POLITECNICO DI MILANO

School of Industrial and Information Engineering

Department of Management, Economics, and Industrial Engineering

Master of Science in Management Engineering

Master thesis

OEE IMPROVEMENT IN A NUTRACEUTICAL STICK-PACK PACKAGING LINE

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ABSTRACT (ENGLISH)

During the course of this project, the A3 methodology has been rigorously followed in order to improve the original situation, in addition with the different lean tools and principles that have defined the theoretical framework of the project. Thus, the initial scenario has been defined and quantified, and the relevance of the project for the company has been evaluated. It has been observed that one of the biggest areas for improvement, due to its high impact on OEE, was the batch change, so the project has focused on them. Subsequently, some goals have been established to be reached with the improvement project, in order to be able to benchmark the results obtained. Once it was clear, using techniques such as the "5-Why's" and the Ishikawa diagram, a selection of possible causes that affected the problem was successfully identified. To mitigate or eliminate these causes, countermeasures have been developed. These countermeasures have been implemented following a defined roadmap and the results from the final scenario have been monitored. Thanks to the implemented countermeasures, a very positive outcome has been obtained, reducing the batch change time from 72 minutes to 58 minutes, exceeding the nice-to-have target, and the SKU change time from 46,4 minutes to 41,8 minutes, reaching the must-have target. In order to maintain this improvement and to prevent it from reverting to the original situation, some control charts have been designed to identify any out-of-control observation, analyse it, and detect the possible causes. To continue striving for the best, some future development countermeasures have been designed and presented, ready to be implemented in the future by the company.

ABSTRACT (ITALIANO)

Nel corso di questo progetto, la metodologia A3 è stata seguita in modo rigoroso per migliorare la situazione iniziale, insieme ai diversi strumenti e principi Lean che hanno definito il quadro teorico del progetto. È così che lo scenario iniziale è stato definito e quantificato ed è stata valutata la rilevanza del progetto per l'azienda. Si è osservato che una delle maggiori aree di miglioramento, a causa del suo alto impatto sull'OEE, era il cambio dei lotti, quindi il progetto si è concentrato su di essi. Successivamente sono stati stabiliti alcuni obiettivi da raggiungere con il progetto di miglioramento per poter fare un benchmark dei risultati ottenuti. Una volta chiarito questo punto, utilizzando tecniche come i "5-Why's" e il diagramma Ishikawa, è stata identificata con successo una selezione di possibili cause che hanno influenzato il problema. Per mitigare o eliminare queste cause, sono state sviluppate delle contromisure. Queste contromisure sono state implementate seguendo una roadmap definita e i risultati dello scenario finale sono stati monitorati. Grazie alle contromisure implementate è stato ottenuto un risultato molto positivo: Il tempo di cambio lotto è stato ridotto da 72 minuti a 58 minuti, superando l'obiettivo nice-to-have, e il tempo di cambio SKU è stato ridotto da 46,4 minuti a 41,8 minuti, raggiungendo l'obiettivo must-have. Per mantenere questo miglioramento ed evitare che si torni alla situazione originale, sono state progettate alcune Control Charts per identificare qualsiasi osservazione fuori controllo, analizzarla e individuarne le possibili cause. Per continuare a cercare il miglioramento, sono state progettate e presentate alcune contromisure di sviluppo futuro, pronte per essere implementate in futuro dall'azienda.

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1. EXECUTIVE SUMMARY

This master thesis is made in collaboration between the Politecnico di Milano and the company Fine Foods & Pharmaceuticals N.T.M. S.p.A., in which a specific concern of the company has been addressed through the application of the A3 framework.

This master thesis opens with a theoretical framework which defines the introduction and scope of the work and details all the theoretical background and tools that will be used during the practical part of the project.

Thus, this theoretical framework describes the history of modern production, from handcraft production to mass production, and finally to lean production. With the introduction of lean manufacturing, the well-known Toyota Production System is presented, in which all types of wastes that can be found are detailed and the two pillars that make up the structure are presented. These pillars, Jidoka and Just-in-time, are explained in order to understand the philosophy of this production system. Subsequently, the Lean Principles are clarified, which serve as a guideline for any continuous improvement project and are complemented by an explanation of the A3 framework used throughout the project. Finally, the different tools used during the project are briefly presented.

Focusing more on the company and its industry, the nutraceutical sector is depicted in order to get an idea of the background in which the company operates, and good manufacturing practices (GMPs) and the manufacturing execution systems (MES) are also presented, as they hold a great weight in the project and in the company.

The theoretical part is concluded with a collection of theoretical cases similar to the work that will be performed in the company, which have been considered very valuable as they are lean manufacturing projects in which similar tools have been applied in sectors comparable to the nutraceuticals one.

As far as the practical part is concerned, it begins by defining the current situation and highlighting its importance of this project for the stakeholders. One of the company's current concerns is the low OEE of its stick-pack lines, which is detrimental to efficiency and generates time and economic losses.

In order to quantify the initial situation, the data available within the company was analysed to try to identify which was the most critical area affecting the OEE. It could be seen that, in both 2020 and 2021, set-up was one of the most important losses. Breaking this category down, the activity that had the most impact was batch change in both 2020 and 2021. In total, around 270 hours were spent on batch changes during 2021. Similar to batch change were SKU changes, which had a very similar procedure but required changing the materials in between because the country of destination of the product varied. For both batch and SKU change it was proceeded to collect data on the durations of these, in order to have a baseline on which to develop the improvement project.

The aim set for this project was to reduce the time spent on the batch change before March by a 10% for the must-have objective, and 15% for the nice-to-have one. For the case of the SKU change, it was included in the scope of the project, and an identical improvement objective was proposed.

Once the problem and the goals had been defined, the root causes that could lead to the lengthening of durations and their variability were analysed using the techniques detailed in the theoretical part. Thus, several causes were found that were subsequently tackled with countermeasures.

Four countermeasures were developed, which briefly aimed to: promote a standard batch change procedure to reduce both duration and variability, simplify some batch opening activities, provide more expertise to all line operators to evenly distribute the activities, and have all reels with the same configuration to avoid the need to change the position of the sensors.

For the implementation of the countermeasures, a roadmap was prepared in which the timeline for applying the different activities that constituted the countermeasures was included. The implementation covered the period from the 11th of January to the 4th of March, during which all countermeasures could be implemented with the exception of the second one.

During the monitoring, the durations for both the batch change and the SKU change were taken in an identical way to the initial situation. A noticeable improvement could be seen in the batch change, which dropped from 72 minutes in the initial situation to 58 minutes, far exceeding the nice-to-have target. For the SKU change, there was also an improvement, as the duration was reduced from 46,4 minutes to 41,8 minutes, thus reaching the must-have target.

In order to sustain this continuous improvement and avoid reverting back to the initial situation, control limits have been set for the batch change time. If there are any observations outside the limits, it will be necessary to investigate them and note down the causes, in order to understand what occurs most frequently. Also, other measures have been prepared and are ready to be implemented, which could help to further increase the efficiency of the line.

2. INTRODUCTION

The project to be presented in this master's thesis will be a collaborative effort between the Politecnico di Milano and the company Fine Foods & Pharmaceuticals N.T.M. S.p.A., which is dedicated to the manufacture of various pharmaceutical and nutraceutical products in a wide variety of formats. In this industry, the processes are complex and require a very strict control of the entire chain, and a stringent set of regulations must be respected to ensure the highest quality of all the products that are manufactured.

Fine Foods & Pharmaceuticals N.T.M. S.p.A. is a company that firmly believes in the continuous improvement of their processes and is constantly applying and developing new initiatives to follow this philosophy. The main objective of this project consists in increasing the efficiency of a manufacturing line, specifically the one dedicated to the production of nutraceutical sticks, called stick-pack line.

Although there are several manufacturing lines in the factory, the scope of this project has focused specifically on the stick-pack, as after careful observation of which projects had higher priority, it has been established that this particular one required higher attention, as this year's OEE (Overall Equipment Efficiency) results were clearly below the expected results. The objective of the company is to strive for perfection, therefore always trying to achieve the maximum efficiency possible. Being under the expected target is not a usual situation, which requires an urgent action to get back on track.

To achieve this, Lean Methodologies learnt during the formation received in the MSc in Management Engineering at the Politecnico di Milano will be put into practice, using the tools covered in the Operations Management course as well as in the Industrial Management Lab and Toolbox project.

The project will rigorously follow the A3 methodology, following step by step all the phases of the process, from the definition of the problem to the monitoring of the impact of the countermeasures. These countermeasures will be applied with the acknowledgment and authorisation of all parties involved and will be constantly monitored to ensure that the results they yield are positive. The outline structure of the project is detailed below:

CHAPTER 3 – Background knowledge: It is a detailed explanation of all the concepts, tools and methodologies that will be used during the project.

CHAPTER 4 – Company overview: This section explains the company's situation and quality certifications in order to provide useful information for the project.

CHAPTER 5 – Problem background: It is dedicated to providing the problem definition and a description of the process that will be dealt during the project.

CHAPTER 6 – Problem breakdown: In this section the problem will be carefully analysed, gathering useful data to quantify the initial situation.

CHAPTER 7 – Target setting: The main objectives of the project will be set in this section, which will be evaluated at the end of the project.

CHAPTER 8 – Root cause analysis: This section consists in the various techniques used to identify the main causes that can be tackled to achieve the objectives set.

CHAPTER 9 – Countermeasure development: It presents the countermeasures designed to solve or mitigate the root causes, in order to achieve an improvement.
CHAPTER 10 – Countermeasure implementation: This section presents the schedule with which the measures have been applied during the whole project.
CHAPTER 11 – Monitoring: The impact of the countermeasures will be evaluated by gathering more data, in order to prove that the targets have been achieved.
CHAPTER 12 – Standardization and future development: In this section all the measures applicable in the future will be explained, and the benefits they can bring.

3. BACKGROUND KNOWLEDGE

- **History of Lean Manufacturing**

Early stages – Handcrafted production

The history of lean methodologies has always been closely linked to the automotive industry, as it was the cradle of great advances in production systems. In order to reach the origin of lean techniques, it is necessary to understand what the industry was like at the beginning with the manufacture of the first vehicles, and how it evolved to become what it is today.

We can trace the origin of the industry back to 1894, when an affluent member of the English parliament decided to purchase a motor vehicle from Panhart and Levassor (P&L). At that time, there were no specialised car manufacturers, but rather a factory made up of various craftsmen who hand-built the vehicles.

For the manufacture of a car, they met with the customer and designed what the car should be like, and according to the specifications, the necessary parts were ordered, and all the contractors were hired. Each part was made by a different contractor, who had their own methods of manufacturing and gauging, and then came to P&L who would fit them together. This sequential fitting produced what we today call "dimensional creep." So, by the time the fitters reached the last part, the total vehicle could differ significantly in dimensions from the car on the next stand that was being built to the same blueprints.

However, the small craftsmen did not have the means for technological advancement or to improve the tools with which they worked, so it seemed that the industry was stagnating. It was at this point that the appearance of Ford, with his new techniques to reduce costs and increase quality, introduced the mass production system.

Evolution to Mass Production

The introduction of mass production happened thanks to the famous Model T (P. Womack, Roos, & T. Jones, 1990), which was already user-friendly by design. It was intended to be driven and repaired by anyone, without the need for a driver or mechanic. So, its target was a farmer who had only home-made tools, and the handbook was already written in such a way that everything could be fixed without specialised tools.

The key to mass production was not only the use of production lines, but the interchangeability of all parts. To achieve this, Ford persistently insisted on using the same gauge for all components. This interchangeability and simplicity of its pieces gave it a huge competitive advantage over its competitors, as it was no longer necessary to spend effort tweaking the components for fitting them together.

Initially, the operator was entirely dedicated to the manufacturing of one vehicle and did not move on to the next until he had finished that one. Thus, it took 514 minutes to complete a work cycle. The first improvement he introduced was that each operator was dedicated exclusively to a single task, and the operators moved from one car to another when they were finished. Thus, the duration of a work cycle was reduced to 2,3 minutes.

The next improvement that was introduced was that instead of the operator moving from car to car, wasting time on the movement, he was always in the same place, and it was the car that reached him by means of a conveyor belt. This reduced the cycle time to 1,19 minutes. The cost of producing a car, compared to the original cost was almost a third.

To support this improvement, it was required to rethink the way the machines worked. From having general-purpose machines, they were adapted to make only one type of piece, so that set-up times were reduced to almost zero, and any operator, even if unskilled or inexperienced, could work on them with only 5 minutes of training. Thus, one machine after the other, all the parts needed for manufacturing were produced. However, this system was not flexible. Everything was designed to produce those specific parts in very high volume but changing the set-up to produce a different one was very time-consuming.

All in all, this mass production did not consider at all the demand and the request of the clients, so vehicles were produced following a Push strategy. They were produced in advance of the demand, and they would be eventually sold. However, in Japan the followed strategy was quite the opposite. With the Pull strategy, products were made when asked by the client, so they became Make to Order products.

The rise of Lean Production

After World War II, Japanese manufacturing companies faced a severe shortage of material, financial and human resources, which were different from the problems of their Western counterparts. These were the conditions that gave birth to the concept of Lean manufacturing. Toyota Motor Company, with its president Toyoda at the lead, recognised that, by the mid-1940s, US companies outperformed their Japanese counterparts by a factor of ten. To improve, early Japanese leaders such as Toyoda Kiichiro, Shigeo Shingo and Taiichi Ohno devised a new disciplined, process-oriented system, known today as the "Toyota Production System". Taiichi Ohno, who was given the task of developing a system that would improve productivity at Toyota, enough to reach the American figures in three years, is generally regarded as the main force behind this system.

Toyota started searching for smart solutions to be able to produce cars according to customers' specifications with minimum investments, eliminating all those actions that did not add any value for the customer and that represented a cost for the company.

Also, there were other significant problems that Toyota had to address. Firstly, the domestic market was very small, and it required a wide array of vehicle types. Also, the native Japanese work force, as Toyota soon learned, was no longer willing to be treated as an interchangeable part. New labour laws introduced enhanced the position of the workers, in terms of salary and working conditions, increasing their bargaining power.

One of the measures that would provide the flexibility to produce any type of vehicle without compromising efficiency and volume would come from Taiichi Ohno's research with presses. The major Western companies used huge presses that allowed them to produce millions of parts a year, but when the dies needed to be changed, they required to be aligned with the finest precision to function and needed the intervention of experts to do that. A small misalignment could cause serious damage to the press, affecting the company timewise and economically. To avoid this, Western companies had a large number of presses to be able to manufacture each type of part, but Ohno and Toyota did not have this capital budget (P. Womack & T. Jones, Lean Thinking, 1996).

The idea he was able to implement with the help of Shigeo Shingo was that, through the use of rollers, the different dies could be moved along a guide, so that they could be changed easily and with precision, and could even be changed by the workers themselves, thus avoiding the need for specialists. Eventually, it was reduced from one day to an astonishing three minutes to change dies, and it was discovered that working in small batches was more efficient than before, as inventories were reduced and an error could be detected easily, affecting only a small number of units. However, this required all workers to be highly motivated, proactive, and not afraid to report any problems on the line, so that they could intervene as soon as possible.

In order to keep workers highly motivated, they implemented many measures to make them feel like they belonged to the Toyota Community. They would have lifetime employment, and their salary would increase with seniority, therefore motivating them to be loyal to the company. The employees agreed on been active in promoting the interests of the company and by initiating improvements. Ohno tried to give the dignity and appreciation deserved to every role and he instructed the workers on stopping the line for any problem they might had, and a team would be there to help them. With methods such as the “5-Why’s”, they were taught to look for the ultimate cause of each error, and then to fix it so it would not happen again. Thanks to that, the reworks at the end of the line plummeted, and the overall quality of the vehicles sold was higher.

This new way of working, by right sizing the machines for the volume needed, pioneering quick set-ups, self-monitoring the line to prevent defects from going on, and producing in small batches, it was possible to obtain a high variety of products of the highest quality, following a Pull strategy that quickly responds to changing customer desires. This Lean Production is what will be known as the Toyota Production System (TPS), which continues to grow worldwide today.

- **Toyota Production System**

Lean Philosophy

The basic principle of lean production focuses on eliminating or reducing wastes and maximizing those activities that add value for the customer, which is what the client is willing to pay for a certain product. These wastes, which are those activities that add no value for the customer, can be classified in three main categories.

- **MUDA**
  It is the Japanese word for "wastes" and corresponds to all those activities around the production that bring no value and have a cost. Toyota Production System identified seven types of "muda", which are the following: (Salam & Khan, 2016)
    - **Transportation**
      Includes any movement of materials that does not add any value for the customer, such as moving materials between workstations or bringing materials from the warehouse. Ideally the output from one workstation should immediately enter the following workstation. It is an inefficient use of labour and can cause spoilage and stoppages of the line.
    - **Inventory**
      This waste corresponds to having an unnecessary high level of stocks, either for raw materials, works-in-progress or finished products. Having too much material in stock can rise the stocking costs, occupies space, and can lead to spoilage of some of the products.
    - **Movement**
      It can include any physical movement or walking of the operators that is not requested for the manufacturing of a product. It could go from looking for a tool around the warehouse, to working in unergonomic positions that require them to make more movements than needed.
    - **Waiting**
      It corresponds to the unproductive time where workers have to be in idle waiting for the next piece, which can be due to bottlenecks, inadequate flow design, lack of synchronisation or stoppages of the line.
    - **Overproduction**
      It is the waste associated with excessive production that will not be sold to the customer. Producing earlier than needed means that some products might have to face obsolescence, requires more upfront capital, and will occupy stocking space for more time than needed, therefore saturating them. Overproduction can lead to having other types of wastes, like increased inventory and transportation.
    - **Overprocessing**
      This waste is related to the extra work done unintentionally that will not be appreciated by the client. An example of it could be painting or polishing a part of a product that will never be seen by the customer.

- **Defects**
  This waste does not only refer to the physical defects but also to late deliveries, errors in the paperwork, excessive use of raw materials or overgeneration of scrap.

- **MURA**
  It refers to all the inefficiencies that come from the variability of the process. Working unevenly between station can bring multiple problems like excessive waiting times, bottlenecks, overproduction, or waste accumulation. The goal of the Lean Production is to level out the capacity of all the stations to smoothen the process.
- **MURI**
  This last category of wastes corresponds to the overburden of a process. The fact of overproducing brings higher costs, stress, and tension to the process, which can lead to breakdowns of the machines or exhaustion of the employees. "Muri" can have negative effects on the quality and the efficiency of the production process.

A great example to understand how "muda", "mura", and "muri" are related is the one in which it must be decided how to transport a product to the client with trucks. For the example, it is assumed that six tons of product must be transported to the client, but trucks can only carry up to five tons.

If we decided to overload a truck, we would be incurring in "muri", as it would be overburdened and could mean that the truck breaks down during the transport, meaning that the client would receive the material with delay and the repair of the truck would have a big economic impact.

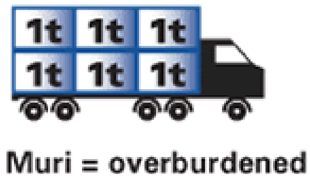

Figure 1. Example of "muri"

If instead of using only one we decided to use three trucks, each carrying two tons of products, we would have "muda". That is because we would be spending unnecessary money in transportation, as with only two trucks it would be possible to transport the six tons of product needed.

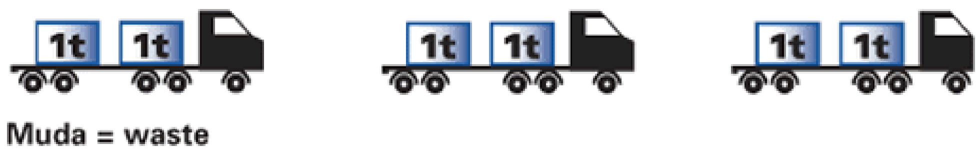

Figure 2. Example of "muda"

If two trucks were used, but the cargo of each one was placed unevenly, like for example two tons in the first truck, and the other four tons in the second truck, we would have "mura".

Even the number of trucks is the optimal one, these unbalance in the load could create problems for the client, as he could need more material than the one received with the first truck or he could have problems with storage space, with the quantity of the second truck.

Figure 3. Example of "mura"

The best option is, therefore, to load the same quantity to each truck, using the minimum number of trucks possible. That would be loading three tons in each of the two trucks, therefore eliminating any overload, any unnecessary cost, or any unevenness in the load.

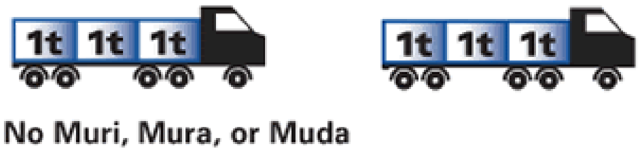

Figure 4. Lean solution without wastes

Thus, in order to eliminate all wastes, whether “muda”, “mura” or “muri”, the Toyota Production System is based on the foundations showed in *Figure 5*.

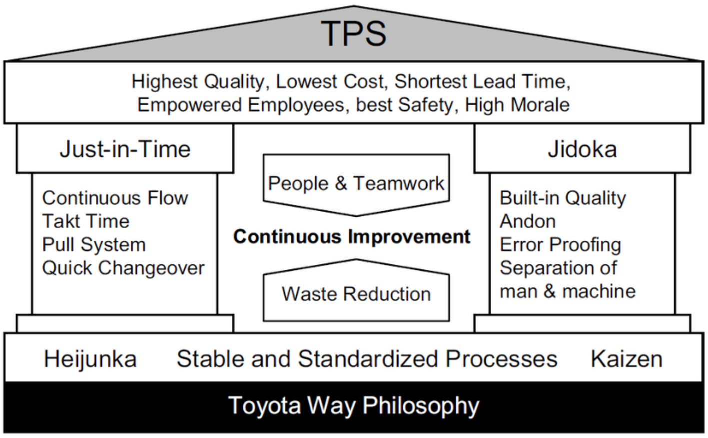

Figure 5. Diagram of the Toyota Production System

The Toyota Production System house is built on a solid ground of continuous improvement, production evenness and standardized processes, where the two main pillars emerge. These pillars are Just-in-time (JIT), which means having the right piece at the right moment, and Jidoka, which can be translated as “automation with a human touch”. The ceiling of the house are the outcomes that can be achieved with this philosophy, which can be interpreted as achieving the highest quality and results with the lowest possible cost.

JUST-IN-TIME PILLAR

Just-in-time is an organizational technique based on producing only the necessary units, in the necessary quantity, at the necessary time by bringing production rates exactly in line with market demand. Therefore, that means that there is no need to have intermediate buffers for the work-in-progress pieces.

This reduction of stocks is the best way to highlight the company's inefficiencies in their production process and their organizational issues. As shown in the example retrieved from the Operations Management course in *Figure 6*, the level of the water simulates the level of stocks that are currently being managed, and the rocks in the bottom of the picture, are the inefficiency pitfalls of a company.

