoid setbacks to the pre-diagnosis situation, with drastic consequences for the efficiency of the process. Thus, the operator can autonomously, consciously and immediately choose the appropriate solution, based on Lean tools, traditional or supported by scanning, thus contributing to the evolution from Lean to Lean 4.0.

6.3 Methodology

This methodology aims to assist in the standardization of improvements implemented in a given production flow. The system developed with this methodology works, in essence, as a system of support to the logic present in an SDCA cycle, and in an adaptation of a PDCA cycle, with insertion of a sensorization system. Its application helps in the efficient standardization of improvement solutions, with a constant verification of their compliance, through the evaluation of the results obtained, and with occasional adjustments to the new method, in case deviations to the target value occur.

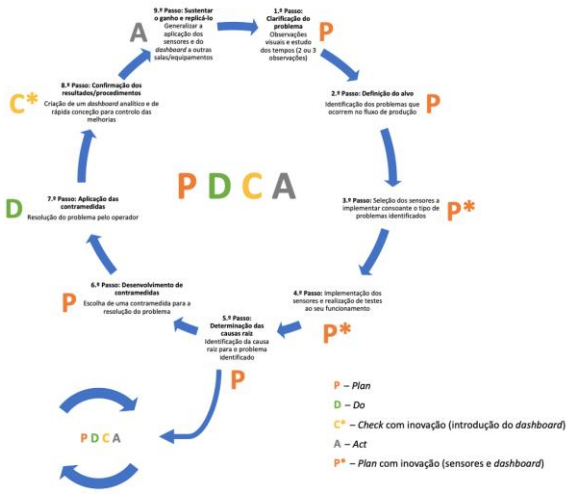

Figure 10 – First part of the methodology - Adapted PDCA Cycle

The PDCA cycle represented in Figure 10 is composed by a set of nine steps performed sequentially, which is initiated by visual observations and study of times and ends in extrapolation of this procedure to other rooms and/or equipment. The third and fourth step consists of an addition of sensing to the traditional PDCA cycle, in order to reinforce the diagnosis made by auditors (human beings) and, later, assist in the stability of the standardization of the improvements implemented. Also, for the fourth step, tests should be carried out regularly for a certain period of time, from one week to one month, depending on the level of complexity of the sensors implemented. For the fifth step, it is essential to set up a general meeting with all employees so that, together, they can determine the root cause for the identified problem. Each problem identified will have its root cause associated (it is in this step that new PDCA cycles are generated, as many as necessary!). As in the previous step, for step 6 it is necessary that the various operators of the organization, together with the auditors, meet carefully to define the countermeasure for solving the problem. The seventh step of the cycle is the implementation of countermeasures/improvements.

Regarding the eighth step of the methodology, it is essential to create a dashboard that contains key process indicators that are related to the problems identified during the observations made. Also, in the dashboard, it is necessary to establish target values to be reached for each indicator. After validating the methodology for a specific production flow, the last step of the PDCA cycle presented in Figure 10 is followed by the support of the gain and the replication of logic for other machines or rooms existing in the company.

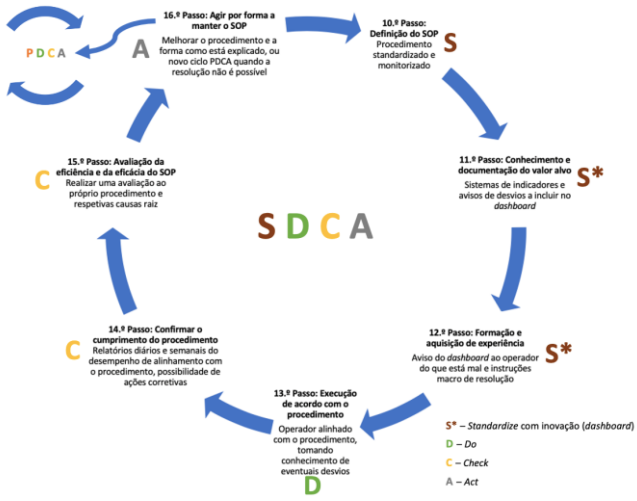

Figure 11 – Second part of the methodology - Adapted SDCA cycle

The SDCA cycle shown in Figure 11 aims to translate the various steps that make up the control of the improvements implemented and the general procedure (SOP). For this, it is necessary to use the data obtained in real time by the sensors and the analysis performed by the dashboard. The operator being notified by the dashboard can immediately correct the problem, through macro resolution instructions, and return to the stability of the standardization of the respective improvement. To ensure compliance with the whole procedure, it is often important to carry out performance reports that may trigger any corrective actions. Eventually, if a situation arises where the operator cannot autonomously solve the problem, a new PDCA cycle is required to determine a new countermeasure.