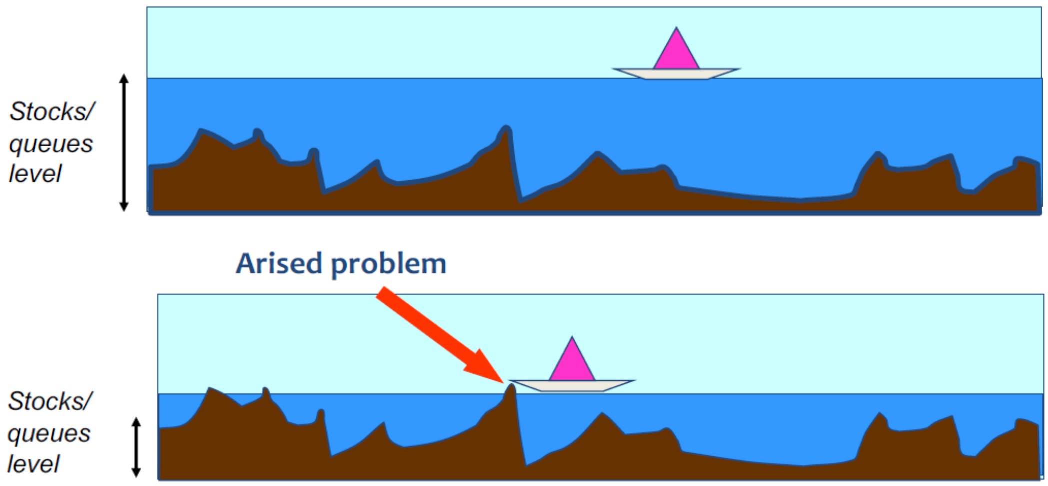

Figure 6. Metaphor for the stock level for lean production

If the stock levels are high, the company is not able to perceive any affectation of those pitfalls, as the stock levels act as a shield and insulates from the impact those can have. However, if the company decides to lower the level, problems start to arise to the surface, meaning that they must be removed in order to keep running smoothly. This reduction of the level of stocks is exactly what the Just-in-time pillar pretends, by trying to reach an ideal scenario where no stocks are needed, and only the products requested by the customer at each moment are being manufactured.

To achieve a smooth process operation when lowering the stocks, it is necessary to take into account the following Just-in-time principles, which are:

1. **Continuous flow**

   When successfully implemented, a continuous production can eliminate any bottlenecks or interruptions in the process. By keeping the products flowing in a steady state, stagnation is avoided. To achieve a continuous flow, it is necessary to streamline the process until a one-piece flow can be achieved, which is the ideal situation where there are absolutely no inventories between the stations and the pieces move continuously along the chain without stopping and accumulating.

2. **Takt time**

   Takt time is the reference number that matches the production capacity with the customer demand. It is calculated dividing the available work time per shift by the customer order quantity per shift. *Takt* is the German word for "meter", and similarly to a metronome, it indicates the pace in which pieces must come out according to the customer demand. If production is faster than the takt time, there is a risk of overproducing, and if it is slower, of having shortages. Understanding the difference between the cycle time[1] and the takt time, as well as producing as close to takt time as possible, are key to reduce stagnation (Thollander, Karlsson, & Rosenqvist, 2020).

3. **Pull system**

   Pull production aims to produce only what is needed, in the moment that is needed. As the contrary to Push production, which produces without considering the demand and accumulates the final products until they are sold, Pull production activates the manufacturing process when there is an order from the customer. Production is therefore pulled by the most downstream stations, forcing each station upstream of the chain to be activated, and produce only the required pieces. In any case, big equipment like presses and other short-cycle or batch-oriented processes can be decoupled from continuous flow operations. To achieve an efficient Pull system, the concept of Kanban can be implemented.

4. **Quick changeover**

   A major constraint to Pull production and continuous flow is having lengthy changeovers, which prevent the company from accurately following fluctuations in customer demand. One of the main reasons companies manufacture in large batches is to reduce the impact of a changeover from one product to the next one on the total cost of production, which can be rather significant. By reducing batch changeover time, using methodologies such as SMED, which will be explained later, the outcome is a much more flexible and agile production system, which allows just-in-time manufacturing.

In order to apply a just-in-time manufacturing, levelling (Heijunka) is a prerequisite. Heijunka refers to levelling both production quantity and variety over all the manufacturing time. This is achieved by sequencing orders in a repetitive pattern and smoothing day-to-day variations in total orders to correspond to the long-term demand. (Rewers, Trojanowska, & Chabowski, 2016)

[1] *Cycle time* is the time that the job takes to complete in a specific work process and must be lower than takt time.

JIDOKA PILLAR

Jidoka is the other principle implemented in lean production according to which the machines are able to stop their production when they detect a malfunction or anomaly in their production. The literal meaning of the word is "automation with a human touch", because instead of a person detecting a fault, it is the machine itself that can self-diagnose and stop production to prevent the error from going ahead, and to prevent further damage from being incurred.

The concept of integrating intelligence and decision making into machines allows a single operator to run several machines at the same time with minimal effort, thus increasing the company's productivity. The aim of intelligent automation is not to reduce the number of operators on the line, but to prevent them from performing activities that do not add value. The operators not only can be freed from being tied to machinery, but they can also be positioned to do more value-adding work in daily business operations.

It is important not only to prevent errors from occurring, but also to investigate the causes of the errors, a process in which all operators must be involved as a team. This empowers frontline workers with a problem-solving mindset that approaches every situation they identify as an opportunity to improve. It is in line with a culture of continuous improvement, in which it is necessary to observe the defects in the process and apply solutions to improve it. All management must also be involved with the resolution of the problems, and when a practical application of Jidoka is achieved, all team members can confidently raise safety or quality concerns and implement countermeasures that can prevent the problems from happening again.

Some tools that can be useful to achieve this built-in quality of the process are the following ones:

1. **Andon lights**

   Andon lights are a visual management system for lean manufacturing in which operators and managers can display and view the status of all lines. The Andon system is formed by three parts, which are the cords, the lights, and the board.

   It works by pulling the cord in order to signal and problem that the operator might encounter or when it needs assistance. This cord is located overhead the assembly line workers, and it can be replaced by a switch or a button. When pressed, the colour of the Andon light is changed, and the update is reflected in the board. The basic colours codes are green (normal production), yellow (problem identified, operator needs help), and red (stopped production). Reflecting every change in the board makes it easy for supervisors to understand how the current manufacturing conditions are, as well as fostering a culture of transparency and accountability.

   With this system it is possible, in real-time, to identify any issues that the line might be having in a very visual and easy way, decreasing downtime, and saving costs.

It empowers front-line operators through an environment of trust and openness and enhances teamwork by allowing all operators to make decisions that increase product quality and reduce the manufacture of defective items.

2. **Error proofing (Poka-yoke)**

   Poka-yoke is a process improvement technique that reduces the number of defects produced by placing barriers against mistakes, which eliminate the opportunities to make errors.

   It is very important to use when there have been repeated incidences of workers making the same mistake, or when the process is complicated or unreliable.

   When poka-yoke is applied, the process becomes more streamlined, and even if it is still unpredictable, mistakes can be caught before they produce any major damage. It can also make the process more robust to external variability, such as for example the mistakes done by the suppliers.

After having carefully defined the main pillars of lean manufacturing, it is necessary to know about the lean principles and their relationship to the pillars, in order to understand how to turn all the wastes ("muda", "mura" and "muri") into value-adding activities for the company.

Lean Principles

1. Identify value

Specifying value accurately is the first critical step in order to achieve a proper lean thinking. If value is not defined correctly before manufacturing, we are incurring in the biggest "muda".

The value of a product can only be defined by the customer, and from this customer's standpoint, a certain product is valuable if it satisfies their needs at a specific price and at a specific time. Value is created by the producers, and on many occasions, what producers think that really adds value to their product, is completely irrelevant for the customer.

In few words, value is what the customer is willing to pay for, and it has affected the way in which the price of a product has been defined. The pricing strategy has shifted from a cost-based perspective to a value-based perspective. In the cost-based, a mark-up is applied to the manufacturing cost, completely ignoring the voice of the customer, while in the value-based, the price is defined by the customer, and by deducting the mark-up, the maximum manufacturing cost is defined. This approach stimulates the company to reduce costs by applying lean manufacturing, while at the same time, provides a product that has a price in line with customers' expectations.

There are three types of activities in a process. The value-adding ones are those that are appreciated by the customer as they fulfil their requirements. Only few activities are value-adding, constituting approximately a 25% of the total. For the non-value-added ones there are two possibilities. The first type of non-value-adding activities are those that do not provide any value from the perspective of the customer but that are necessary for the process unless the existing supply or manufacturing process are changed radically. These activities should be eliminated on a long-term strategy, but it is difficult to get rid of them in the short-term. Approximately a 30% of the activities are from this type. The second ones are those that do not provide any value from the perspective of the customer and are not necessary, therefore are considered as a complete waste (*muda*). These can constitute nearly a 45% of the total activities and should be eliminated by applying lean methodologies, as seen in *Figure 7*.

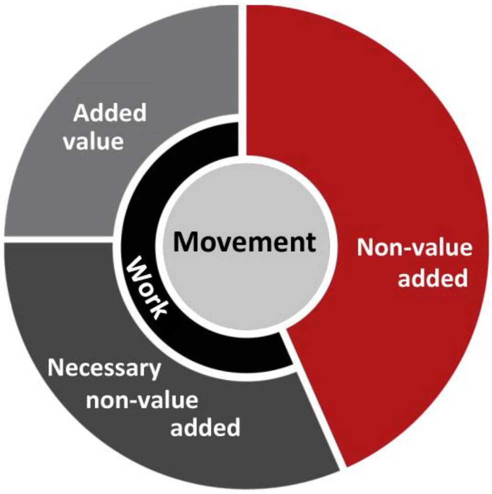

Figure 7. Percentages between value-adding and non-value adding activities

2. Value stream mapping

The value stream is the set of actions that are required to bring a certain product through the three critical management tasks of a business. First task is converting a concept to a detailed design, then making it go through all the engineering operations, and, finally, converting it to a production launch. The second critical management task is going from the order-taking to the detailed scheduling, and finally to the delivery. The last transformation task is related to the physical transformation, which starts with the raw materials to end up with a finished product in the hands of the customer.

With the value stream it is possible to represent in a very visual way the flow of materials and information through all the production process, as seen in *Figure 8*. To be effective, it should represent what is really happening, instead of what is supposed to happen. The main objective of the value stream mapping is to visualize the value creation of each product (or product family) in order to be able to identify what activities are value-adding and which ones are waste ("muda") and, subsequently, focusing on eliminating as many non-value-adding activities as possible.

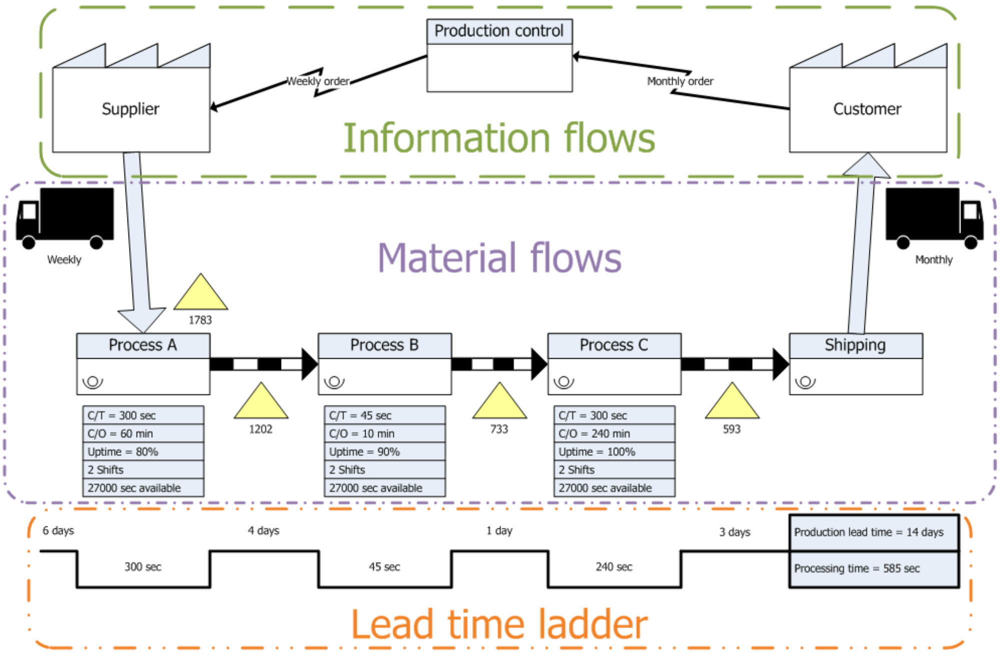

Figure 8. Example of a Value Stream Map

3. Create flow

Once the value has been defined, the value stream has been mapped and the obvious wasteful steps have been eliminated, the next step is to make this value-creating steps flow, which can be rather non-intuitive.

Many organizations are divided in departments, and they seek to get the maximum efficiency and machine utilisation by running big batches, in order to justify their need for more dedicated and high-speed equipment. However, producing in batches means that products have to wait a long time to be processed until the current batch finishes, and also creates repeated actions that serve no purpose to the product, like movements from one department to the other.

However, instead of producing with this batch-and-queue model, tasks could be accomplished in a much more efficient and accurate way if the product was continuously worked from the raw material to the finished good. The product would not have to wait and accumulate before being processed through the next step, and the movements would be reduced only to the necessary ones. It is necessary to focus on the product and its needs, rather than on the needs of specific departments or equipment.

As explained in the history of the lean production, Henry Ford was the first one to create continuous flow, but he only produced one product with the same parts and specifications, so his method was very rigid and only worked with very high volumes. The real challenge for continuous flow comes with low-volume production, and it only can be achieved by changing tools and set-up quickly and effectively, and rightsizing machines so they can be used one next to the other, keeping the product in a continuous flow of value-creating activities.

Even if it could seem counter-intuitive, the lean manufacturing requires to redefine the work of departments and focus on the needs of the product, in order to make it flow through all the necessary steps in the quickest way with the least effort.

4. Establish pull

Once all the system is as connected as possible, pulling orders from it becomes a reality. Instead of following predictions, which are mostly inaccurate, now only the quantity and variety requested by any customer at any moment is produced, avoiding pushing unwanted units to the customer which might not be sold.

In a push system, Materials Requirement Planning (MRP) is used to predict the demand, which sets up a long-term production schedule, being then dissected into more detailed schedules for purchasing, production, etc. This type of forecasting is very complex and difficult to control, sometimes can be wrong. In the new pull system however, customers pull products from the most downstream station, and consequently, each station pulls the output from the preceding station as it is needed in order to respond to the demand.

By using a right sized capacity, companies can manufacture in small lots of products and customers can replenish more frequently, in order to follow their demand precisely. To achieve a good pull system, the use of *Kanban* cards can be very helpful, which are a visual information system that informs upstream stations of what to produce and the quantity at each moment of time, and which adapt to the customer requirements.

5. Seek perfection

When all the previous principles have been applied, it is the moment to go beyond what is already working and try to find even more places to improve. Getting the products to flow faster and faster always exposes hidden "muda" in the value stream that was not initially seen. It is also important to keep understanding the concept of value that the customer has, to offer them products that can fulfil as much as possible their needs.

New process technologies and product concepts can be investigated to improve even more the productivity of this new system. A very important incentive for perfection is transparency, as all players (contractors, suppliers…) must see the whole process, the big picture, to help identifying even more possible areas of improvement and discovering even better ways to create and deliver value.

- **A3 Framework**

The origin of the A3, as the name suggests, comes from the paper sheet format ISO A3 (297mm x 420mm), as it was the biggest format faxes could send, and all the improvement project needed to be summarized in it. The main idea behind the A3 is to follow Shewhart's PDCA cycle (Plan-Do-Check-Act), which is an extremely useful technique for problem-solving and continuous improvement. It states that every project must follow these four steps in order, and in a cyclical manner. (Koskela, Tezel, & Pikas, 2020)

The A3 process emerged at Toyota as part of the Toyota Production System during the 1960s, and it was mainly used to summarize in a very visual manner all the *kaizen* activities that were taking place, and it evolved until today. The A3 must be extremely visual and easy to understand, but at the same time it must also effectively capture all the aspects of a complex project. Following the philosophy on eliminating any waste, it reduces the time spent on inefficient conventional report writing and reading activities. (K. Sobek II & Smalley, 2008)

A3 typically contains 8 different sections, which will be detailed below.

1. **Problem background:** It is necessary to state the problem that is preventing the company from performing correctly. It is important to signal why this problem is meaningful for the company and justify if it is worth investing in solving it.
2. **Problem breakdown:** The context and the current state of the problem must be defined, in a numerical manner, after having analysed all the possible data.
3. **Target definition:** The scope of the improvement project must be established, by listing the desired outcomes and the targets for the future state.
4. **Root cause analysis:** In this step, it is needed to figure out all the causes that might be affecting the problem by using different methodologies.
5. **Countermeasure development:** It involves the proposal of different possible solutions that might address the causes of the problem. They can be quick-wins, light investments, or structural investments, and the must have a great impact.
6. **Countermeasure implementation:** It consists of the timeline for the phases for the implementation of the countermeasures proposed, as well as the assignment of the responsibilities for each measure.
7. **Monitoring:** In this step, an analysis is performed on the process with the new countermeasures applied, and it is measured the impact those have had.
8. **Follow-up and standardize:** The actions still to be applied must be shown, as well as adopting the new practices that bring better results than the former ones.

- **Relevant lean tools for the project**

1. Kaizen

Kaizen is a Japanese word that consists in two terms; "Kai" can be translated as "change", and "Zen" as "good". The whole meaning of the word can be understood as "continuous incremental improvement" and is one of the main business ideas behind the Toyota Production System. In contrast with *kaizen*, there is the word *kaikaku*, which could be translated as "radical improvement".

Both activities are needed and complement each other when implementing lean manufacturing techniques. When for example the whole process is rearranged in order to introduce flow, therefore changing the way of working from departments to a chain, or manufacturing cells, the company is experimenting *kaikaku* as they are radically changing the way they have been working.

However, as the main objective is to strive for perfection, *kaizen* is very important in a day-to-day basis to keep improving slowly but continuously the current processes through incremental innovations. It is the combination that can bring endless improvements.

2. Gemba walk

A *Gemba walk* is a very powerful technique to observe, interact and gather information about how work is being performed and how this is creating value. It uses the combination of three Japanese works, which are *Gemba*, which means "the real thing", *Genchi Genbutsu*, that can be translated as "go and see", and *Genjitsu*, which refers to "real facts". By going directly to the workplace, managers can get first-hand, personal knowledge to understand the complexities of the real situation. Managing performance from the office does not provide enough understanding of what is really going on and can hide many wastes that can be easily spotted just by direct observation. (P. Womack, Gemba walks, 2019)

Gemba walks provide an up-close view of all the tasks and behaviours performed during the production, providing insights of the activities, and enabling the identification of possible improvement opportunities within the process. They are also a very important leadership tool, as the let managers directly engage with the operators at their own working environment, allowing the workers to be the experts among their managers. It can help in boosting morale with their presence and appreciation of the work that the employees perform, as well as receiving the most direct feedback on what to improve. (Romero, Wuest, Gaiardelli, & Powell, 2020)

3. SMART Objectives

Goal definition is a basic step in order to evaluate the impact that the possible countermeasures might have on the problems they have to tackle. The metrics used to measure the achievement must give quantified information. To select and develop those objectives, a very useful technique to define them is the SMART Principle, which are those that are specific, measurable, achievable, realistic, and timely. (Basuki, 2017)

- **Specific:** The objective must address a very precise area and avoid being too general.
- **Measurable:** The objective must be able to be quantified by using data obtained from the process.
- **Achievable:** It is important to set realistic objectives that can be reached with the countermeasures.
- **Relevant:** The objective must provide value for the organization and fulfil their requirements.
- **Timely:** It must be completed within the time period agreed for the project.

4. "5-Why's" methodology

The "5-Why's" methodology was a technique developed by Sakichi Toyoda for Toyota Industries Corporation, and it is very helpful to reach the root cause of a problem.

For every effect there is a cause, however, many times the connection between the effect and the cause is not evident at first glance, but the opposite. (Serrat, 2009)

To use the technique, it is necessary to have a precise and complete statement of the problem, to answer the questions with honesty, and to be determined to get to the bottom of the problem. To conduct the questions, it is important to gather a team, and the first question must always be: *Why is problem X taking place?* For all the plausible answers, they must be written down and the team must continue to ask "why?" until, at least, five times. When asking "why?" gives no further information, the team will have the most probable root cause for that problem and will be able to develop actions to solve it.

5. Ishikawa diagram

The Ishikawa diagram, also called fishbone diagram, is basically a cause-effect diagram, which is a graphical representation of the connection between a result and the factors that can have an influence on it. This method was proposed by the Japanese professor Kaoru Ishikawa during the 1960s, when he was working at the Tokyo University.

The elaborate the diagram, it is necessary to accurately define the problem, elaborate the graphical structure, brainstorm all the possible causes that might affect the problem, and classify them depending on the category they belong. When analysing it, it is possible to highlight the main factors that affect the problem, or those that can effectively be solved. The Ishikawa diagram is a very useful stepping-stone for the development of the possible countermeasures, as it helps understanding the process, and triggers the innovative ideas.

The groups into which the causes are divided are drawn as the bones of the fish, and the most typical categories used, in order of relevance, are:

- **4 M's:** The categories are *Manpower*, *Machine*, *Method*, and *Materials*.
- **7 M's:** The previous categories plus *Marketing*, *Money*, and *Management*.
- **4 P's + O:** The categories are *Policies*, *Procedures*, *Plants*, *People* and *Others*.

The Ishikawa diagram brings great results if it is used in combination with the "5-Why's" methodology explained earlier, as they can complement in reaching the root cause of a certain problem. A great improvement for this diagram could also be to include a risk or a priority score for the causes that appear on it, in order to allow for a deeper analysis of the causes that might affect the main problem.

6. SMED

During the 1950s, Shigeo Shingo, who worked as a consultant to the major Japanese automotive companies, started developing a technique that would reduce set-up times drastically, which took nineteen years to develop. This single-minute set-up technique, which it is popularly called SMED (Single Minute Exchange of Die), has been able to reduce many set-ups that took hours or days to complete, into activities that take less that ten minutes, therefore expressed in a single digit. Although not every set-up can be reduced into single-digit minutes, it is the goal of the SMED system, and it can be met in the majority of the cases. Even where it is not possible, a great reduction in the set-up time can always be achieved. (Shingo, 1985)

The first experience that Shigeo Shingo had with SMED was while he was conducting an improvement project for Toyo Kogyo's Mazda plant in Hiroshima, where he realized that there are two kinds of set-up operations:

- **Internal set-up (IED):** IED comes from Inside Exchange of Die, which could only be performed when the machine was shut down for obvious safety reasons. For the application of SMED methodology, IED consists of all those activities that require the machine to be stopped when performing them.
- **External set-up (OED):** OED comes from Outside Exchange of Die, which were activities that were done even when the machine was running. For the application of SMED methodology, OED consists of all those activities that can be performed without stopping the machine.

In order to apply the SMED methodology effectively, it is necessary to follow these steps:

1. The first activity to perform is to observe all the tasks that are needed for a set-up, taking notes or videos for the changeover, trying to get as much information as possible, such as the time needed, incidences that might happen, if it is done with the machine working or stopped, etc.
2. From the list of activities that conform the set-up, they must be classified into the two possible categories, internal or external set-up.
3. At this step, it is necessary to re-organize the order of the activities so external activities are grouped together in the beginning and the end of the changeover. Then, as many internal set-up activities as possible must be converted into external set-up. This step is the most effective in order to reduce the time that the machine is shut down, in which it is unproductive.
4. For the activities that cannot be transferred from internal to external set-up, they must be optimized in order to reduce even more the time in which the machine is stopped.
5. For those activities that belong to the category of external set-up, it is also needed an optimization process to reduce their duration. Even if external set-up does not affect the downtime of the machine, it is important for not overloading the workers, as they can also be dedicated to multiple machines at the same time.

6. The last step is the standardisation of the set-up activities. It must be made sure that the new procedure is applied to all the set-ups, in order to obtain the minimum duration with the machine stopped possible. (Silva, et al., 2021)

There is a great number of solutions that help reducing set-up time with SMED, of which a selection of examples is shown in the list below and in *Figure 9*:

- Preheating of elements
- Checklist to ensure having all the necessary parts
- Tools in order and easy to reach for the operator
- Convert transportation into external activities
- Use quick fastening systems like pear-shaped holes, snap method, magnets…

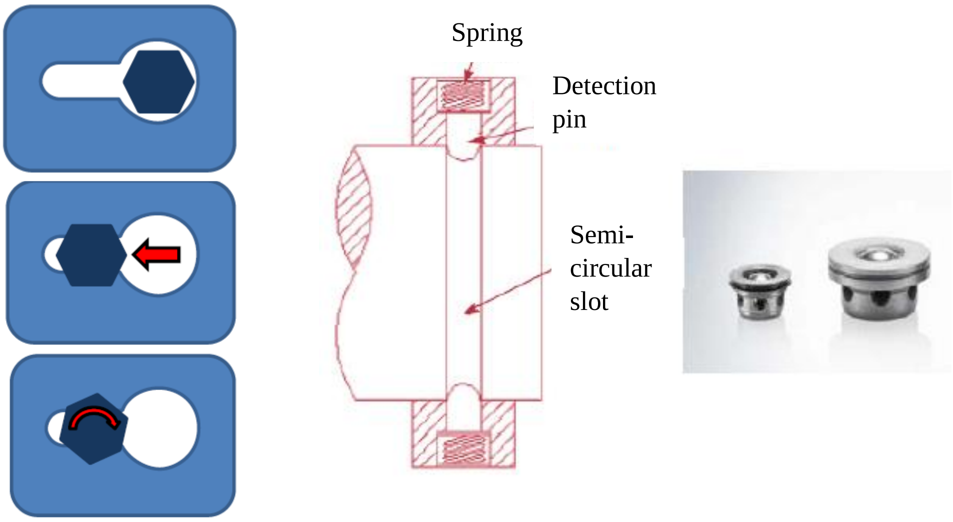

Figure 9. Examples of SMED applications

The benefits from applying these steps are enormous, as the downtime is reduced with simple, easy-to-apply techniques, and this leads to increased flexibility of the process. Another benefit it brings is that it maximizes line availability and utilisation while at the same time reducing the tools needed and the skills required, getting rid of the need for specialist professionals.

7. KPIs

Key Performance Indicators (KPIs) have a very long history, which can be traced to the Chinese Wei Dynasty emperors, which monitored the performance of their members in a rudimentary KPI usage. During the early 20th century, many companies began formally monitoring the performance of their employees, investments, and processes. The introduction of the balanced scorecards during the 1990s was very useful to provide feedback on both internal business processes and external outcomes to continuously improve strategic performance and results. They monitored financial, customer, process and learning and growth indicators.

KPIs are an essential part of lean manufacturing, as they serve for monitoring how well the process is performing and if the objectives are being achieved. KPIs should be measurable with numbers, objective and precisely defined, as well as their performance must be controlled by the department that is measuring them, and they should help to reach the goal proposed. KPIs for lean manufacturing must follow the characteristics listed below: (L. Stamm & Neitzert, 2008)

- Must foster improvement rather than just monitor performance.
- They can change over time according to needs change.
- Simple and easy to use.
- Must provide fast feedback to both managers and operators.
- They must be directly related to the manufacturing strategy.
- Use of non-financial measures.

The use of KPIs must be aligned with the objectives set for an improvement process, as they will be necessary to understand if the targets have been achieved and at what level. It is very important to count with the active involvement of front-line employees to update those KPIs, and the process of data gathering should be standardized in order to always have comparable and reliable information.

- **Overall Equipment Efficiency**

One of the most widely used methods to measure the efficiency of a manufacturing line is the Overall Equipment Efficiency (OEE), which was introduced as a metric for the Total Production Maintenance by Seiichi Nakajima. This index compares the time the line has been effectively running, against the time available it has had to produce. This percentage is affected by the Six Big Losses proposed by Nakajima (Nakajima, 1989), which are classified in the three main categories that conform the OEE. Those losses are:

- Breakdowns or equipment failures
- Set-ups and adjustments
- Minor stoppages during production
- Reduced speed
- Reworks: products with minor defects that can be reworked
- Rejects: defective products that cannot be reworked

AVAILABILITY

This first category englobes the first two big losses and expresses the percentage of time that an equipment can operate. It is calculated as follows: (Bonada, Echeverria, Domingo, & Anzaldi, 2020)

$$Availability = \frac{(available\ time - unplanned\ downtime)}{available\ time}$$

$$Available\ time = Total\ available\ time - Planned\ downtime$$

For planned downtime it is considered the time spent on planned breaks of the operators, planned maintenance, communication breaks, team meetings, etc. For unplanned downtime it is the time lost in breakdowns, set-ups and adjustments, delays in material delivery, etc. Any planned activity agreed on the employment contract therefore does not affect availability, but everything in addition does.

QUALITY

The third and the fourth losses are included in the Quality category, and it is defined as the ratio between accepted quality products and the total number of produced parts, considering all the faulty items that need to be reworked or replaced.

$$Quality\ rate = \frac{(total\ produced\ parts - defective\ parts)}{total\ produced\ parts}$$

PERFORMANCE

This last category consists of the fifth and the sixth big losses and shows the percentage of the actual number of parts produced against the planned number. This percentage of maximum operation speed used and is affected by every minor stoppage or reduction in speed. The formula is the following:

$$Performance = \frac{\left(\frac{total\ produced\ parts}{operating\ time}\right)}{idle\ run\ rate}$$

$$Operating\ time = Available\ time - Unplanned\ downtime$$

$$Idle\ run\ rate = Number\ of\ parts\ per\ minute$$

The idle run rate is actually the theoretical production pace, and the operating time only considers the time in which the machine is really producing.

Once all the indicators have been calculated, the OEE is the obtained by multiplying them.

$$Overall\ Equipment\ Efficiency\ (OEE) = Availability * Quality * Performance$$

In this equation, OEE can never be higher than 100%, and indicates how good the equipment is being used. Even though the OEE is very useful to picture the situation, there are some pitfalls to consider first. The OEE is a measure of internal efficiency, and it should not be compared with other machines or platforms. As there can be some slight variations in the calculation of the OEE, it is dangerous and pointless to directly compare it with other plants or companies. (Rautio & Järvenpää, 2020)

Although the three indicators are very useful to describe the efficiency, the OEE does not take into account any economic costs or the efficient use of the raw materials. To improve the efficiency of a process, it is necessary to look at the big picture, rather at just one category, as could happen that improving a category generates a bigger loss on the others, affecting the overall performance. (Morella, Lambán, Royo, Sánchez, & Latapia, 2020)

- **Nutraceutical industry**

The word nutraceutical comes from the combination of "nutrient", which is a nourishing food or food component, with the word "pharmaceutical", which defines a medical drug. This name was coined by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine, an American organization that encourages medical health. According to his definition, a nutraceutical is any substance that is food, or part of food, and provides medical or health benefits including the prevention and treatment of disease. (DeFelice, 1997) (Prabu, Prakash, Kumar, Kumar, & Ragavendran, 2012)

Nutraceuticals feel attractive for many people due to the benefits they can bring from their point of view, which some of them are the following: (Pandey, Verma, & Saraf, 2010)

- May be perceived as more natural than traditional medicine.
- May present food for special needs' population (nutrient-dense for the elderly).
- They rarely have side effects.
- They can be easily absorbed after ingestion.
- They do not need to be prescribed by a health care provider.
- They are recognized to produce health benefits.

The nutraceutical industry began in the early 1980s and exploded when the health benefits of some products like fish oil or calcium were scientifically proven by clinical studies published in distinguished medical journals. Some factors that affected this revolution were the increase in the general practitioners' acceptance of these products, and the mass media, with legitimated the promotion of nutraceutical products.

Since its inception, the global market for nutraceutical products has expanded into a multi-billion-dollar industry, which is still in a very positive growth trend. The only limitations on growth come from the international necessity to assess the health benefits and safety that these products bring. The United States of America (USA) are currently the biggest and fastest-growing market in the world for functional food and nutraceutical market, although China and India are also becoming major players as they are experiencing a significant growth. As a result of this steady growth, this market has been reported to be worth almost 353 billion dollars in 2019, and valued 454,55 billion dollars in 2021, and it is expected to expand at a compound annual growth rate (CAGR) of a 9% in the following decade. Research and development of this products has also expanded, with over 70.000 published articles between 2010 and 2020.

The pandemic caused by the coronavirus disease (SARS-Cov-2) has had a positive impact on the industry, triggering the sales as customers sought for extra protection from viral infection by trying to boost their immune system with the consumption of these products.

The increasing awareness levels about healthy lifestyles and well-being are also propelling the expansion of the nutraceutical markets globally, which will occupy the actual landscape of healthcare products, with the serious implications it can have for other health-related industries. (Lordan, 2021)

This growth of the nutraceutical industry also means that the pressure exerted on the safety and the quality of these products is also on the rise. As they made are for direct consumption by human beings, safety is the main concern of any producer, which is even more important than the efficacy that they might have. In order to ensure the quality, the safety, and the efficacy of nutraceutical products, the manufacturing process must be strictly regulated, by following the established Good Manufacturing Practices (GMPs).

- **Good Manufacturing Practices (GMPs)**

Good Manufacturing Practices (GMPs) are the European regulations that are applied in the pharmaceutical industry in order to guarantee maximum safety for the final user in all circumstances. The rules that are applied in this industry can be found in the Volume 4 of "The rules governing medicinal products in the European Union", which contains the interpretation of the principles and the guidelines for the manufacture of any medicinal product dedicated to humans. These rules are contained in the Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

GMPs are applied to all the lifecycle stages of the manufacturing of a product, including the commitment of suppliers and distributors as well. Senior management has full responsibility of the attainment of this quality, and the participation and commitment of all the staff, at all levels within the company, is required. It is organized as follows:

1. Part I – Basic requirements for medicinal products
    - I. Chapter 1 – Pharmaceutical Quality System
    - II. Chapter 2 – Personnel
    - III. Chapter 3 – Premise and Equipment
    - IV. Chapter 4 – Documentation
    - V. Chapter 5 – Production
    - VI. Chapter 6 – Quality Control
    - VII. Chapter 7 – Outsourced activities
    - VIII. Chapter 8 – Complaints and Product Recall
    - IX. Chapter 9 – Self Inspection
2. Part II – Basic Requirements for Active Substances used as Starting Materials
3. Part III – GMP related documents
4. Annexes

All these sections contain very precise information on how to perform each activity according to the European regulations, in order to ensure the effectivity, safety and quality, of the products manufactured. It englobes not only the pure manufacturing activities, but also everything related to the process, like the documentation that must be filled to ensure the compliance, the quality control and inspection of the products and the process, or the control of the outsourced activities to third parties. There are many other sections have not been included previously, as they do not affect this project's content. (European Comission, 2003)

To ensure that these regulations are being strictly followed, local competent authorities perform controls to certify compliance with the stipulated regulations and may even deny the authorization to produce if they detect any infringement of these guidelines. In this context, it is the AIFA's (Agenzia Italiana del Farmaco) duty to ensure that any Italian pharmaceutical company is in compliance with the GMPs.

- **Manufacturing Execution System (MES)**

Manufacturing Execution Systems (MES) are made to deliver information that allows to optimize production processes, from the launching of the order to the delivery of finished goods. It can provide and use process data to improve the efficiency of the operations, as well as reducing the non-value-added activities that might take place. It is very responsive to changing conditions and enables a bi-directional communication.

MES is not a single function, but a group of functions that support, guide and track each of the production activities. The functions that MES can perform and have been identified by the Manufacturing Enterprise Solutions Association (MESA) are: (Fraser, 1997)

- Operations Scheduling
- Resource Allocation and Status
- Dispatching Production Units
- Document Control
- Product Tracking
- Performance Analysis
- Labour Management
- Maintenance Management
- Quality Management
- Data Collection

Therefore, it allows the consolidation of different functions that are now performed by specialised programmes, by integrating all of them together in the MES, as in *Figure 10*.

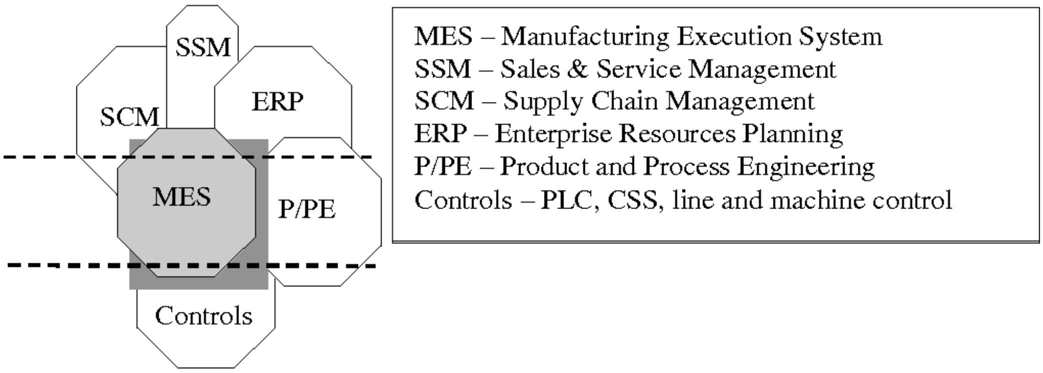

Figure 10. Illustration of the working areas of the MES (Souza das Neves, Silva Marins, Kazue Akabane, & Kanaane, 2014)

- **Case studies**

In order to provide a general idea on how to approach this project, different case studies were reviewed, among which those that provided the most insights were the two detailed below.

To find these case studies, as the project was being defined with the company, the search for information for the theoretical framework began. Some of the papers that were consulted were very valuable because they dealt with industries similar to the nutraceutical sector, or because they used lean tools that were also going to be used during the course of this project.

In this literature it is possible to find the lean methodologies application guidelines, as well as an estimation of the impact they can achieve. They are very useful to have a practical perspective of all the concepts detailed in the theory and can provide ideas and insights.

1. **The contribution of lean manufacturing tools to changeover time decrease in the pharmaceutical industry. A SMED project. (Al-Akel, Marian, Veres, & Horea, 2017)**

This article provides a detailed application of SMED techniques to reduce batch changing time on a pharmaceutical manufacturing line in Romania. This time reduction will provide economic savings to the company, as well as greater flexibility to manufacture its products. To measure the impact of the project, the Overall Equipment Efficiency will be monitored, which will increase according to the reduction of the batch change time.

The initial scenario indicates that 2 FTE are needed for the batch change, which happens 37 times a year, and takes on average 25,3 hours. The objective is to reduce this figure to 16 hours, as well as to reduce the standard deviation of the process.

The DMAIC structure has been applied in order to successfully implement the SMED methodology. By means of Gemba Walks and the representation of the batch change process with Gantt diagrams, the root causes of the problem have been identified and the value-adding activities have been separated from the non-value-adding activities. Thus, all possible activities have been externalised in order to reduce the time that the machine is stopped. For the representation of the new standard procedure, the A3 template has been selected, so that it is very visual, and any operator can understand what to do in a simple and concise way.

The result of the application of SMED methodologies has been that the batch change time has reduced to 17,8 hours. Even if the target has not been reached, which was 16 hours, it is a significant improvement. The variability of the batch change durations has also been lowered, which translates into a better process standardization, a higher customer satisfaction as a result of improved flexibility, and an optimal FTE distribution.

2. Improvement set-up time by using SMED and 5S (an application in SME) (Guzel & Shahbazpour Asiabi, 2020)

In this case study, the SMED and 5S techniques have been used to lower the set-up time of a manufacturing plant. This company produces up to 300 different parts, and during this study, ten set-ups could be measured and recorded by video in order to identify all the activities that conform the set-up.

These activities were then classified into sixteen categories, and for each, it was written whether it was value-adding or non-value-adding, and if it was performed internally or externally. Apart from the optimization of the set-up procedure obtained by the application of the SMED methodology, also the 5S technique was used, which is a systematic approach to organize and standardize the workplace, thus reducing the time lost in search or cleaning of the tools. Some of the measures applied consisted in arranging the set-up tools placing them close to the centre, grouping them by product families or marking the tools and their useful life in a very visual manner.

Thanks to the application of both SMED and 5S techniques, a reduction of a 46,7% on the average set-up time was obtained. Due to the nature of this particular company, which produced up to 300 different parts, this improvement has led to maintaining the same flexibility but greatly reducing the costs, as well as increasing the ergonomics of the operators, thanks to the categorization and sorting of their tools.

4. COMPANY OVERVIEW

4.1 Fine Foods history, evolution, and present status

Fine Foods is a Contract Developer and Manufacturer of Medicinal Products and Food Supplements in solid oral forms in the plants of Brembate (BG) and Zingonia (BG). Cosmetics, Medical Devices and Biocides are developed and manufactured in the Pharmatek-PMC plant, located in Cremosano (CR).

Fine Foods was born in 1984 from the business idea of entering into food supplements for pharmaceutical companies looking to differentiate their portfolio. This synergy has been the driving force behind Fine Foods since its inception. The company's values prioritise maintaining customer loyalty and customer retention by offering the best service and quality.

The first manufacturing plant was established in Brembate in 1991 for the pharmaceuticals sector. For the nutraceuticals business, the Zingonia plant became operational in 1997, while the warehouse became fully functional in 1998. In the following years, thanks to the growth of the company, the Brembate and Zingonia plants were expanded to cover a larger production and stocking capacity.

Figure 11. View of the Brembate plant

Figure 12. View of the Zingonia plant and offices building

In 2010, the two companies in the pharmaceutical and nutraceutical sector merged to create what is currently known as Fine Foods. In the following years, expansions of the Brembate and Zingonia plants followed, as well as listings on various stock exchange markets.

It is listed on the Alternative Investment Market (AIM Italia), managed by Borsa Italiana S.p.A. since 1st October 2018, that focuses on small and medium-sized Italian companies with high growth potential, which receive strategic financial support to implement their development and internationalisation plans. The acquisition of the 100% of Pharmatek-PMC, on 19th January 2021, for 17,2 million euros, meant entering the cosmetics and biocides sectors, allowing them to exploit the synergies between the two business models.

Pharmatek-PMC was founded in 2003 in the Milano area, in the heart of Italy's industrial culture, with a production site of only 400 m^2. Their goal is to be a landmark in innovation for the disinfectants and cosmetics industries, and a channel to test and disseminate advanced production solutions, while offering their clients a flexible, tailor-made and highly innovative service.

The 21st of September it was also announced the acquisition of Euro Cosmetic S.p.A., first by the purchase of the 72,9% of the company's share capital, and then with a takeover bid for the remaining shares. The total acquisition has accounted for 27,1 million euros, enabling the company to become a significant player in the development and contract manufacturing of cosmetics, offering new products to both existing and future customers.

Fine Foods can count on 113 different manufacturing lines and produce more than 2.000 different SKUs, considering all the different business areas in which they work. They employ more than 650 people. The Brembate plant, which is the one dedicated to the pharmaceutical products, has a covered manufacturing area of 14.200 m^2, with 15,2 million euros worth of investments, where they produce more than 80 active pharmaceutical ingredients, some of which include the well-known ibuprofen and paracetamol, among others. These products are manufactured in a variety of formats, including capsules, tablets, film-coated tablets, effervescent granules, and powders. These are then packaged in several pack formats, such as blisters, bottles, bags, and sachets.

The plant of Zingonia is the largest food supplement manufacturing plant in Europe, which offers a unique combination of technology and manufacturing capacity. The unique positioning as a CDMO of food supplements and medicinal products, makes of Fine Foods a privileged partner for pharmaceutical companies with particularly high expectations. In the Zingonia plant, the entire manufacturing process is characterized by efficiency, flexibility, and speed. Numerous procedures and best practices are applied with discipline to manufacture competitive and outside of ordinary products, that interpret or anticipate the market trends. Ready-to-market or tailor made, so products can address every customer's need. This plant has a covered area of 28.800 m^2, which includes a recent expansion of 12.900 m^2 worth 19,7 million euros, and they follow 145 food supplement projects per year.

As well as in Brembate, the products are manufactured in many different forms, such as capsules, tablets (effervescent, fast-melting, chewable, coated…), granules and powders. These forms are then packaged in bags, sticks, sachets, jars, bottles, blisters, and many other containers.

In what regards the other three production areas, Pharmatek-PMC offers a diversified portfolio of products, available to its customers and ready to be marketed. Biocides, cosmetics, medical devices, medical and surgical products that reflect their technological know-how and can satisfy a wide range of production and marketing needs. They take care of the entire production process, therefore being able to provide flexibility in addressing the needs of individual projects, experimenting innovative solutions with an agile approach. Based on the client's brief, they offer different services. In full-service, they take care of each step in-house, from the formulation and transformation of the active ingredients to production and packaging. They can also provide formulation service, in which receive client formulas in processing, or transform client's active ingredients, to obtain results that are tailored to their needs. Last service is production, where they produce medical and surgical products, cosmetics, and medical devices on the basis of its registered formulations, as well as according to client's instructions. The plant has over 10.000 m^2, and they also produce in many forms, such as gels, creams, ointments, pastes, among others, which are then sold as skin disinfectants, face creams, body lotions, toothpastes, deodorants, and many more.