In conclusion, with the implementation of these two cycles presented in Figure 10 and Figure 11, it is possible to not only guarantee the necessary support to control the standardization of the measures, but also the reinforcement of the diagnosis made by the auditors. The increased credibility of the diagnosis is ensured since the sensors installed allow for the collection of data in real time, and in a much higher amount than those obtained by auditors and, therefore, closer to what is reality.

6.4 Methodology applied to the case study

For the present case study, the idea of sensing arose after the diagnosis. Thus, the sensors developed for this particular case are not intended to reinforce the previously made diagnosis, but rather to monitor the standardization of the improvements implemented.

The following figure (Figure 12) represents the flowchart of the two possible scenarios, from visual observations to improvements being fully implemented and successfully standardized. Surrounded by the dashed rose, there is the logic followed for the study case. Blue is represented the

scenario of the methodology proposed in Figure 10 and Figure 11. The purpose of this comparison is to highlight, in a visual and fast way, the two logics of approach and the different actors.

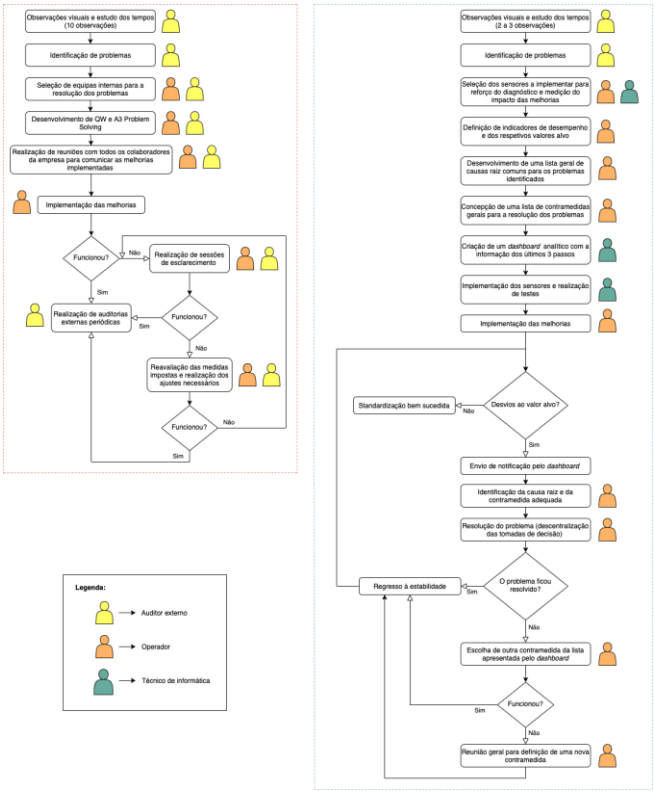

Figure 12 – Methodology used: real case (in pink) and proposed case (in blue)

The beginning is similar in both approaches, it consists of first observing the course of the process and identifying their problems. In the traditional approach used to solve the present case study (the rose), after the initial phase described it is necessary to select teams, develop solutions based on Lean tools, and hold meetings with all employees of the company to communicate the improvements that will be implemented. In this study, after the aforementioned meetings, improvements were implemented. When there were significant deviations to the target values, that is, failures in standardization, it was necessary to perform several clarification sessions, with the help of external experts. Subsequently, it was necessary to evaluate the effectiveness of these sessions and to make possible corrections to ensure stability. According to this logic, it is also necessary to carry out periodic external audits by contracted specialists, with their associated costs.

The methodology proposed in this dissertation (in blue), after the initial phase common to both approaches, presents as the next phase the selection of the necessary sensors, with the help of a computer technician, to reinforce and validate the diagnosis obtained with the observations to the process. Then, it is important to define key process indicators and their target values for the results that will be measured by the sensors. Operators should also, and together, build a general list of root causes and countermeasures to the problems encountered. They should, then, request a computer technician to design an analytical dashboard containing all this information. The technician shall install the sensors and carry out their tests, ensuring the necessary interconnection between the dashboard and the sensors developed. Only after this sequence of operations are the improvements implemented, contrary to what happens with the actual case surrounded by the rose line. If deviations occur to the pre-established target values, the dashboard promptly notifies the operator, who will act immediately to identify the root cause and the appropriate countermeasure. If the choices made by the operator are appropriate, a return to stability in standardisation is observed.

If the choices have not allowed to resolve the problem, it is again the operator who has the responsibility to choose another countermeasure from the list presented by the dashboard. If it still does not work, then the operator must convene a general meeting so that new countermeasures are defined according to the problem encountered.