The Group has a significant concentration of revenues on its main customers, amounting to approximately 76% on the top five customers as of 30th of June 2021. The loss of one or more of these relationships would have a significant impact on Group revenues. The Company supplies its pharmaceutical and nutraceutical products to customers by entering into multi-year product development and supply contracts. Based on such contracts, Fine Foods is identified as the developer of certain pharmaceutical or nutraceutical formulations and the manufacturer based on such formulations. Under these framework contracts, the company undertakes to manufacture and deliver products based on orders received each time from the customer. The way orders are handled depends on the type of customer, which can be categorised into three categories.

There are customers who make a forecast for the following year, knowing the quantities they will need at each point in the year, those who make a forecast for the following year but do not specify when they will order, and those who cannot make a forecast and order at the time they need. In some cases, contracts with customers allow the possibility of withdrawal at any time and without the obligation to provide a reason with written notice. They might also allow early termination if there is failure to comply with the contract terms without remedying the situation or inability to comply with the service standards on several occasions (or delays or revocation of authorisations by the relevant authorities).

Fine Foods does not have trademarks or hold any product patent rights. These remain the customer's property. It has relationships with circa 100 loyal customers, including major Italian and multinational pharmaceutical and nutraceutical companies such as Amway, Aesculapius, Alfasigma, Alkaloid, Angelini, Apotex, Aptalis, Aurobindo, Avon, Bayer, Bial, Biopharm, Chiesi, Coop, Doc, Dompè, EG, Ennogen, Fairmed Healthcare, Farma-Derma, Fidifarm, Giuliani, Guna, Herbalife, IBSA, Italfarmaco, Krka, Laborest, Menarini, Molteni, Named, Nestlé, Novartis, Omega Pharma, Pensa, Pepsico, Pharmanutra, Pierre Fabre, Recordati, Sanofi, Sofar, Teva, Viatris, Zentiva.

Figure 13. Examples of products manufactured

Fine Foods does not handle the logistics of the products, and once they are ready, the client is notified so that they can organise their transport to collect the final product, with the client being in charge of all the logistics.

From the 2020 financial year statement, the revenues rose from 159,7 million euros in 2019 to 172 million euros in 2020, recording an 8% increase, mainly thanks to the growth on the sales of the nutraceutical sector, which had a positive change of an 11%. As of 30th of June 2021, the expansion trend of the last few years was confirmed: the item Revenues in the Income Statement increased from 75,4 million euros in the first half of 2020 to 98,6 million euros in 2021, with an increment of 31%. Part of this gain stems from the Pharmatek-PMC acquisition, which generated revenues of 6 million euros in this period, while the remaining 17,1 million euros increase is part of the Company's organic growth.

4.2 Production site layout

Even though the company Fine Foods has multiple manufacturing plants, this project will be focused only on a specific manufacturing line for the nutraceuticals sector, therefore corresponding to the Zingonia (BG) plant. This facility is divided into two different areas, even if they are completely connected.

The first area, also known as *Zingonia 1*, consists of three floors, dedicated to the production of bags, sticks, sachets, blisters, strips, and tablet bottles. The lower floor is the principal one of them, as it is where most operations are carried out during the day.

It comprises the laboratories, offices, and the majority of the machines and manufacturing lines, in which the ones that will be object of this study are highlighted in yellow (stick-pack 2 and stick-pack 3). In the same floor there is also the warehouse for finished products and the one for raw materials, highlighted in blue and green respectively. In red is marked the area dedicated to the cleaning and drying of all the equipment used by the machines, as it can be seen in *Figure 14*.

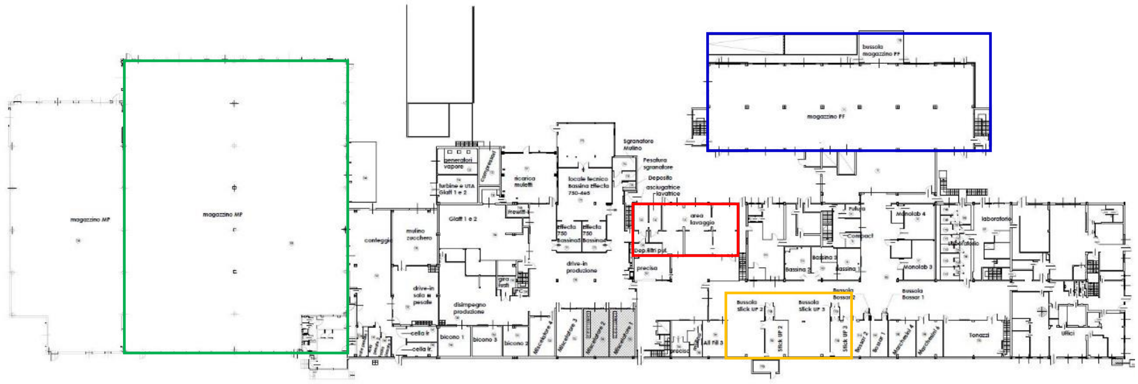

Figure 14. Zingonia 1 lower floor layout

On the first floor, the most interesting area for what regards this project is highlighted in pink, and it is where the deposits with the granulated formula are stored, moved, and mounted into the required positions, as in *Figure 15*. On that floor there are also other production lines, offices, and employees' facilities. On the second floor there are other manufacturing lines, however they have no relation with the objective of the project.

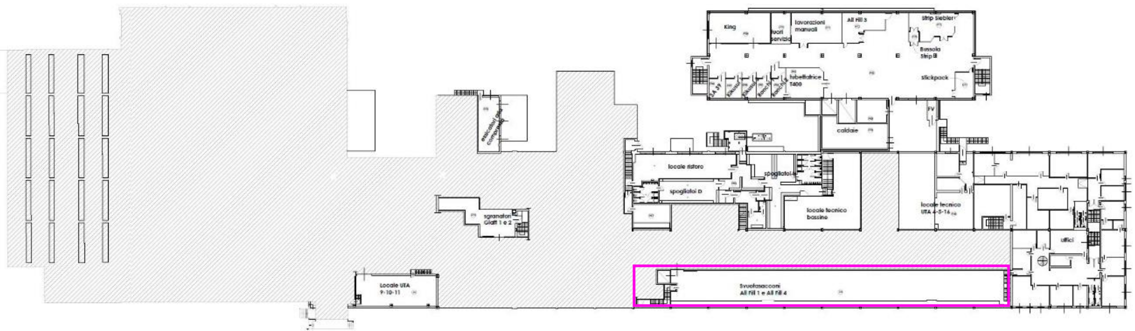

Figure 15. Zingonia 1 first floor layout

The second area, also known as *Zingonia 2*, also consists in three floors, and their main production is based on the jars. As with the *Zingonia 1* distribution, also here both lower and first floor have a great importance, as they contain the all the machinery, laboratories, and warehouses, both for raw materials and finished products. The second floor is only composed by the offices and files storage areas.

4.3 Quality certifications and Good Manufacturing Practices

Fine Foods has a series of certifications in order to ensure the highest quality of their processes and products, as well as environmental sustainability. The certifications awarded to Fine Foods are listed below:

• UNI EN ISO 9001: It is the standard that defines the quality management system requirements. The scope is on the research, development and production of food supplements, food for special groups, and pharmaceuticals for third parties.

• UNI EN ISO 14001: It is the standard that defines environmental protection management system requirements. The scope is on research, development and production of food supplements, food for special groups, and pharmaceuticals for third parties through the following processes: reception and storage of raw materials and packaging materials, grinding, mixing, granulation, screening, compressing, filming, capsuling; packaging in bags, blisters, bottles, jars, and tubes; storage and finished goods' shipment.

• ISO 45001: It is the standard defining Occupational Health and Safety Management System requirements. The scope is on research, development and production of food supplements, food for special groups, and pharmaceuticals for third parties through the following processes: reception and storage of raw materials and packaging materials, grinding, mixing, granulation, screening, compressing, dedusting, filming, capsuling; packaging in bags, blisters, bottles, jars, and tubes; storage and finished goods' shipment.

• SMETA (Sedex Member Ethical Trade Audit): It is an audit and reporting methodology created by Sedex (one of the world's leading business ethics organisations) using a best practice model in ethic business audit techniques. It provides a central and standard audit protocol for organisations interested in demonstrating a commitment to social issues and ethical and environmental standards in their supply chain. Fine Foods uses a SMETA audit as a tool to enhance the practices adopted in its ethical and responsible business. SMETA bases its assessment criteria on the ETI (Ethical Trade Initiative) code, integrating it with applicable national and local laws and comprises four modules: health and safety, labour standards, environment, and business ethics.

• FSSC 22000: Food Safety System Certification Scheme 22000 is a certification scheme developed by the Foundation for Food Safety Certification for the accreditation of food producing organisations and aims to harmonise certification requirements and methods to achieve food safety systems in the supply chain.

• ESG rating: EcoVadis awarded Fine Foods the Gold rating and the management confirmed their commitment to improve the group's already advanced sustainable model.

In addition to holding the above certifications, all processes related to the manufacturing of any of its products have been designed in compliance with the European GMPs. While the regulations for the pharmaceutical sector have already been described in the theoretical framework, the regulations for the nutraceutical part, which is the focus of this project, are slightly different.

In Fine Foods, for the nutraceutical division, the regulations of the Code of Federal Regulations (CFR) are strongly followed, which are published in the Federal Register by the executive departments and agencies of the federal government of the United States. Within the different chapters present in the CFR, it is only considered the Title 21 – Food and drugs, which are specifically designed for products that serve as food supplements. Inside this title, Section 111 from the first chapter is entirely dedicated to "Current good manufacturing practice in manufacturing, packaging, labelling, or holding operations for dietary supplements". (U.S. Government, 2005)

This Section 111 is organized in sixteen subparts which provide guidelines regarding the same points as the European GMPs. It has to be said that, even though it is less strict than the pharmaceutical regulations, it also guarantees the safety and quality of any product manufactured, as it must be safe and effective for human beings. It places particular emphasis on the traceability of all the activities that take place, in order to have full control over the entire process.

In addition to the CFR, Fine Foods also manufactures in accordance with the Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements. Inside this directive there are two main regulations, which are:

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs.

5. PROBLEM BACKGROUND

Fine Foods & Pharmaceutical N.T.M. S.p.A. has adopted for a long time the philosophy on continuous improvement for all the processes done in the company, in order to perform at the maximum level on an ongoing basis.

This continuous improvement idea is why this company turned to the Politecnico di Milano, in order to introduce a student coming from an external context, to provide a different perspective on the issues they are facing.

During the first visits to the production site, I was informed that one of the projects that currently required more improvement efforts was the stick-pack project, as it was performing below expectations and would not meet the target set for this year.

The target was based on equalling or exceeding the OEE of the previous year, 2020, which stood at 32,1% in the case of stick-pack 3, and 38,9% for stick-pack 2.

This loss of performance means that, to achieve the same output, more hours are necessary, which incurs higher costs and increases the number of shifts required to obtain the volume of products requested by the client. It would be expected for these production lines that, with all the continuous improvement projects that are being applied, they would have gained in performance, or at least not worsened it, but unfortunately this has not been the case.

5.1 Problem definition

In order to quantify the importance and magnitude of this problem, a more thorough investigation was carried out to find the impact of the efficiencies and to be able to convert them into time and cost units.

To obtain data related to the OEE, in this first phase of the investigation, it was used the collection of historical data available for 2020 and the ongoing 2021. There, it is registered how many hours have been dedicated to each activity, which are then grouped in macro-categories depending on the type of activity. They can be activities related to set-up, to technical issues, or they can also be other inefficiencies that affect the production but are not activities as such, like reprocesses or slowdowns.

For stick-pack 2, the overall sum of all inefficiencies during 2020 amounts to 1.250 hours lost, while by 2021 this sum reaches 1.709 hours. The case of stick-pack 3 is not significantly contrasting: in 2020, 1.619 hours are lost due to inefficiencies, and in 2021, it reaches 2.237 hours. It is necessary to point out that the total working hours are different for each machine and year, therefore, the percentage of hours lost compared to the total hours available follows as: stick-pack 2 percentage of inefficiencies for 2020 and 2021 is 61,03% and 62,70% respectively, while for stick-pack 3 and for the same years is 67,91% and 64,55% respectively.

All in all, the total amount of hours lost in inefficiencies during this year 2021, considering both lines stick-pack 2 and 3, equals up to 3.946 hours. From an economic point of view, considering that the hourly cost of having two FTE necessary for the production is of 53,2 €/hour for both, the annual cost of these inefficiencies reaches nearly 210.000 € per year.

This project is intended to increase the efficiency a manufacturing line of Zingonia (BG) facility, benefiting the company Fine Foods & Pharmaceuticals N.T.M. S.p.A., and around this project there are multiple stakeholders of which we will discuss its roles and how they can benefit from an improvement in their area, which appear in *Figure 16*.

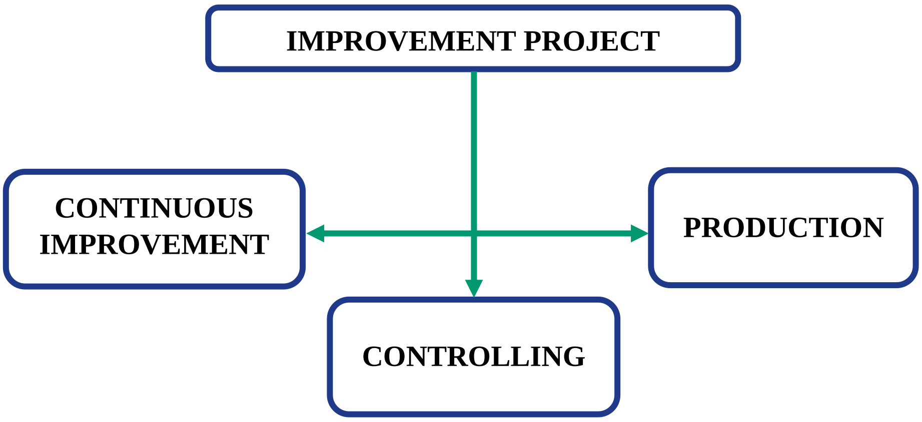

Figure 16. Map of the stakeholders involved in the project

- **Production Department**

The production department is formed by Mauro Rocca, who is the Production Execution Manager, and Andrea Sacchi, who is the Food Supplement Plant Director. This department is in charge of everything related to planning for the successive weeks, shift management, quality control, etc. Thus, they are responsible for all aspects of product manufacturing, controlling the personnel working at any given moment, the purchase of materials, the maintenance of the machines and any problems that may occur on the lines.

- **Continuous Improvement**

The Continuous Improvement department is formed by Luca Garghentini, Oana Andronache, and Giacomo Pulcina, which works for the Brembate plant but also participates in projects in Zingonia. The role of this department is to identify and implement new improvement projects in order to increase the efficiency of the lines, look for weak points and carry out innovative solutions in order to increase their performance.

- **Controlling**

Finally, the Controlling department includes Giacopo Berinelli and Brando Viganò. There is also Cristina Baragetti who works in collaboration between this department and the Continuous Improvement one, and Giovanni Eigenmann who is in charge of both departments. The objective of this department is the control of all expenditures, as well as budget planning and control, and the monitoring of the profitability of the sales force.

5.2 Description of the productive process

The study of this project will be based on following one of the many production lines in the Zingonia nutraceuticals plant, which is called stick-pack. This is made up of two identical lines, stick-pack 2 and stick-pack 3. These lines are responsible of converting the granulated formula into boxes of sachets that must be transported to the end customer, in a process that will be detailed below.

As it can be seen *Figure 15*, there is a dedicated area where the deposits containing the granulated formulas are located. These are connected to the floor at the underside of the deposit by means of a tube (*Figure 17*) and a mechanical agitator that helps to prevent the powder from caking and allows it to flow smoothly down to the lower floor, where all the machinery is located.

Figure 17. Machine's feeding tube

The powder from the deposit enters the machine through the upper part of it. There, when the sensor detects that the powder level is below the minimum, it switches on the motor which introduces more powder into the buffer (*Figure 18*). The buffer is constantly being spun to prevent it from accumulating at the inlet, as it always enters the machine at the same point.

Figure 18. Powder buffer

From there, the material is fed through ten equal tubes (*Figure 19*). First, it is fed through funnels with a worm screw inside, which rotates and gradually lowers the powder. Depending on the speed at which the screw rotates, a larger or smaller quantity of material is introduced. Below the screw there is a plate which opens or closes to allow or prevent the flow of material into the stick. Around the tube there is another one of slightly larger diameter, and through the gap between the two, all the excess powder that has not been introduced into the stick is aspirated, in order to avoid dusting the machine.

Figure 19. Stick filling tubes

At the other side of the machine is the reel with the aluminium roll that will become the wrapping for the sticks (*Figure 20*). This is kept tight and is rolled around the inside of the machine. At the feeding entry of the reel, there is a photodetector that reads a small black band, which gives information to the machine about the position where the data for each stick has to be laser engraved.

Figure 20. Feeding entry of the reel

After being read, the film of aluminium circulates until it reaches an area where it is laser-engraved with the batch number and expiry date, already specified at the beginning of the production process (*Figure 21*). Once it has been engraved, the film goes through another photodetector that will give information about the length of the stick, which will be useful for the seaming and the cutting. After that, it continues to circulate until it reaches the section where the tubes that supply the powder are located.

Figure 21. Laser-engraving of the aluminium roll

From that point, the aluminium film is split vertically, and each strip is made to encircle the tubes that feed the powder. These strips go down around the tube until they reach a point where they are seamed vertically. As they continue down, they reach a point where they are seamed horizontally at the bottom, closing the stick by three sides, and then the powder is stuffed into the stick. Once the right quantity has been introduced, it is seamed horizontally at the top (which will be the bottom of the next stick) and pressed, and it then proceeds downwards (*Figure 22*).

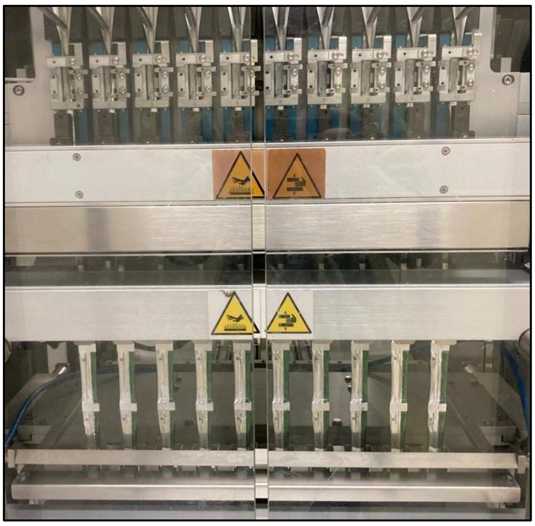

Figure 22. Strips of sticks ready to be cut

After being hermetically sealed by all parts, the strip of sticks continues downwards until it reaches an area where it is cut horizontally, and separated into individual sticks, which are gripped by the bottom and placed in a conveyor line. This conveyor line is engaged in moving the sticks to the following station, the cartoning machine, while also progressively joining them together until they are next to each other, with no space between them.

Figure 23. Start of the conveyor line

Just as they start to move along the conveyor line, each stick passes over a very precise scale, which is tared with the weight of the aluminium wrap and the weight of the powder (*Figure 23*). If the total weight is outside the tolerance limits, it is discarded. If only one stick has an incorrect weight, only that one is discarded and the rest go on to the cartoning machine (although that final product will be later discarded on the general scale because it is missing one stick), while if there is more than one incorrect stick, all ten are discarded, but they are separated into two different deposits, one for the correct ones and the other for the wrong ones.

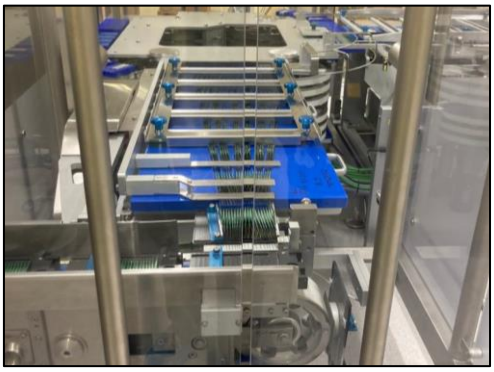

Figure 24. End of the conveyor line

Depending on the type of packaging, it will be necessary to put together ten, twenty, thirty or any other number of sticks, so the cartoning machine must be able to adjust to the needs of the product. Once the correct number of sticks have been gathered, they are moved into the cartoning machine (*Figure 24*). There is a cardboard box rack, which has all the boxes folded, from where the machine lowers the boxes one by one and unfolds them. It then inserts the sticks into the box, as well as an instructions' leaflet for those products that require it, closes the box, and adds a small drop of glue on the flaps according to the customer's needs. After leaving the machine, the box is printed some information relative to the lot number and the expiration date, and it is checked with a camera that the information is legible and correct.

It goes through another conveyor belt until reaching the sorting balance, which takes into account the weight of each individual stick, the weight of the box and the occasional weight of the instructions leaflet in case there is. If the weight is outside the control limits, it is discarded, and the operators open it to count how many sticks there are. If there is the correct number of sticks, it is completely discarded, but if there is one missing, the operators take a stick from the deposit of correct discarded ones and introduce it in the box, which will be re-weighted.

In case the box is not discarded, it goes the last station which is the bundler and shrink-wrapping machine. Then, every ten boxes are put together and packed with a light transparent film, which is very useful to allow the boxes to be picked up ten at a time and moved. They are then collected by an operator and introduced into resistant cardboard boxes, which will be closed and placed into a pallet.

When the number of units required by the customer is reached, the production of that product is terminated, and the machine and line are changed over and cleaned. As the powder used in the previous product is all throughout the machine, to avoid cross-contamination with the new product to be manufactured afterwards, it is necessary to disassemble all those removable components that have been in contact with the powder, and then carry out a thorough cleaning and drying process.

This cleaning is carried out in a pressure washer chamber where all the residues of powder that may have been adhered to the components are removed. As the components are made of stainless steel, there is no need to be concerned about oxidation. Once they have been thoroughly washed, they are moved to an area where they are dried. This chamber is provided with very low humidity conditions to ensure that the components will be completely dry, because if there is excessive humidity, the powder can create caking that can affect further operations. Once all the components are dry, they are moved from the cleaning zone to the machine and installed so the production of the new product can begin.

5.3 Process monitoring

To be able to obtain data about the performance of the equipment and the operations, the entire process occurring within the manufacturing area is monitored. At the end of each shift, or at the end of the manufacturing of a product, a sheet must be filled in with the time spent on the activity specified in the column title. For example, there are columns that refer to set-up activities, others that refer to stops for technical reasons, organisational reasons, etc. Once the time spent on these activities has been written down (it is only necessary to fill those activities that have actually taken place), this sheet is given to the office to be entered into the Excel database. In order to avoid losing time filling this paper sheet, and to obtain a more precise and truthful data, MES systems are being implemented to monitor any process performed within the facility, substituting the actual method. Also, every day, there are several meetings to ensure that the process is running smoothly and to provide quick help for any issue they might have encountered during the production. These two process' monitoring techniques will be explained in detail below.

- **MES**

MES corresponds to *Manufacturing Execution Systems*, which are computerized systems used in manufacturing to track and document the process. MES provides information in real time that helps manufacturing decision makers understand how current conditions on the plant floor can be optimized to improve production output.

MES may operate across multiple function areas, and creates the "as-built" record, capturing the data, processes, and outcomes of the manufacturing process.

Although MES is now only being used to load data from the offices to the machines, the monitoring function has not yet been enabled, as it is still at a very early stage, and needs more time and adjustments to become fully reliable. When it will become completely reliable, paper sheets will no longer be used, and all the data will be transferred by the MES system.

One way or another, once all the data is written in the database, it can be analysed to see how efficient the shift has been, and in which categories the most time has been lost. This database contains historical data from 2020 and 2021, which is very useful to see what categories accumulate the biggest losses of production time, and also to understand the evolution of the OEE of each line during this period.

In Fine Foods, MES system has been implemented previously in other manufacturing lines, and this year, it has been also introduced into the stick-pack line, which is the focus of this project. It follows the same architecture, which can be seen in *Figure 25*.

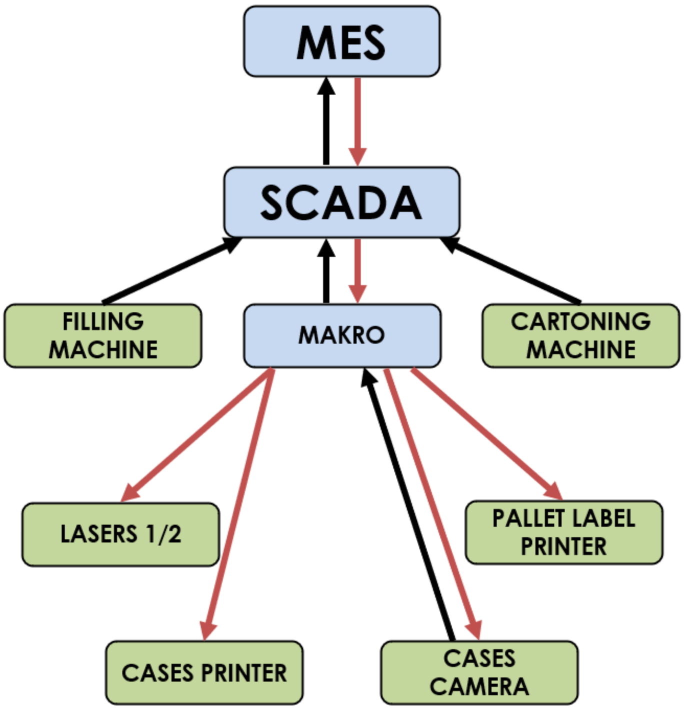

Figure 25. MES architecture

The MES is located at the top of the chain, as it serves as a link between the offices and the productive area. By using the MES, information generated by the engineering and administrative personnel in the offices can be transferred directly to the production operators, without the need for intermediate steps or the printing and delivery of the information. Also, data can be transferred in the opposite direction, which means that the office personnel could receive, in real time, feedback on how the process is performing at any given moment, when the function becomes enabled.

Directly below there is the SCADA system, which stands for Supervisory Control and Data Acquisition. This system is responsible for the collection and distribution of all the data that is entered or recorded by the system, and it also performs all the calculations and operations that allow the appropriate transfer of information to each machine. The SCADA system receives information from both the powder filling machine, and the cartoning machine, like for example the number of sticks produced, the operating time or the number and durations of stops. It is also connected with the MAKRO hub, which is in charge of managing different machines along the line.

The MAKRO hub delivers the information sent by the MES to printers, lasers and cameras that are placed along the line. The information it gives is commonly related to the expiring date, batch number and any other data assigned to the product that is being manufactured. The cases camera, which monitors the quality of the print of each case and discards those that are illegible or damaged, stores information on the number of accepted and discarded cases, which is sent to the MAKRO and, eventually, to the MES system, making it visible for the office personnel.

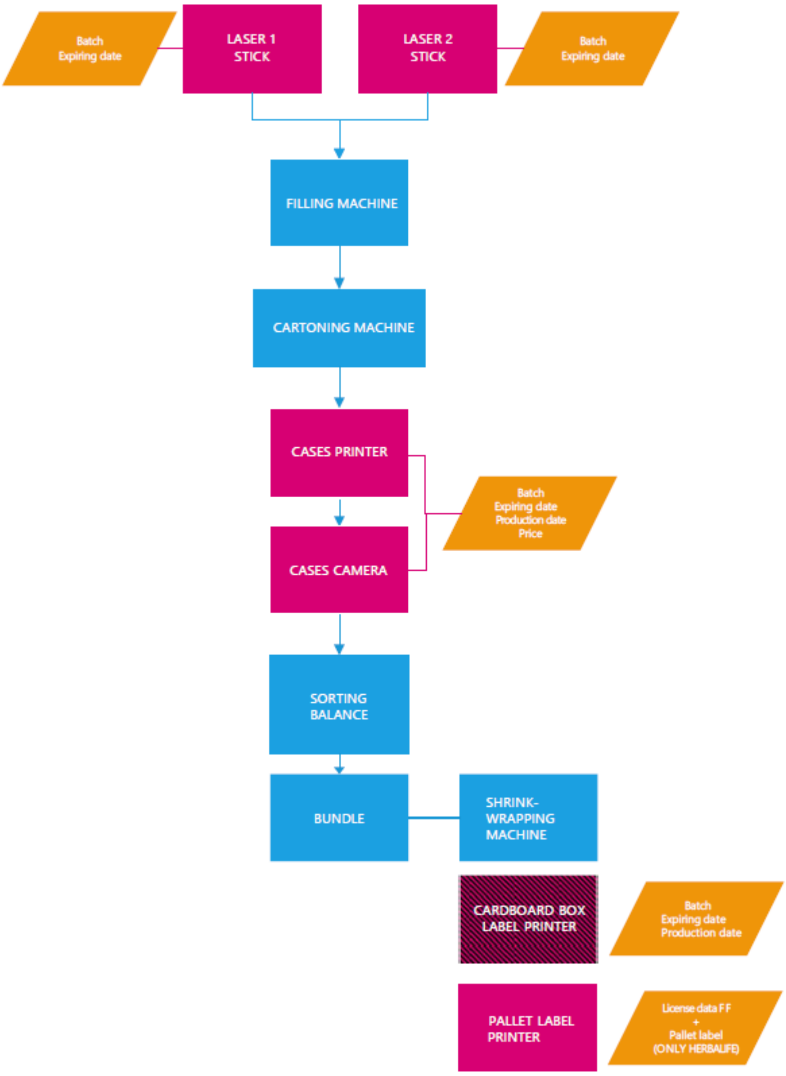

Figure 26. Distribution of the machines connected to MAKRO along the line

In *Figure 26* it is possible to observe the distribution of the machines along the line. In magenta colour, are displayed those machines that are connected to the MAKRO interface, and the possible information that they can receive (not always all the same inputs are sent). The cardboard box label printer, despite receiving data from the MES, is not located on the line but in the production offices, so it has been painted in a mixture of black and magenta.

Once the architecture of the system has been defined, it is necessary to deepen into the details of the process and how the orders are sent from the offices to production. This includes the rules that are followed to collect the data as well as the additional actions carried out by the operators themselves.

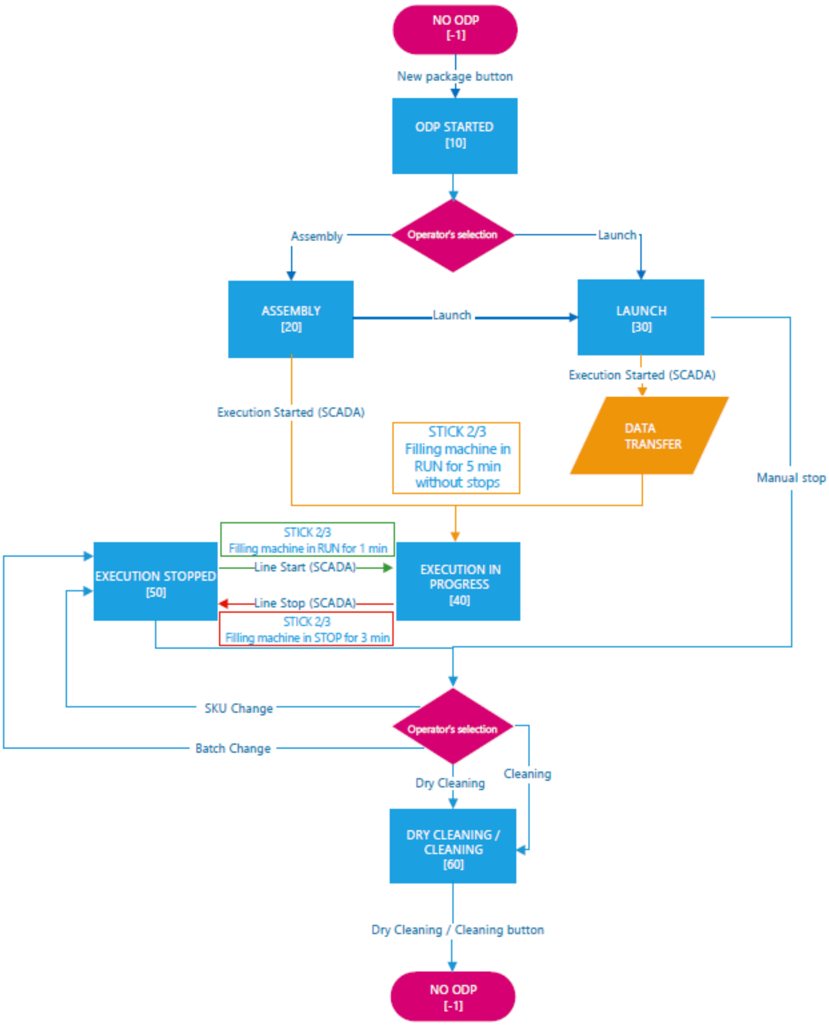

Figure 27. Operational scheme of the MES

The *Figure 27* shows the whole process, and the default mode, which corresponds with the initial and final states, refers to when there is no production order (ODP) present in the system. When a new production order is sent from the office, and the operator clicks on the "New package" button, the status becomes "ODP Started". At this point, the operator has two options. For the first scenario, in case the machine is all set up and ready to work, is the "Launch", in which the production can begin.

The second option, which is the most common, is that the machine still requires assembly. Therefore, the operator changes the status of the system by pressing the "Assembly" button, and when all the parts have been fully installed, the system switches over to "Launch" again.

Once the "Launch" phase is completed, production can begin and also data transfer from the machines to the MES can start. To track the functioning, only the Filling machine is monitored, as it is the pacemaker. This is because there are no buffers in the system, being one-piece-flow, so that if the first machine is producing the whole system runs, and if there is any problem in the line, it is the first machine that stops. When the MES detects that the Filling machine has been running uninterruptedly for five minutes, it automatically goes to the next phase, which is "Execution in progress". In this stage, it moves back and forth between the states "Execution stopped" or "Execution in progress", changing to the first one if it is stopped for at least three consecutive minutes, and moving to the original one if it starts running for one minute continuously. It can be stopped manually at any point of the system.

With the state "Execution stopped" activated, the operator has four different alternatives, which are performing an "SKU Change", a "Batch Change", a "Dry Cleaning", or a "Cleaning". For the first two, once the change is finished, production can be restarted, and it will keep running in the same way it has been working as before the change. For the last two, if pressed, the state of the system will move to "Dry cleaning/Cleaning". After this action has been performed, production will be completely finished and the production order will be completed, therefore going to the default state, "No ODP".

- **Lean Manufacturing Tiering**

The other system used to understand the process and address the issues it might face every day is the so-called Lean Manufacturing Tiering. During the course of each shift, and during the course of production, some scheduled meetings are organized, which are the L1's, L2's and L3's.

L1 takes place in every turn, respectively at 8:15 for the first turn, 15:15 for the second turn, and 22:15 in the third turn in case it is necessary to have a night shift. In these meetings, it is necessary the presence of the foreman, and one operator. There, they ask themselves seven established questions on how the lines are working until that point and share and write any issue that might be affecting the production of that turn, which are:

- Are there any events/actions not yet solved in the last 24 hours?
- Are there any problems related to safety?
- Are there any problems related to materials?
- Has there been any problem that required a mechanical intervention?
- Are there micro-stops that slow down the production?
- Are there any other problems still not yet highlighted?
- Is the assigned target being respected?

For each production line the questions might differ, as well as the schedule, so the questions and the meeting times stated above are only for the stick-pack lines, which will be the ones on which this project will focus. In the whiteboard that can be seen in the *Figure 28 (left)*, the weekly performance is showed so all operators can become aware of the efficiency they have had the previous week. It is in front of that whiteboard where the L1 meeting takes place. On the dedicated section shown in *Figure 28 (right)*, operators must write the issues they have faced during their production turn, stating the date, line, product, problem category, and finally providing a short summary of the problem and the opening and closing date of it.

Figure 28. L1 board (left) with the detail on how the incidences are written (right)

L2 takes places every day at 9:20, in the Production office, and it is necessary the presence of the Production Responsible, the Plant Manager, the Maintenance Manager, the Warehouse Manager, and a representative of the following departments: Industrialization, Planning, Continuous Improvement, Quality, and Automation (if needed). In that meeting there are addressed all the issues that could not be solved during the L1, which might need a more thorough solution or an authorisation from higher departments. It is also useful to get an idea of how the production is going, to understand if they are anticipating compared to the theoretical production or if they are being slowed down by the issues.

Finally, L3 happens every two weeks, and requires the presence of three representatives from the Engineering department, the Delegated Administrator, and the manager of the following departments: Maintenance, Industrialization, Production, Controlling and Continuous Improvement. The purpose of the L3 is to take care of the issues that could not be solved during the L2, which are normally related to problems that might require a higher financial investment, such as repairs or replacement of machine parts, or the intervention of a specialized technician.

6. PROBLEM BREAKDOWN

As shown in the previous section, one of the activities that most compromise the efficiency of the stick-pack lines are the batch changes, so the project will focus on analysing possible improvements to reduce the impact of batch changes, which are necessary and therefore cannot be eliminated. Along with batch changes, SKU changes will also be considered, which also occur during the course of production and also represent machine downtime.

In this way, for each kind of change, a time taking will be conducted personally, in order to quantify the initial situation and to have a reference point to assess the impact of the countermeasures that will be implemented to reduce these times.

6.1 Current situation analysis

Having identified the problem, and the impact it causes on the company in terms of both time and cost, it is necessary to go into more detail in order to understand what exactly generates all these time losses, so that we can then investigate the possible reasons for them and propose appropriate countermeasures.

To do so, various *Gemba walks* have been performed, carried out over several days and during different time slots, to be able to talk with multiple operators that are directly involved in the process and learn from their experience.

During the visits to the production site, it was possible to understand how the whole process operated, from the raw materials to the finished products, and thanks to the conversations with the operators, it was possible to understand which problems occurred to them most frequently and how they solved them. It has also been very useful to be able to spot all those moments in which inefficiencies occur, such as technical downtimes, machine set-ups, assembling and disassembling of the machine, etc. Thus, it has been possible to observe all the possible casuistry to better understand the process itself, and to be able to interpret more solidly the data that can be analysed so far.

This data is contained in a dataset in which, for each day and for each shift, all the times required to complete the different activities are specified. In this dataset, the time lost in slowdowns, assembly, set-up, etc. can be displayed. Thanks to this, it is possible to analyse which activities have a greater impact on the OEE calculation.

All the main categories for inefficiencies are:

- **Set-up:** Includes all the times dedicated on preparing the machine for production, which might be the assembly, disassembly, launching, cleaning, etc.
- **Technical:** It considers all those problems related to mechanical or physical issues with the machinery.
- **Organizational:** It is formed by all the waiting times for documents, maintenance operators, supervisors, materials, or programmed pauses.

- **Slowdowns:** This category sums up all the times lost during micro-stops, those which are less than five minutes, and which might be caused by any factor.
- **Delta speed:** It is the difference between the target speed, which is the optimal rate at which the machine can produce, and the real speed, which can be influenced by different issues.
- **Reprocesses:** It is the time lost in retrieving those products that have been erroneously discarded.

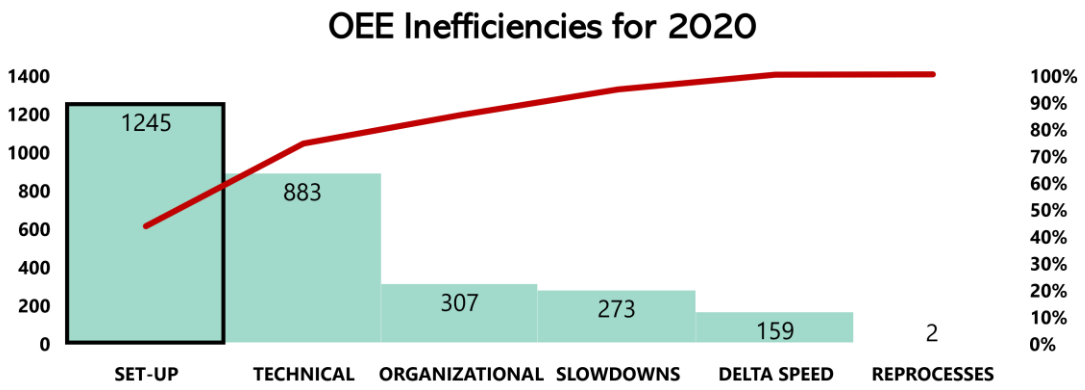

Figure 29. Pareto chart of the inefficiencies for 2020

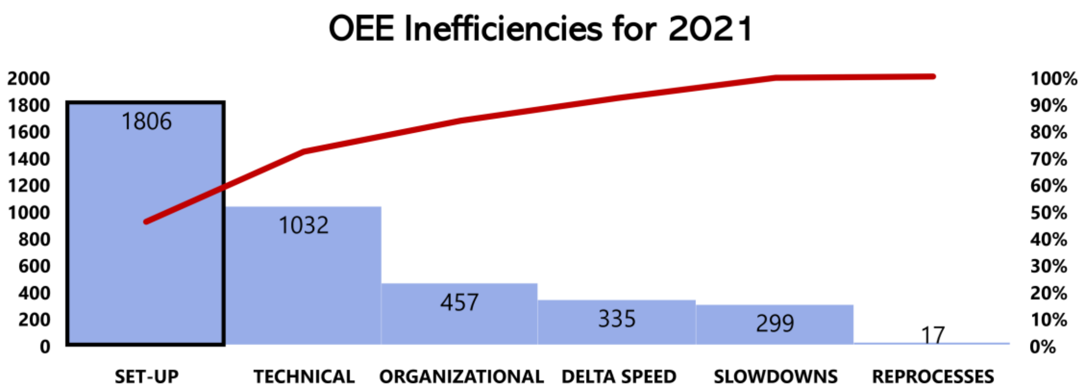

Figure 30. Pareto chart of the inefficiencies for 2021

As shown in the Pareto charts above, *Figures 29* and *30* it can be extracted that the most time-consuming activity in 2021, as well as in previous year, is the set-up, which represents approximately the 50% of all the possible inefficiencies. It is followed by the technical issues, which have a weight of more or less between a 25 and a 30%. This chart is very useful for understanding the impact of each possible cause and it also provides information on what categories are more critical and should be addressed more promptly.

Once it has been possible to pinpoint the causes that have the greatest impact on OEE, it is necessary to go into detail on these, in order to be able to identify more precisely what the focus of the project will be and how it will be approached.

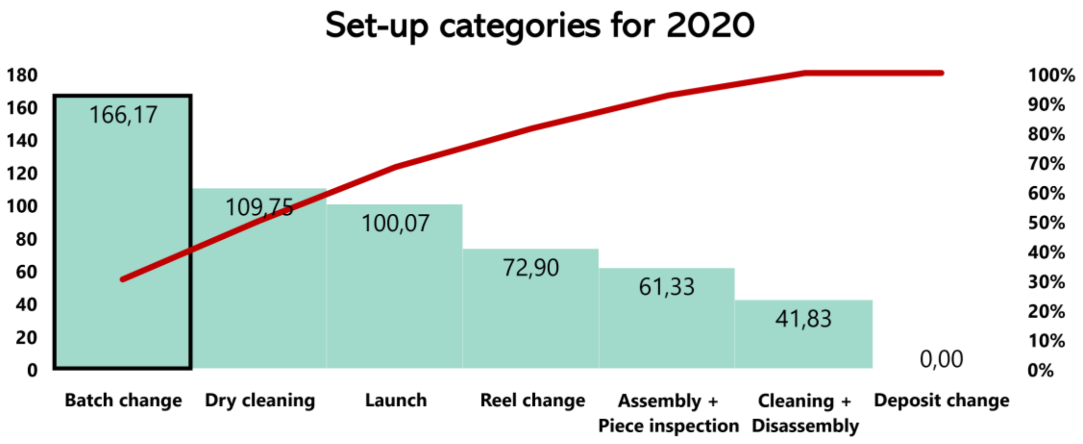

Figure 31. Pareto chart of the activities that conform the set-up category for 2020

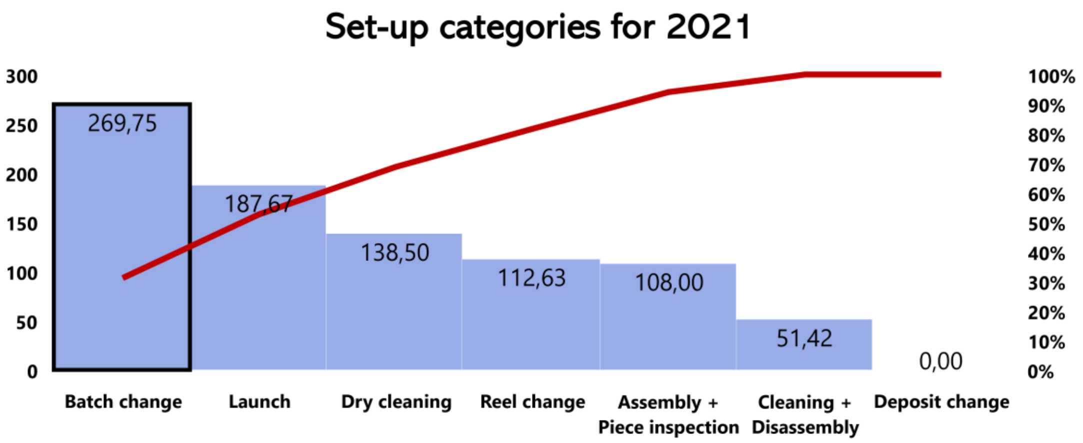

Figure 32. Pareto chart of the activities that conform the set-up category for 2021

As with the inefficiencies, the set-up category also groups together a set of actions, as seen in *Figures 31* and *32*, details of which are given below.