Thus, this methodology allows not only for an evolution from Lean to Lean 4.0, but also for a notorious decentralization of the decisions, by passing the responsibility of the resolution of possible deviations, from top management directly to the operator, increasing their motivation, dedication and emotional investment to future processes. At the same time, it ensures the monitoring of the standardization of the improvements implemented, in an automatic and continuous way, contributing to the increase of the autonomy of the company, avoiding the performance of sporadic external audits and the costs that these entail.

7 Conclusions

This thesis has as main objective to demonstrate, through the application of a proposed methodology, the importance of the evolution that is necessary to make at the technological level in companies. The dissertation acts at the level of problem diagnosis and in the assistance in standardizing improvements, ensuring competitiveness and preparation for possible changes at the business level. The thesis aims to demonstrate that this adaptation to a new reality can be made in a simple and relatively fast way, with an associated investment tolerable by companies with a low level of maturity in i4.0.

The dissertation began with the realization of a diagnosis in a company dedicated to the production of biopharmaceuticals, where a room and a production flow were selected to make its diagnosis and, later, identify its problems, root causes and solutions. The chosen room, named in this dissertation by room Y, is dedicated to the assembly and packaging of parts. Thus, the process encompasses all phases present in the preparation/production of a part, from the selection of its components, to its packaging to be delivered in storage. Because it is a type of industry that excels in strict and constant hygiene and disinfection, in addition to production, the cleaning process of the room was also analysed.

Through observations and timings made to the process, it was possible to identify the main problems. For its resolution, two traditional Lean tools for problem solving were used: Quick-Win and A3 Problem Solving. The identified problems were categorized into one of the two types of tools mentioned. Subsequently, teams responsible for the preparation of countermeasures and their implementation were selected, with the help of external experts. This first phase, from the beginning of the diagnosis to the beginning of the implementation of countermeasures resulting from the application of problem-solving tools, lasted about 2 months and involved a significant effort. The question was therefore raised as to whether it would be possible to make the diagnosis in an automatic and, consecutively, more robust way, something already recurrent in companies with some level of industrial automation, contrary to what happens in the company under study, where there is a high incidence of

manual work, without automatic data collection, and where the fear of significant investments is a reality.

The waiting times to which the part is subject during the process, the numerous entrances and exits of the room, the high incidence and time spent in manual records, and the uncertainty of cleaning operators as to the number of equipment inside the room, proved to be the most recurrent and significant problems when carrying out a process. In the second part of this dissertation, two models representing the room under study and the interior of a drawer were constructed, as well as a set of sensors applied to these problems, acoording to i4.0 design principles, with a low level of complexity and cost, and which, if properly installed at the time of diagnosis, based on observations and study of the times, would allow it to be validated and increased its robustness. The sensors were later installed in the models developed in order to illustrate their purpose.

In a traditional approach, after the implementation of the improvements, the standardization phase of procedures would be followed to ensure the change of habits and the consistent application of procedures. To verify and sustain this standardization process, internal audits are often used to assess the impact of these improvements, verify the standardization of the countermeasures implemented and assist in the resolution of any problems. However, given the ease in the implementation of these sensors, and provided that performance indicators appropriate to the process and their target values are defined *a priori*, it was considered the possibility of performing these audits in an automatic and continuous way, using digitization through support dashboards, adapted according to the situation under analysis, and adjustable from company to company.

Thus, a dashboard was developed for a more analytical interpretation, allowing real-time access to production data, and an immediate decision-making by the operator in case of possible deviations in the implementation of the solutions. The corrective actions taken ensure the return to stability of the standardization of the procedures, and avoid setbacks to the pre-diagnosis situation, with drastic consequences for the efficiency of the process.

In the case study described in this dissertation, the improvements implemented sometimes triggered some resistance to change, forgetfulness, or difficulty in their compliance by employees. Faced with this difficulty, the need arose to develop a methodology that would support the company in the autonomous and automatic control of the improvements implemented with a view to the stability of standardization. The consolidation methodology describes all the steps needed from visual observations to standardized improvements, including the part dedicated to sensor selection and installation and dashboard creation to monitor implemented countermeasures. For its formulation, an adaptation of a PDCA cycle and an SDCA was made, visible in Figure 10 and Figure 11.

Although this methodology was only exemplified directly for the case study of this dissertation, it is an instrument to support the standardization phase of any procedure. It is, therefore, applicable to the entire industrial sector, and allows the involvement and contribution of all levels of the organization so that together they can achieve the same objective: to mitigate possible deviations and consolidate the standardisation of the improvements implemented.

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