- **Batch change:** It considers the time to change the lot of a product, in which it is necessary to change the code written on the sticks and cases, and also to compile documentation to certify it has been performed correctly.
- **Dry cleaning:** It involves the time required to superficially clean the machine with pressurised air, to remove any powder and residues that may remain due to the production itself.
- **Launch:** It includes all the necessary transition time for the activation of the machine, its own adjustments for dosing and speed, the checks to make sure that everything is flowing smoothly, and the tests to make sure that the products coming out are in the correct weight range and are hermetically sealed.
- **Reel change:** It comprises all the time dedicated in removing the old reel, introducing the new one, and testing that the change has been performed correctly.

- **Assembly + Piece inspection:** It is the time dedicated to the assembly and fitting of all the removable components of the machine after they have been thoroughly washed and dried, and the subsequent examination of these to see that they are in optimum condition.
- **Cleaning + Disassembly:** It is the time devoted to the disassembly of all the removable components after the machine has finished the production of a product and has to start another. It also considers the time for thoroughly cleaning and drying all the components to avoid cross-contamination between the two products.
- **Deposit change:** It is the duration of changing the deposit when it is emptied.

Before entering into the graph creation, a preliminary data analysis was carried out to see if there were any anomalies in it. It was found that, on several occasions, there were actions that could take up to an entire shift, such as an assembly and inspection that lasted 7.5 hours. After checking this data with the responsible managers of the database and with other colleagues in the Continuous Improvement department, a maximum has been established for each category, which is 3 hours for the launch, and 2 hours for the rest of the categories. This phenomenon is due to the fact that sometimes unexpected events can occur (breakdowns, technical failures, etc.) that completely paralyse the activity. Instead of specifying what has happened, operators simply note the entire duration without taking into account that a large part of this duration is due to a problem, and not to the activity itself. Therefore, the *Figures 31* and *32* above show only those activities that have a reasonable duration, and which do not include any unexpected events.

The fact that the deposit change time is always zero is not due to an error, but rather due to another motive. As the deposit is connected on the lower side to a tube that leads to the machine's feeding system, the amount of powder that fits in the tube is sufficient to keep the machine running during the time the deposit is being replaced. Due to the small dosage that is introduced into the sticks, approximately two grams of powder per stick, this tube filled with the material serves as a sufficient buffer to manage the deposit change without having to interrupt the machine due to lack of feeding, so that even if the change lasts between 15 and 20 minutes, the stoppage time is always zero.

It can therefore be seen that batch change is the activity that involves the most downtime, both in 2020 and 2021, and is thus the one that requires the most immediate implementation of measures to reduce it. Therefore, the project to be developed and analysed will revolve around reducing the downtime of batch changes, trying to understand the causes of it and possible countermeasures.

6.2 Batch Change situation

- **General explanation**

The batch change occurs when the customer requires the same product, but separated into different batches, as this will later be useful to distribute them among the end customers. For each batch, the amount of powder that will be needed in the deposit to produce the required number of stick cases is calculated.

To perform the batch change, it is necessary to empty the entire line of the previous sticks, change the variable data that is laser-printed on the stick and the case, fill in documentation to close the previous batch and open the current one, change the deposit, obtain the new tare for the sticks and cases with the process balance, and further activities around the line. At the end of the batch change, the production begins again with the new the batch number printed on the sticks and the cases. Customers can define, for every batch, the quantity of final products they want, so the time between the batch changes can be very variable, as it also depends on external factors such as stoppages for technical or organizational issues.

- **Detailed time taking broken down by activity**

In order to start analysing the batch change, all the stakeholders in the project have been asked to collaborate to gather timings and to be able to identify all the actions that take place during the batch change. This is because it is an event that, although planned, is also subject to the variations perceived by the production process, so if it goes faster or slower, it advances or delays the moment in which the batch change will take place. In addition, it must be taken into account that, depending on the week, there are three shifts, so all those batch changes that occur during late afternoon or the night shift, or that are carried out during the days when I do not attend the company, cannot be monitored in person. It is important to add that the measurement of timings is not simple either, as batch change is an action that is carried out by two operators, and therefore it is necessary to take the time of each action that each operator performs.

That is why, whenever a batch change is going to happen, I will be notified a few hours beforehand so that I can measure the timings personally, and if it happens at a time when I am not in the company, there will be people in charge of taking the duration and they will provide it to me afterwards. Regarding the batch changes not measured by me, it was not possible to take into account the detail of all the activities that take place during the batch change, however, the data extracted from this time measurement is still useful to understand the process and to see the average times and the variability and range between them, in order to get a general idea of the whole situation.

The use of a portable video camera (GoPro) has also been requested in order to facilitate the taking of times, and to individuate all the actions that are carried out in the process. This will be one of the most useful tools, because by having the recordings, it will be possible to see simultaneously what actions each operator is doing, and the duration of each of these actions. This is a tool that has already been used in previous projects where the SMED methodology has been applied, so it does not represent an absolutely new investment or procedure. In any case, in order to obtain the recordings, it has been necessary to establish contact between the various departments of Production, Continuous Improvement and Human Resources to sign all the necessary authorisations and documents that allow the recording, as well as the announcement of this operation to the employees and their trade unions.

While that authorisation process was taking place, which is a lengthy and complex process, I proceeded to measure the time taken to carry out batch changes. For those that coincided with my presence in the company, I was able to measure them personally, noting down the steps that I could and interacting with the operators to understand what they were doing at each moment, as well as being able to identify potential areas where they were spending more time, where there were more inconveniences, or where there was more margin for improvement.

After collecting the times of the batch changes that took place during approximately one working month, and breaking them down by activity, it was possible to prepare this chart which displays all the batch changes that could be followed in *Figure 33*, as well as the average of these, which was 72 minutes. It can be appreciated in the chart that there is a great amount of variability, as these batch changes ranged from 50 minutes to 113 minutes in one particular occasion.

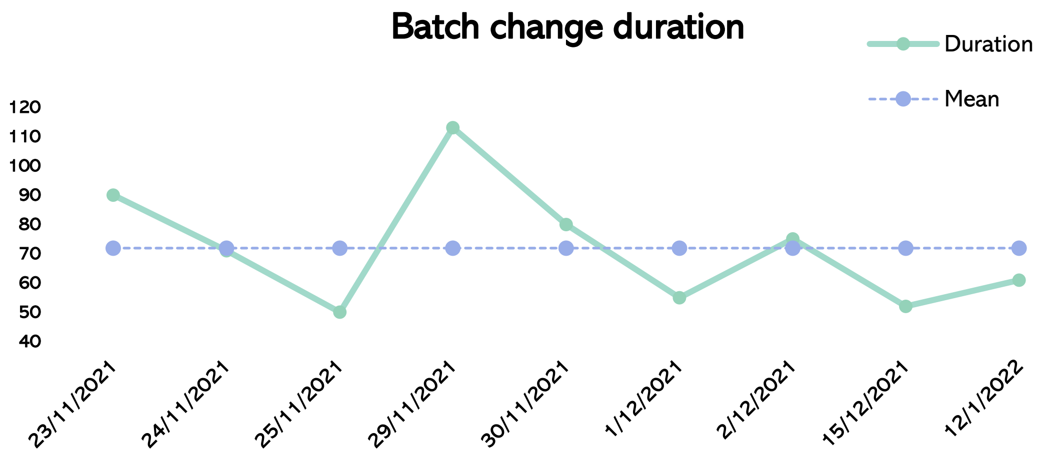

Figure 33. Time series plot of the data collected for the batch change

The fact of having a high average time seriously undermines the efficiency of the system, but the existence of such high variability means that the rest of the activities that surround it cannot be planned reliably and in advance, thus generating additional difficulties for these activities.

Batch change is a complex activity, which require many sub-activities that must be followed in a certain order. Some can be performed by either the “macchinista” or the “fondo linea”, or exclusively by the “macchinista”. To illustrate the difference between these two types of operators, the “fondo linea” is dedicated to the simpler tasks of packing the cases into the cardboard boxes and then onto the pallet, while the “macchinista” is responsible for the machine operation and is more experienced. When it comes to the batch change, the “macchinista” performs all the activities that require higher responsibility, while the “fondo linea” does those that are more manageable. Also, some activities are very simple and take a little time to be completed, while others can last as much as half an hour.

In *Table 1*, all the activities that constitute the batch change will be displayed, with the average time obtained during the previous on-site time measurements.

	ACTIVITIES	AVERAGE (min)
Previous batch	Collection of the deposit sheet	**3**
	Send sorting balance and process balance printouts	**1,50**
	Retrieval of the printouts and the batch record for the following batch	**2**
	Document closure	**15,33**
	Waste removal and weighing	**10**
	Material counting	**9,33**
Following batch	Material control for new work order (“Buono di lavoro”)	**1,33**
	Cases' coding change	**1,67**
	Cases sampling for batch record and picking of 10 cases and leaflets for tare	**1**
	Sticks' coding change	**1,67**
	Sticks sampling for batch record and picking of 20 sticks for tare	**2,8**
	Variable data setting of process balance + sticks' tare + printout + cases and leaflets' tare	**9**
	Document compilation	**30**
	Variable data setting for the sorting scale + initial printout	**2,2**
	Retrieval of the initial printout of the sorting scale	**1,33**
	Deposit change + new deposit inspection (double check)	**16,33**
	Batch record double check	**4**
	Checklist + production start	**2,4**

Table 1. Average time for the sub-activities that conform the batch change

To sum up, regarding the batch change, the mean of the durations measured during the time-taking period is exactly 71,89 minutes, which can be approximated to 72 minutes, with a range of 63 between the fastest and the slowest batch change. The values obtained in the time measurement have been compared with the historical values collected in the company's dataset, with which the calculations are then made to determine the OEE of the line. According to the dataset for the whole year 2021, 311 batch changes have been carried out, which have meant a total of 270 hours, thus obtaining an average duration of 52 minutes per batch change. As mentioned in the previous section, only durations of less than two hours were taken into account. It should be noted that this average duration is 20 minutes lower than the measured duration, so it might not be fully reliable, as the durations introduced are handed by the workers, which make a rough estimate on the time they have spent to perform the batch change. However, the number of batch changes carried out is more accurate and will be useful later on.

6.3 SKU Change situation

- **General explanation**

The SKU change is a scenario that occurs less frequently than the batch change. This mainly involves the products from the brand *Herbalife*, and in few words, it is very similar to a batch change which also involves a change of destination. As the product is intended for many countries, the language of these countries is generally different, so that to the batch change scenario it is necessary to add the fact of also having to change the reel and the cases. It can happen however, that only the cases change but the reel remains the same, or the opposite.

Generally, the batch number remains the same for all the different SKUs produced, so the SKU change is considered different to the batch change. Another main difference, apart from the change of material, is that the documentation that must be filled is lower, making the overall activity quicker to perform. The quantity of finished products for each SKU is generally low, so they are performed frequently when these products are manufactured.

- **Detailed time taking broken down by activity**

For the SKU change analysis, all project stakeholders were also involved in order to have their participation in letting me know when a SKU change was going to happen, as well as to measure the total durations of those that I could not be present.

Taking advantage of the authorisation for the recording of the batch changes, it was also decided to record some SKU changes in order to be able to review the video as many times as necessary and individualise the activities that constitute the SKU change, as well as the distribution of these activities between the two operators and the synchronisation in which they work.

While batch changes generally happen every week, SKU changes are less frequent to occur, so the time-taking has started a few weeks later and has been briefer. However, in those weeks in which there is manufacturing of a product that requires SKU changes, these can take place more than once a day, as the quantity of units for each SKU tends to be small.

After gathering the times of the SKU change that took place during two working weeks, the chart in *Figure 34* was elaborated. As well as with the time-taking performed for the batch change, it was broken down by activity, to make it easier to identify those that take more time or those that can be performed faster. The average of the durations for the SKU change stands at 46,4 minutes and has ranged between 41 and 55 minutes. It can already be seen that it is quicker than the batch change, and even if there are different types of SKU change according to the materials that have to be changed, the variability is also lower.

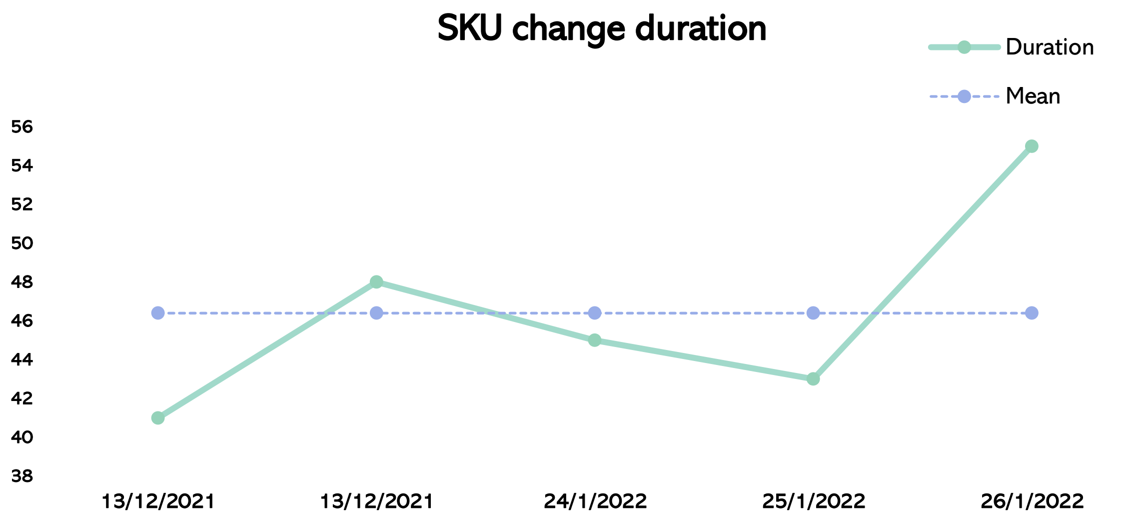

Figure 34. Time series plot of the data collected for the SKU change

Regarding the SKU change, the activities performed are very similar to the batch change, and the main differences lie in the following facts:

- It is not necessary to change the deposit, as the same powder is used for all the SKUs that are sent to different countries. However, if the deposit is nearly empty, they can either change it during the production of that SKU, or do it during a SKU change, even if it is not a routine operation.
- Depending on the type of SKU change there are the added activities of changing the reel, changing the cases, or changing both of them. This adds variability to SKU changes as not all changes perform the same activities.
- The documentation for closing and opening the new SKU is shorter and easier to complete than with the batch change.

	ACTIVITIES	AVERAGE (min)
Previous SKU	Send sorting balance and process balance printouts	**1**
	Retrieval of the printouts and the batch record for the following batch	**1**
	Document closure	**15,33**
	Waste removal and weighing	**6,5**
	Material counting	**5,67**
Following SKU	Material control for new work order ("Buono di lavoro")	**1,25**
	Cases change	**6**
	Cases' coding change	**1,67**
	Cases sampling for batch record and picking of 10 cases and leaflets for tare	**2,25**
	Reel change	**12**
	Sticks' coding change	**1,67**
	Sticks sampling for batch record and picking of 20 sticks for tare	**2,5**
	Variable data setting of process balance + sticks' tare + printout + cases and leaflets' tare	**8,25**
	Document compilation	**23**
	Variable data setting for the sorting scale + initial printout	**2**
	Retrieval of the initial printout of the sorting scale	**1,5**
	Batch record double check	**3,33**
	Checklist + production start	**1,33**

Table 2. Average time for the sub-activities that conform the SKU change

To sum up, regarding the duration of the SKU changes, from the empirical time taking, it was registered an average of 46,4 minutes, and suffered less variability than the batch change, with a range between the slowest and the fastest SKU change of 14 minutes. As far as SKU changes are concerned, these are not recorded as such in the company's database, so calculating how many occur throughout the year involved a rather different approach. First, it was necessary to find out which product codes belonged to *Herbalife*, which are the majority of the SKU changes, and then also to identify which *non-Herbalife* products were manufactured for more than one country. Comparing month by month, it was counted how many different destinations had been produced for each product code, and the result was that during 2021 there were approximately 213 SKU changes.

7. TARGET SETTING

As detailed in the previous sections, the time dedicated to the batch change is too high, and above all, it is excessively variable, so it is impossible to predict how long it will last, and at the end of the year, many hours of production are lost in this action.

Once the starting point has been defined, it is important to set objectives that can be used as a benchmark to assess the impact of the countermeasures that can be applied to improve the initial situation.

The objectives must follow the SMART methodology detailed in the theoretical framework, so that the targets must be relevant to the nature of the project, they must be quantitatively measurable, they must be appropriate to the type of project, meaning that they must be achievable, and finally, they must have a deadline for their completion.

These objectives will be divided into two parts. The first will be the must-have objective, that is, the improvement that needs to be achieved in order to ensure that there has been some progress as a result of the project. On the other hand, there will also be the nice-to-have objective, which is desirable if it can be achieved or exceeded, but it is not absolutely essential to reach it in order to be able to claim that the project has brought about a positive change to the initial situation.

- **OBJECTIVE 1 – Reduce the time spent in batch change by March**

MUST-HAVE TARGET

The must-have objective consists in reducing a 10% the time dedicated to the batch change by the end of March. Currently the average time is close to 72 minutes, so with a 10% reduction of the average duration, it could go down to 64,8 minutes. This saving, taking into account that there have been 311 batch changes in the year 2021, means a yearly reduction of 37,3 hours. This improvement in terms of productivity, considering an average hourly rate of 53,2 €/hour, would mean a saving of nearly 2.000 € per year.

In addition, it is expected that with the measures that will be detailed later on, the variability of batch changes will also be reduced, making the process more standardised.

NICE-TO-HAVE TARGET

As a nice to have objective, it is considered to increase this reduction from 10 to 15% by the end of March, going down to a batch change duration of 61,2 minutes, thus saving an extra 18,7 hours per year. Translated into economic terms, the nice-to-have objective would add up to 1.000 € extra per year in savings.

- **OBJECTIVE 2 – Reduce the time spent in SKU change by March**

MUST-HAVE TARGET

As far as the second objective is concerned, this is very similar to the first one. **The must-have objective consists in reducing a 10% the time dedicated to the SKU change by the end of March**. The average SKU change time is 46,4 minutes, so a 10% reduction would bring it down to 41,8 minutes. The SKU change occurs about 213 times a year, so this reduction of 4,6 minutes would mean a potential decrease of 16,5 hours per year. In economic terms, considering the same hourly cost as in the previous objective, a saving of 875 € per year would be achieved.

NICE-TO-HAVE TARGET

As a nice to have objective, it is considered to increase this reduction from 10 to 15% by the end of March, going down to a SKU change duration of 39,4 minutes, thus saving an extra 8,25 hours per year. In a monetary perspective, the nice-to-have objective would save up to 438 € extra yearly.

8. ROOT CAUSE ANALYSIS

Once the process has been fully understood and mapped, the impact of inefficiencies on the company has been quantified and the objectives have been established, it is time to explore with an in-depth analysis the potential root causes that impact the process, in order to identify the areas that can be tackled with possible countermeasures.

As already pointed out, the efficiency of the stick-pack line is inferior to the target efficiency assigned for this year, and after having thoroughly analysed the data available, it was found that the most significant area of losses was the one related to batch change.

To analyse which causes are affecting the duration of the batch change, as well as the SKU change, lean manufacturing techniques such as the "5-Why's" methodology and Ishikawa diagrams have been used. These have allowed to reach to the underlying root cause of the problem, and to separate into groups all the possible causes that increase the duration, placing them in a very visual way, easily understandable by any person.

8.1 "5-Why's" technique application

Having established the scope of work, the "5-Why's" method was used to deepen into the possible root causes. To correctly apply this technique, it is necessary to define the main problem, and then, ask why this problem happens. For each answer, it necessary to ask why again, until this has been repeated at least five times. By the last question, the root cause of the problem should be clearly identified. It can be found in *Figure 35*.

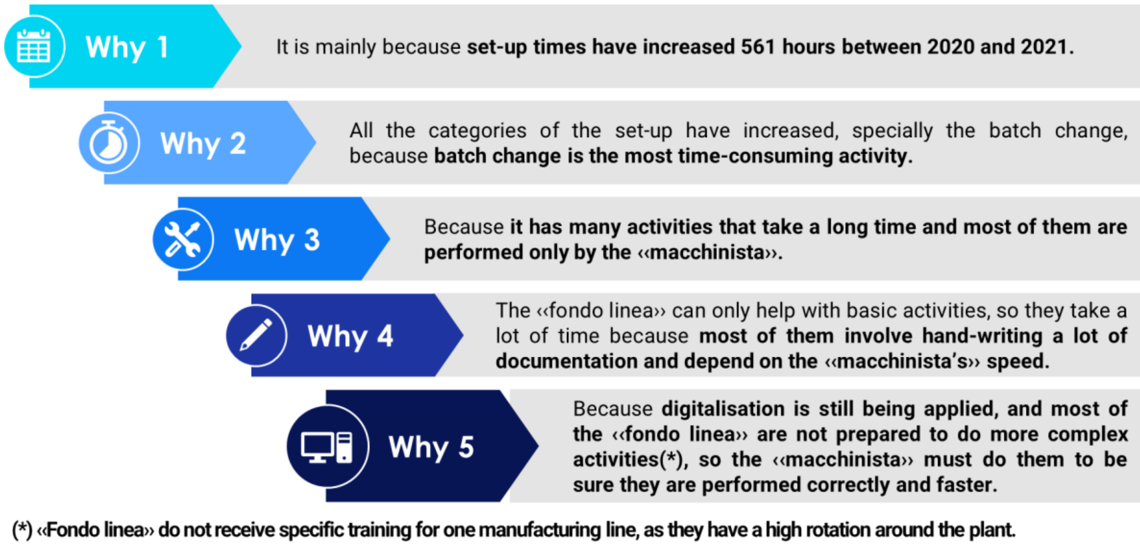

Figure 35. Summary of the "5-Why's" methodology

The problem defined is: **OEE of the stick-pack line is lower than expected**.

1st Why: Why is the OEE of the stick-pack line lower than expected?

After having analysed the historical data obtained during this year and the previous one, it was found the OEE was impacted due to the growth of the time lost in set-up, which had increased 561 hours between 2020 and 2021.

2nd Why: Why did set-up times increase 561 hours between 2020 and 2021?

Entering into the detail of the activities that are comprised in the batch change, it was analysed how these activities had increased from year to year, and also which of them accumulated the greatest amount of time lost. It was found that all the set-up activities had increased, especially the batch change, which was undoubtedly the most-time consuming activity in both years.

3rd Why: Why is the batch change the most time-consuming activity?

In order to go into detail on the activities that make up the batch change, it is essential to enter the production area and observe how the batch changes are performed, in order to note down all the activities that are carried out and, afterwards, to be able to measure the time that is dedicated to each activity. During these field visits, it was observed that there were many activities that required a lot of time and that were only performed by the "macchinista".

4th Why: Why do some activities take a long time and are only performed by the "macchinista"?

During the batch change there are two people present. It can either be two "macchinistas", which both have a very extensive experience on the machines they use and are the ones in charge of ensuring that all the process is working smoothly, or it can be a combination of one "macchinista" and one "fondo linea". The "fondo linea" are the operators that work in the end of the line, picking the finished products and introducing them into boxes, which will therefore go to the pallets. The "fondo linea" can either have some experience or be relatively new, but in either case they are limited in the tasks they can perform, as some of the require manipulating the machines.

That justifies why the "fondo linea" can only help with basic activities, so most of the activities fall on the responsibility of the "macchinista". These activities also involve hand-writing a lot of documentation, both for closing the current batch and opening the successive one, and the time needed to complete them highly depends on the "macchinista's" writing speed.

5th Why: Why most time-consuming activities require handwriting and depend on the "macchinista's" writing speed?

Most of the documentation filled is for internal company use, as if there is any problem with the product delivered to the customer, it must be possible to retrace all the steps that have been performed on a product.

However, digitalisation of this documents is still being applied, but in the meantime the actual system still requires filling up these documents by hand. With the introduction of the MES system and electronic batch records, it will be for sure possible to reduce the time the "macchinista" spends with the documentation part of the batch change.

The other reason why the batch change still falls heavily on the "macchinista's" responsibility is because the "fondo linea" is not prepared to perform more complex activities. This is due to the fact that "fondo linea" have a lot of rotation around all the machines in the facility and do not receive specific training on the stick-pack, so either they cannot perform the activity, or the "macchinista" prefers to do it himself as this ensures that it will be completed more quickly and correctly.

8.2 Ishikawa diagram visualization

Once it has been possible to understand what root cause affects the efficiency of the stick-pack line, it has been decided to collect, using the Ishikawa diagram, all the possible reasons that can impact on the duration of a batch change, separating them into the different bones of the fish, which refer to Machine, Material, Method, and Manpower. The diagram can be seen in the *Figure 36*, and further on all the causes and why they have been considered relevant for the batch change duration will be detailed.

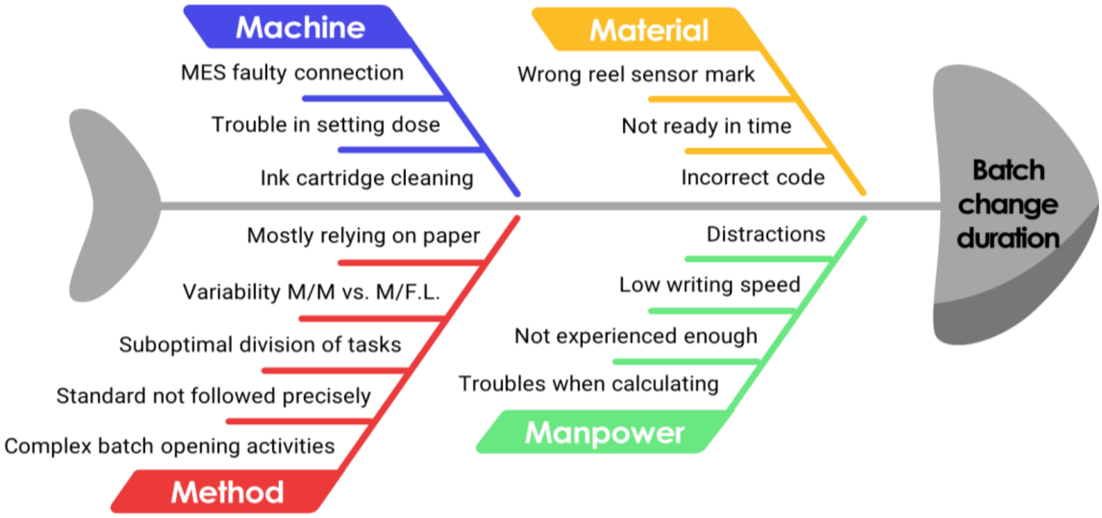

Figure 36. Ishikawa diagram for the batch change duration

- **Method**

This category comprises the way in which the procedure is established, and what actions of this procedure might negatively affect the duration of the batch change.

  - **Mostly relying on paper:** The documentation that must be filled in the batch change must be done exclusively in paper, which is a lengthy task and depends greatly on the writing speed of the "macchinista".

  - **Variability M/M vs. M/F.L.:** The batch change can be performed by both "macchinistas" or by one "macchinista" and one "fondo linea". There is a lot of variation in the duration of the batch change, as in the first case they both can perform different activities simultaneously, therefore working in parallel, while in the second case only a few tasks can be performed at the same time.

  - **Suboptimal division of tasks:** The procedure that is being followed places many activities on the responsibility of the "macchinista", leaving the "fondo linea" inactive for most of the time. This makes the "macchinista" the bottleneck of the process, as the duration depends solely on its speed.

  - **Standard not followed precisely:** There is a standard procedure defined for the batch change, which if not followed correctly, could mean longer durations of the batch change. It is also slightly outdated with the recent introduction of the MES.

  - **Complex batch opening activities:** During the opening of the new batch there are many activities that the "macchinista" must perform while he compiles the documentation for the new batch. One of these activities that are complex and require time, for example, is performing the tare of the sticks. The balance used has a very high precision, up to four decimals, so the slightest air flow can upset the measure. This means that it takes a lot of time until it reaches a stable weight, lengthening the duration of the batch change.

- **Manpower**

It includes everything related to the operator who performs the batch change, and all the actions or problems that may affect the duration of the activity.

  - **Distractions:** As both operators are working in a facility with multiple things going on at the same time, it is normal that they might get distracted by an activity external to the batch change. These activities could go from talking to a colleague to helping another with an activity they are having troubles.

  - **Low writing speed:** Due to the amount of documentation that must be filled, it depends mainly on the writing speed of the "macchinista", so if one is slower when writing, the duration of the batch change elongates.

  - **Not experienced enough:** Some "fondo linea" might be relatively new to the stick-pack line, due to the rotation they have around the facility, so they might take more time than expected to perform some activities or they might not know what to do or how to do it.

  - **Troubles when calculating:** When performing the activity of material counting, some operators might spend more time than usual performing the calculations, although they have a pocket calculator.

- **Material**

The category of material covers all the problems related to the raw materials that are required for the manufacturing of the products.

  - **Reel wrong laser mark:** It can only occur in the SKU change, in the scenario where the reel must be changed, and what happens is that the contrast sensor mark of the new reel is on the opposite side of the previous one. This occurs because some reel suppliers place it in the right part, and others in the left part. If it happens that between the two batches the position of the mark changes, the position of the machine photo-sensors will have to be changed. This operation requires some time as one of the two sensors is not in an easily accessible place.

  - **Not ready in time:** Could happen that, when the materials are needed for the next batch, they are not ready. The operators must therefore contact the responsible for the materials delivery and wait until they are brought into the production area.

  - **Incorrect code:** Could also happen that, when the operators go to pick the material to place it in the machine, they found out by checking the code that those are incorrect. Then they must contact the responsible, and wait for the wrong materials to be taken away, and the correct ones brought in.

- **Material**

This considers all the causes that are related to the machinery, all the possible stopovers that require an intervention or an extra time in using any of the machines.

  - **MES faulty connection:** It happens that MES has connection problems with some of the machines, so operators lose time either trying to fix the connection trouble or introducing the data manually in the machines.

  - **Trouble in setting dose:** The powder filling machine adjusts the dose by weighting all the sticks produced and sending feedback to itself, in order to know if it must increase or decrease the dosing to produce sticks that are in the required weight range. Sometimes it may happen that it takes more time than normal, increasing the total duration of the batch change.

  - **Ink cartridge cleaning:** The cartoning machine performs an operation which is printing the lot number and the expiring date on the box. It can happen, when they are producing some sample boxes for the batch record, that the operators find that it is printing blurry o faintly. The operator has to open the machine, extract the ink cartridge, clean the surface of it and introduce it again.

8.3 Summary of root causes and selection of improvement areas

CATEGORY	ROOT CAUSE
5-Why's	Digitalization is still being applied, so documents must be handwritten.
	"Fondo linea" operators do not receive effective training so they cannot help "macchinistas" on many activities.
Method	Mostly relying on paper
	Variability M/M vs. M/F.L.
	Suboptimal division of tasks
	Standard not followed precisely
	Complex batch opening activities
Machine	MES faulty connection
	Trouble in setting dose
	Ink cartridge cleaning
Material	Wrong reel sensor mark
	Not ready in time
	Incorrect code
Manpower	Distractions
	Low writing speed
	Not experienced enough
	Troubles when calculating

Table 3. Summary of all the root causes divided by category

Once both methods have been applied to find the root causes that affect, or can affect the duration of the batch change, they can all be found summarised in *Table 3*. In this table all the causes have been grouped according to the different categories they belong, and it can be seen that the causes obtained through the use of the "5-Why's" are also similar to some of those obtained through the brainstorming carried out for the definition of the Ishikawa diagram. The first one, related to the digitalization of the documentation, which is nowadays filled exclusively by hand, is related to the Method cause *"Mostly relying on paper"*, as well as with the Manpower one *"Low writing speed"*. The second one, which states that "fondo lineas" are not able to help "macchinistas" in many activities due to lack of specific training for the stick-pack line, can be matched with the Method causes *"Variability M/M vs. F.L."* and *"Suboptimal division of tasks"*, as well as with the Manpower causes *"Not experienced enough"* and *"Troubles when calculating"*.

The causes that are not highlighted in any colour are those that either:

- Occur very rarely, such as "Not ready in time" or "Incorrect code".
- Would require a lot of time and investment to be solved, such as all those in the Machine category.
- Are part of ongoing projects by Production, which is working on implementing a new Batch Record that would already incorporate many data by default, reducing writing time and moving closer to the complete digitalisation of the documentation.

On the other hand, all root causes that are highlighted in colour represent those that will be tackled with countermeasures to eliminate them, or at least, mitigate their impact as much as possible, thus reducing both the duration and the variability of batch changes.

- Highlighted in blue are those root causes that will be addressed with the first countermeasure, which focuses on the definition of a new procedure that would cut the duration of the batch change by dividing in a more balanced way the tasks performed by both operators.
- Highlighted in green is the root cause that will be tackled by the second countermeasure, which main objective is to simplify some activities performed during the batch change, streamlining all the process.
- Highlighted in yellow correspond all those root causes that will be dealt with the third countermeasure, which consists of a training directed specially to "fondo linea", in order to enhance their competences and support the implementation of the new procedure.
- Highlighted in red is the root cause that will be solved by the application of the fourth countermeasure, which involves negotiating with the reels suppliers in order to always have the sensor mark in the same part of the reel, therefore eliminating this non-value-adding activity of having to move the sensors.

9. COUNTERMEASURE DEVELOPMENT

Once the potential causes that impact on the duration of the batch change have been listed, a brainstorming phase has been conducted to suggest countermeasures, taking into account those that have been highlighted during the visits done in the production area, as well as those that have arisen as a result of the questions posed by the “5-Why’s” method and the Ishikawa diagram.

Once all the possible countermeasures had been listed, on 30th of December a meeting was held with Production, as well as with Continuous Improvement, to propose all the ideas that had been thought of and to be able to define, in more detailed terms, which measures would be possible to implement, which ones had already been tried, or which ones would be impossible either for budgetary, logistical, or temporal reasons.

The measures that were eventually selected to be undertaken in the following months are those that will be detailed below. They have been chosen as all participants agreed that they could have a significant impact on the duration of the batch change, they did not represent a substantial budget requirement, and they did not involve major changes to the current way of working.

9.1 Countermeasures proposed

- **Countermeasure 1**

The first countermeasure will be mainly devoted to straightening out some of the causes concerning the Method bone, in the Ishikawa diagram. Currently, each “macchinista” has his particular version of the batch change procedure, and this leads to a lot of variability in the duration of batch changes, as the division of tasks is very unequal between the two operators. Also, due to the high turnover of the “fondo linea”, many “macchinistas” prefer to perform more tasks themselves than having to explain them to the “fondo linea”.

This countermeasure is therefore about establishing a new standard procedure. In order to design this procedure, a list of the activities involved in batch changes was prepared, and with the use of Gantt charts and flowcharts, a new procedure has been defined. All the details about the design of the procedure will be explained in the following section, which is related to the implementation phase of the countermeasures.

Taking advantage of the design of a new procedure, other countermeasures were proposed to reduce the duration of some of the most critical activities. As it can be seen in *Table 1*, both activities of closing the documentation of the current batch and opening the documentation of the next batch are the most time-consuming activities. In order to shorten the time spent on these activities, Production department has decided to introduce, if possible, simultaneously with the new procedure, a new Batch Record that is much easier to fill in. Instead of having to write down all the information, some of it would be pre-written, so that the operator would only have to sign that everything is correct and handwrite much less information. This would reduce the duration of this activities but would also made them more robust to the variability of the writing speed.

For what regards the material counting activity, the way in which it is currently performed has been revised. Now, all the activity is carried out during the batch change, with the machine completely stopped, so it is an internal set-up activity. The proposition is that the "macchinista", before the end of the ongoing batch, will write all the identifying information of the materials (batch number, code, etc.) that will be used for the following batch. Then, during the batch change, it will only be necessary to count and write the quantity of units of each one of the materials that will be used for the following batch, whose information is already written. This will allow to convert part of the activity from an internal set-up, with the machine stopped, to an external set-up, with the machine running, therefore cutting the time needed for the batch change. It is not possible to externalize the whole material counting activity, as materials can only be counted when the machine is completely stopped. In the *Figure 37*, which represents the materials counting sheet for the ongoing batch *(left)*, and for the following one *(right)*, it can be seen highlighted in red the information that must be written before the end of the ongoing batch, while the quantities will be written during the batch change.

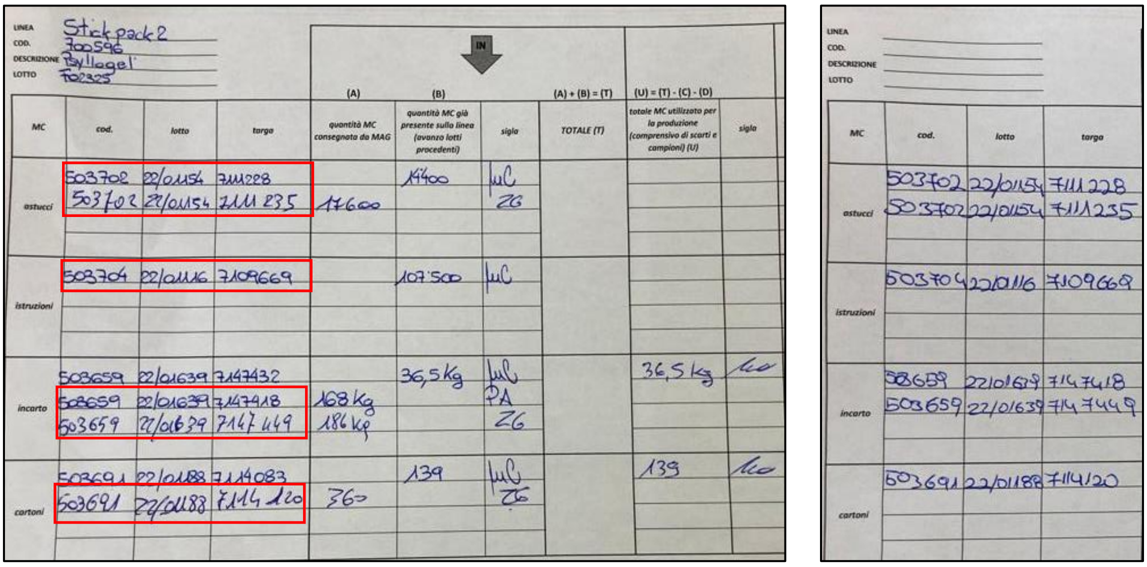

Figure 37. Information to be transferred from the current batch materials sheet (left) to the new batch materials sheet (right) before the end of the current batch

To evaluate the economic impact of this countermeasure, first it is necessary to estimate a theoretical duration of the batch change with the new procedure. For what regards the introduction of the new batch record by Production, it has not been considered for the calculation of the theoretical duration of the batch change, as it is not certain when it will be introduced. With this new procedure, as well as with the new way of performing the material counting, the batch change duration would be reduced to 56 minutes[2].

[2] The reasoning behind the theoretical batch change duration can be found in *10.1. Countermeasures applied (Countermeasure 1)*

Considering that the current average duration is approximately 72 minutes, it would mean a reduction of 16 minutes per batch change. With 311 batch changes performed during the year 2021, it would mean a decrease of 82,4 hours per year. Translated into economic terms, with the cost of 53,2 €/h, this would sum up to approximately 4.400 € annually.

As a summary, this new procedure should provide a more equitable division of tasks, so that the current bottleneck, which is the "macchinista", could be less busy and shift activities to the "fondo linea", reducing the overall batch change time. In addition, this would mean that the variability between a batch change done by two "macchinistas" or by a "macchinista" and a "fondo linea" would be reduced, as in both situations all operators would be able to perform plenty of activities. However, in order for this procedure to be fully effective, it needs to be in line with Countermeasure 3, which will be detailed below. The theoretical time could be reduced further with the implementation of the Countermeasure 2, which will also be explained below. The teams in charge of the operation of this measure will be the Continuous Improvement and the Production team.

- **Countermeasure 2**

The second countermeasure would tackle the complexity of the batch opening activities, searching to simplify them, and streamlining all the process. Out of the activities that the "macchinista" must do during the compilation of the new batch record, there is one which is significantly lengthier than the others, which is the sticks tare calculation. During the batch change, a tare calculation is performed for the new batch, the value of which will be introduced later in the sorting scale, which will separate the final products with a weight within the tolerances from the ones that are outside the tolerances. To perform this tare, it is necessary to weigh 20 sticks individually on the process scale, which is very accurate having up to 4 decimal places, and which needs a long time to stabilise on a weight, as any slight movement or air current alters the last decimal places.

Once the 20 sticks have been weighed individually, 10 empty cases are weighed simultaneously and then 10 leaflets are weighed at the same time, and the weight obtained for each component is divided by 10. Finally, the tare weight of the final product is calculated, which will be 10 sticks, one case and one leaflet (in case the product needs it).

The issue that makes it necessary to consider improving this activity is that from one batch to another, the raw materials do not change, but only the code that is printed on the sticks and the cases. This is the reason why, as the same materials are always being used, the tare weight of the previous batch and the following batch should be almost identical, thus undermining the idea of resetting the tare weight every time there is a batch change.

In order to implement this countermeasure, it will be essential to have a meeting with the Quality Assurance department in order to share both points of view and reach an agreement on how to improve the efficiency of this activity, as the existing method has been established by them. Therefore, it will be necessary to look for a common ground in which the time necessary to complete the activity can be reduced without compromising the quality of the process.

The duration of the sticks', cases', and leaflets' tare takes, on average, 9 minutes, from which 7 minutes are only the sticks tare, as it has to be done one by one, twenty times. Considering the best-case scenario, which would be eliminating the activity of the tare from the batch change and performing it only at the start of the manufacturing of the product, 9 minutes would be saved from overall duration of the batch change. Taking into account the 311 batch changes per year, this would mean a saving of 46,7 hours, which in economic terms would be around 2.500 euros per year.

This activity is also performed in the SKU change; however, it is not possible to exactly quantify economically the impact it would have. That is because, as there are many types of SKU change, for those in which the reel doesn't change it would not be necessary to do the tare of the sticks, but the tare of the cases and leaflets should be performed anyway, as those do change. Nevertheless, it would for sure have an impact on the reduction of the duration of the SKU change, but there is no data on how many SKU changes of each type are performed every year, making it impossible to estimate a theoretical economic impact.

This countermeasure should lead to a reduction in the total batch change and SKU change time but depending on the outcome of the meeting with Quality, it would be necessary to reformulate the implementation of the Countermeasure 1. It refers to the new standard procedure, and as one of the activities would be either reduced or eliminated, a new proposal or an adaptation of the existing one would be needed. The team involved in the application of this measure would be Continuous Improvement, Production and Quality.

- **Countermeasure 3**

The third countermeasure is aimed at solving the problems that generally concern the operators' formation and seeks to enable them to be more knowledgeable and perform more effectively. Currently, although most operators are highly skilled and trained to perform their tasks around the line, there are many "fondo linea" operators who undergo high rotations around the machines of the facility and are therefore unable to become specialised and confident with a particular production line. Despite trying to reduce turnover, it is still necessary for personnel requirements and to adapt production capacity to demand.

This measure is focused on providing training for both the "fondo linea" and the "macchinista", in which the new standard procedure will be introduced. The actions that are normally handled by the "fondo linea" will be refreshed, as well as those that they will have to perform with the new procedure, which includes tasks that they had never done before. The actions selected after field visits and identification of critical tasks are:

1. **Material counting:** It has been seen that many times "macchinistas" prefer doing this task as "fondo lineas" can take some more time to perform it, or even they could not know how to do it. It is very important, for being in line with the new procedure, that this activity is carried out by the "fondo linea" and done in a reliable and efficient way.

2. **Cases sampling for batch record and picking of 10 cases and leaflets for tare:** This is an activity that is now performed exclusively by the "macchinista", and which is very simple. Picking of 10 cases and leaflets for tare is just taking them from the raw materials and placing them close to the "macchinista", thus saving movements and time. Sampling cases is an activity that consists of pressing a button of the cartoning machine and it automatically produces empty cases, which have to be picked and brought to the "macchinista".
3. **New procedure introduction:** Both "macchinista" and "fondo linea" will receive formation on the purpose of the new procedure and the new division of tasks. It will be very useful to provide training on the new procedure to "macchinistas" as they will be responsible of following the new standard and helping "fondo lineas" in any doubt they might have about the activities or the overall procedure.

All in all, it is not possible to calculate the direct impact that this countermeasure can bring on the reduction of the batch change duration, as it will be used more as a supporting tool to implement the Countermeasure 1. It will be useful to communicate everything that will be done during the implementation phase, and it will also enhance the ability and pace with which the "fondo linea" perform their tasks, whether they are those that have been doing for a long time or new ones. This countermeasure will require the Continuous Improvement and Production team.

- **Countermeasure 4**

The last countermeasure is to solve the problem of the wrong reel laser mark, referring to the Material bone. Currently, when it is necessary to change the reel during a SKU change, due to a different destination than the previous one, it may happen that the next reel has the mark for the sensor on the opposite side, so additional interventions are required. Therefore, it is necessary to call the maintenance technician, who will reposition the sensors, and eventually run a few tests to check that everything is working smoothly. There is a sensor that is accessible and easy to move, while there is another one that is in a more internal part of the machine and is more challenging. It can be seen in the *Figure 38*, circled in red, the dark mark for the sensor, and circled in yellow, the external sensor, which is the one easy to reach.

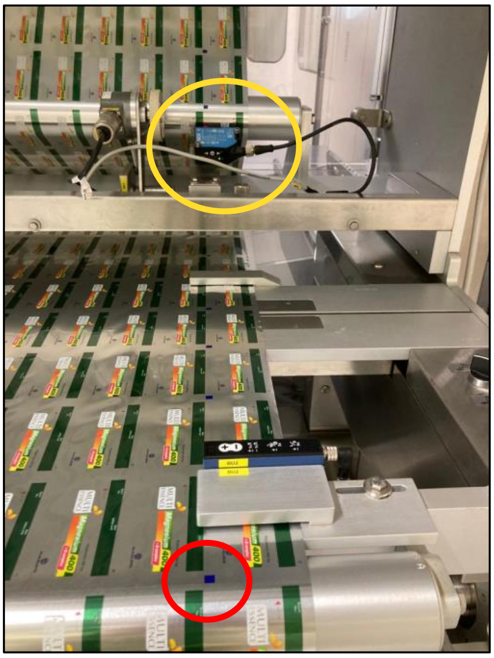

Figure 38. Position of the external sensor

The time observed once for the resolution of the incident was 17:30 minutes, of which 10 minutes were spent waiting for the technician, and 7:30 minutes for the actual resolution. However, technicians can have urgencies to attend, so the 10 minutes waiting time could grow significantly if all of the maintenance technicians are busy.

Given the impact this has on the duration of batch changes, two proposals have been considered, and it will be necessary to conduct a feasibility and economic analysis to assess which of the two proposals is superior and then implement it. Those are:

1. **Installation of a new sensor and a switch command:** This proposal suggests installing another two sensors of the same specifications in the opposite part of the actual sensors, and a switch command to select which ones will be used. With that, it will be possible, depending on the position of the reel sensor mark, to choose between left and right by just clicking a button, therefore saving the time lost in repositioning both internal and external sensors.
2. **Renegotiating with the reels' suppliers:** This other approach would consist in asking the suppliers to put the reel sensor mark always on the same side of the reel. This would mean that all the reels would have their sensor mark positioned correctly, and it would save the costs of having to buy to new sensors, the switch, and the installations costs related to manpower and production time lost.

As a result of this countermeasure, either by the first or the second approach, the time lost in changing the position of the sensors will be reduced to zero, as it will no longer be necessary to perform this action ever again. However, it is difficult to calculate the impact of this measure alone, as it is impossible to know how many times this occurs during the year, as not in all SKU changes it is necessary to change the reel, and when it is, it does not always happen. Nonetheless, the overall impact it will have on the total amount of time lost during the year will be significant. This countermeasure will be followed by the Continuous Improvement and Production team.

9.2 Prioritization matrix and summary of the countermeasures

Once all the countermeasures had been clearly defined, in order to be able to optimally schedule their implementation, a priority matrix was developed, in which the time necessary for the execution, the associated cost, and the impact it could have on both the first and second KPIs were considered as factors. This matrix can be found in *Table 4*, and the formula used to calculate the final result has been a sum of the factors, as follows.

$$TOTAL = Time + Cost + Impact\ KPI\ 1 + Impact\ KPI\ 2$$

"Time" is defined as the duration needed to apply this countermeasure, using a scale where 1 means that it takes a long time, and 10 that it can be implemented quickly. For what regards *"Cost"*, it refers to the economic investment needed to implement the countermeasure, where 1 means that is very expensive, and 10 that it has a very low cost.

The columns for *"Impact KPI 1"* and *"Impact KPI 2"* show the effect that the measures can provide to the KPIs, where 1 corresponds to a low effect, and 10 for a strong effect.

The *"Type"* column refers to the category of countermeasure they belong, which can be:

- Q.W. refers to Quick Win, which are those measures that can be implemented quickly and practically at zero cost.
- L.I. are Light Investments and are those measures that need a small investment in terms of cost or time to be implemented.
- S.I. corresponds to Strong Investments, which are those measures that require a high investment and are intended for long-term improvements.

For what regards the two KPIs considered, the first one corresponds to the first objective, which is reducing by a 10% (or 15% in the nice-to-have) the duration of the batch change, while the second one consists in reducing by a 10% (or 15% in the nice-to-have) the time spent in the SKU change.

Countermeasure		Type	Time	Cost	Impact KPI 1	Impact KPI 2	TOTAL
CM1	New procedure	L.I.	6	10	10	6	**32**
CM2	Batch opening activities	Q.W.	8	10	5	5	**28**
CM3	Training	L.I.	7	8	8	8	**31**
CM4	Wrong reel sensor mark	Q.W.	8	9	0	9	**26**

Table 4. Prioritization matrix of the countermeasures

It can be noticed that Countermeasure 1, which consists in a new standard procedure for the batch change, is the one that can bring the greatest improvement, as its effect would be very beneficial in the case of the batch change, and relatively helpful for the SKU change, as although the standard procedure is not designed for the SKU change, it can still benefit from this measure. In terms of time, it requires a certain amount of time to introduce the measure and for it to establish itself among the operators, without requiring any budget. The light investment is therefore applied in terms of time, not cost.

Countermeasure 3, related to the training of the operators, specially the "fondo linea", is the second most beneficial countermeasure, as it can boost the performance of the first one, as well as increase the competences of the operators. However, it has a certain time and cost impact, as it is necessary to stop momentarily the line to perform the training.

The Countermeasure 2 can have a mild impact on both KPIs, as it would only affect the sticks, cases, and leaflets tare activity, performed in both batch and SKU change. It has no cost associated, and it only requires a certain amount of time to prepare a meeting with Quality, and to write the new guidelines to perform the activity in a new way.

The last one in order of priority is the Countermeasure 4, that consists in correcting the wrong reel sensor mark, and would only affect the SKU change, as it is the only one in which the reel can be changed. The economic and time impacts are low, as it would only be necessary to inform the reel suppliers of the new requirements for the following orders.

10. COUNTERMEASURE IMPLEMENTATION

Following the definition of the different countermeasures that will be applied to improve the current situation, in this section, the timeline for the implementation of each one will be detailed, as well as the overall organization.

The implementation period lasted from the second week of January to the first week of March. During this period, the maximum dedication has been put into the project, considering that it is a very time-consuming task and that it has to be adapted to the production needs and the company's own temporalities.

10.1 Countermeasures applied

- **Countermeasure 1**

Countermeasure 1 main purpose is about establishing a new standard procedure, so activities can be performed in an optimized way, reducing the time needed. In order to design this procedure, a list of the activities involved in batch changes was prepared. Once it was established what constitutes a batch change, the following tasks were performed.

1. Selection of which activities are value-adding or non-value-adding.
2. Establish which activities are currently being performed by the "fondo linea" or by the "macchinista".
3. Quantify average duration of each activity to identify which of them are more time consuming or have more variability.
4. Note down which activities were performed in the same way by all operators, or which ones had variations depending on the person performing them.

Once aware of how the batch change is structured, what the current distribution of tasks is like, and which variations in the way the activity is carried out were most effective, the next step was to design what will be the new standard procedure. In order to do so, all the activities were placed in a Gantt chart.

Thanks to the Gantt chart, it is possible to visualise how all the activities are distributed over the duration of the batch change, which activities are done by each operator, which activities are done in parallel and what precedence there is between them. It is very useful because it provides an overview of all the process, making it easier to identify where they spend more or less time working.

Therefore, based on the Gantt chart for all the activities of the batch change process, it was proceeded to modify the arrangement of some of them, to shift the assignment of some of them from the "macchinista" to the "fondo linea", and to highlight all those that could be improved. In this way, considering all the constraints, which are related to the precedence of some activities over others, and to the responsibilities, as there are activities that can only be undertaken by the "macchinista", the following Gantt chart was obtained. The expected duration with this rearrangement of the activities will be of 56 minutes.

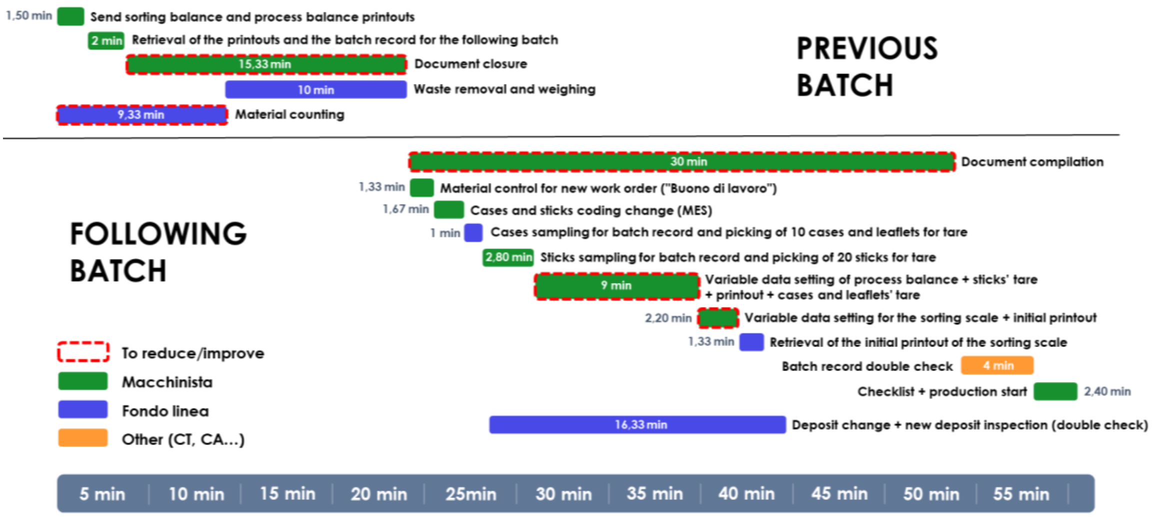

Figure 39. Gantt chart for the batch change

In the Gantt chart of *Figure 39*, the activities painted in green are the ones that will be performed by the "macchinista", which are all activities that they have been carrying out for a long time. In blue, are the activities that will be done by the "fondo linea". Some of the activities in blue are new for the "fondo lineas", as they were not performed by them previously, so they will have to be taught during the training. In yellow there is only one activity, the *Batch record double check*, as it has always been performed by a third person in order to assure that no mistakes are overlooked.

Highlighted in red are those activities that will benefit from improvements aimed at reducing their complexity and duration, among which some will be introduced in this project, and others will be left for the Production department's projects.

In order to analyse how to improve the *Document closure* and *Document compilation* activities, discussions were held with Production between the 11th and 12th of January on how they wanted to approach the improvements, and a trial version of what the new batch record should look like was provided to me. Currently, a lot of information has to be typed by hand in the batch record, so the "macchinista" has to type the same data repeatedly, wasting a lot of time. Production's proposal is that the batch records come pre-filled with certain information regarding the product, so that the "macchinista" only has to read it, check it, and sign it. Thus, it tries to reduce the complexity of the document, making them much more intuitive and easier to fill in. As this new version of batch record was first designed for another manufacturing line, the *Marchesini*, it has priority over the stick-pack line, making the implementation date for the stick-pack completely uncertain. During the course of this project, the new batch record for the stick-pack has not been introduced, although it is still in the portfolio of measures of the Production department.

For what regards the activity *Variable data setting of process balance + sticks' tare + printout + cases and leaflets' tare*, the improvements will come from Countermeasure 2, which implementation will be explained in the following section. The *Variable data setting for the sorting scale + initial printout* activity is also signalled in red as a meeting was held with Automation in order to understand if there was room for improvement.

The results of this meeting were positive, as there were possible improvements, but not feasible to be done in the duration of this project. However, in the *Future development* section it will be possible to get insights of this activity and what to do to reduce it.

The last activity to be improved, by means of the application of SMED techniques, was the *Material counting*. As previously explained, part of the internal set-up activity is to be shifted into external set-up, thus reducing the stoppage time of the machine during the batch change. Between the 13th and 21st of January, a field test was carried out in the production area, in which prior to each batch change, the "macchinistas" were required to write down the informative data of the raw materials before finishing the batch, so that the time needed to write this information was taken. The average time obtained to write down the material's data was 2,5 minutes, from an activity that originally took 9,33 minutes in average to be performed. As results were positive, this new procedure for the *Material counting* activity was adopted and included in the new batch change procedure.

Once these activities were defined, it was still needed to know the outcome of the Countermeasure 2, as depending on the decision from the meeting with Quality, the batch change procedure could be designed in different ways. For the reasons that will be explained in the implementation of the Countermeasure 2, and for Production scheduling issues, the application of the new procedure did not begin until the 28th of February. These challenges concerned the time needed to design and approve the final version of the new procedure, and the fact that in the week prior to the start of the implementation of the procedure, between the 21st and the 25th of February, there were no batch changes at a time that could be followed on-site by myself. The final version of the procedure was designed as a flowchart, in a format that could be printed and pinned on the workspace wall, so that it would be visible to all employees and would be intuitive and easy to follow for any operator. The final version of the flowchart has been drafted in Italian, for a better understanding of the operators in the manufacturing area, although the version shown in *Figure 40* has been translated into English.

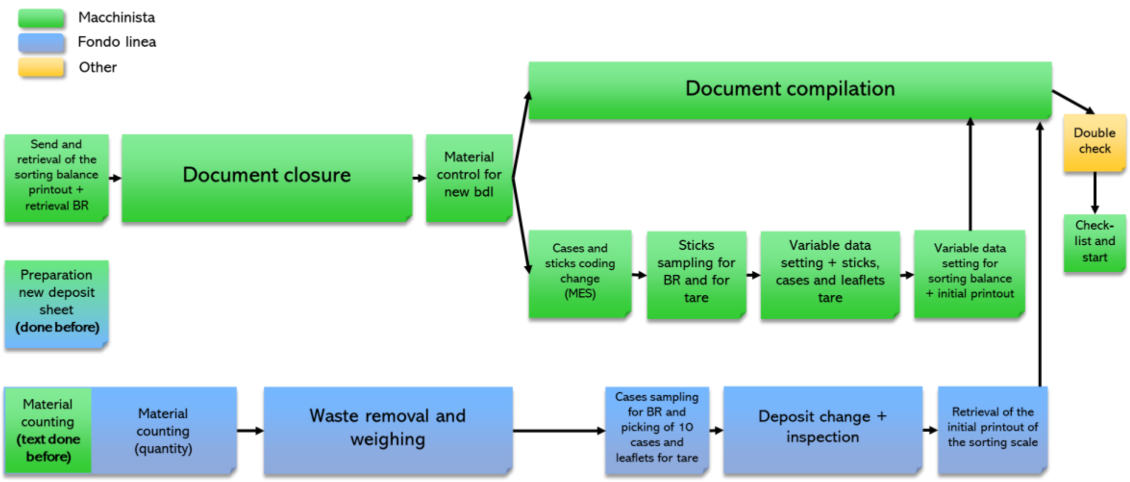

Figure 40. Flowchart of the new standard procedure for the batch change

In order to successfully implement the new procedure, the managers of the production area were informed so that everybody could work together and could act as a communication link with the operators. After having carried out the Countermeasure 3 training, in which the new procedure was presented, efforts were focused on truly applying and following the new procedure from the 28th of February to the 4th of March.

During this week of implementing the new procedure, the monitoring of the times was also started. As will be seen in the data collection for the monitoring, there were very successful weeks in which many batch changes and SKU changes could be monitored, as they were all happening on a schedule that could be followed, and other weeks that were not successful, as all batch changes were happening in the night shift or at the end of the afternoon shift. Although requested to record the start and end times of those I could not follow, in most cases unexpected issues occurred that did not allow me to obtain the duration, as the people in charge of this task were also subject to other responsibilities linked to the pace of production.

All in all, it can be concluded that the implementation of Countermeasure 1 has been successful, as it has been possible to introduce it completely and the initial results it has provided have been positive.

- **Countermeasure 2**

The main objective of the second countermeasure is to reduce the complexity of some batch and SKU opening activities, specifically, the *Variable data setting of process balance + sticks' tare + printout + cases and leaflets' tare* activity.

The steps that have been carried out for this countermeasure are as follows. First, an estimate has been made of the time spent on this activity throughout the year, and the economic impact it has on the company. For the tare of the sticks, it is necessary to run the machine with no load to obtain sticks sampling for batch record and to pick 20 sticks for tare, which takes on average 2,8 minutes, and then to calculate the tare of the sticks and the cases, which takes on average 9 minutes. While the first activity would not be removed, as it is necessary for the batch record, the second activity could be avoided with the proposed countermeasure. As explained in the Countermeasure development section, the savings that could come would add up to 46,7 hours and 2.500 € yearly.

The second step carried out has been to collect data of the sticks, cases, and leaflets tare for each batch and during batch and SKU changes in order to have data to analyse and decide if it is worth to remove this activity of it could compromise excessively the quality of the products manufactured. A responsible person in the facility has been commissioned to collect data on the tare weight of the previous and subsequent batches every time there is a batch change, so that an analysis can be carried out to support our opinion when the meeting with the quality department is held. Also there has been some data collected by me in order to have more information available, which can be found in *Table 6,* below the one collected by Production of *Table 5*.

Code	Product	Stick format (mm)	Weight 1 empty stick (g)	Weight 1 leaflet (g)	Weight 1 case (g)
400384	MULTIESSENCE	23X90	0,512	1,99	13,93
400576	VERTASE	23X90	0,518	/////	10,46
400749	MULTIESSENCE	24X90	0,513	1,99	10,64
700601	POLIMAG FAST	24X90	0,510	/////	10,39
2273	IMMUNE BOOSTER	55X120	0,692	1,96	11,43
2273	IMMUNE BOOSTER	55X120	0,683	2,00	14,00

Table 5. Summary of the data collected by Production

Code	Product	Batch	Type	Previous batch tare (g)	Following batch tare (g)	Difference (g)
700601A / 700602	POLIMAG FAST	F00065	CAMBIO LOTTO	0,5148	0,5105	0,0043
2273A	IMMUNE BOOSTER	1922424C → 1922425C	CAMBIO SKU	0,6981	0,6950	0,0031
2273A	IMMUNE BOOSTER	1922425C → 1922426C	CAMBIO SKU	0,6892	0,6844	0,0048
400454A	MAGNESIUM	F00029 → F00030	CAMBIO LOTTO	0,5071	0,5075	-0,0004
400384A	MAGNESIUM	F00032 → F00033	CAMBIO LOTTO	0,5032	0,5043	-0,0011

Table 6. Summary of the data collected by the student

Once enough data was gathered, a presentation was prepared to be shown at the meeting, in which the project would be made known to all stakeholders who were not directly involved in the project, and in which the relevance of the activity, the data collected so far, and the proposed solutions would also be presented. This presentation also included a slide with the analysis of the data, in which it was highlighted how low was the difference of the sticks' tare during the batch changes, as well as how constant it was the tare of the leaflets.

The data collection took place from the 17th to the 28th of January, while the meeting should have been scheduled for the Week 5 of 2022. However due to medical reasons of the Quality Assurance Manager, Barbara Pagani, the meeting had to be postponed to the following week. The meeting was finally held the 10th of February, after the L2 meeting, and the Continuous Improvement, Production and Quality Assurance departments were present.

During the meeting three possible solutions were discussed. The first one involved assuming always the same tare depending on the format of the sticks. That is, if the format was 23x90, using a default tare for this format, if it was 24x90, another tare for that specific format, and so on. This solution was the riskiest one, as depending on the type of reel used, there could be changes in the weight, which would never be detected. An alternative, which would be less risky but would also give an optimal result in terms of efficiency, would be to perform the tare only at the start of production, and not during batch changes or SKU changes. This would mean that only one tare would be performed, and it would be more protected from weight fluctuations.

These two solutions were discarded as they were very dangerous measures, which could compromise the quality of the final product. The last solution proposed, which was the most coherent in terms of seeking a compromise between efficiency and quality, was to maintain the taring activity, but to weigh all 20 sticks at once, instead of weighing them one by one, and then divide the total weight between the number of sticks. This proposal managed to open a negotiation path with the Quality Assurance department, so after the meeting, they decided to evaluate this countermeasure and adopt a decision on the matter.

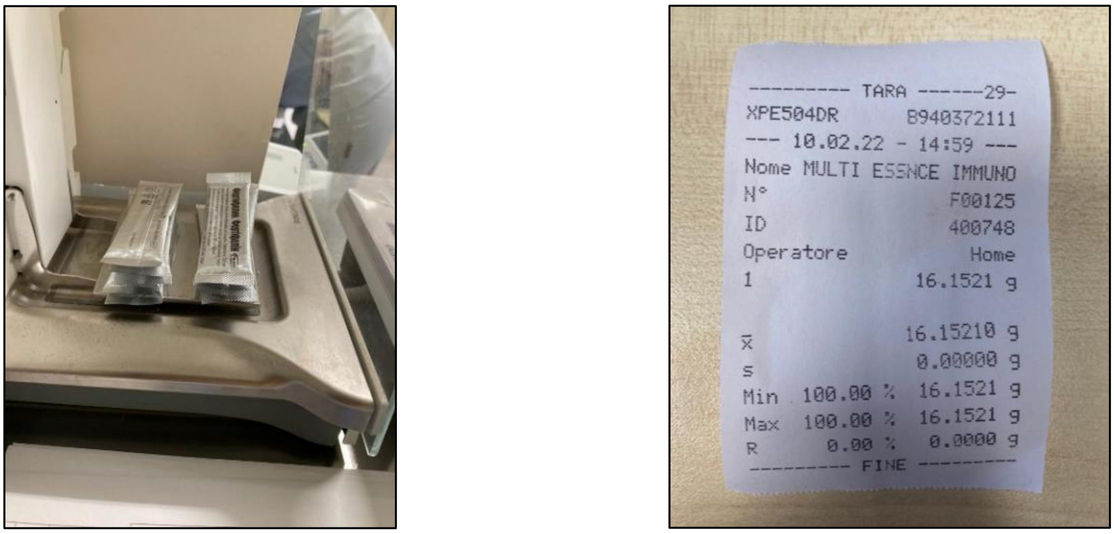

Figure 41. 10 sticks weighed at once (left) and its corresponding printout with the total weight (right)

The results of the negotiation came a week later, in the middle of Week 7, and were negative. The proposal had been rejected as, in order to comply with current GMP regulations, it was necessary to provide all the data of the tare process as it had been done so far. The concern of the Quality Assurance department was that, by mistake, the "macchinista" would include 19 or 21 sticks instead of 20, incurring a tare error that could lead to fraud if the amount of product was not the minimum stipulated, or overdosing if it was excessive. To avoid this, in the current process, the 20 sticks weighed were recorded, and the printout had to be attached to the batch record, certifying that the process had been done correctly. In contrast, by weighing all 20 at the same time, there was no way of proving that it had been correctly performed, as seen in *Figure 41 (right)*.

Thus, having been unable to find any option that could improve efficiency without compromising the existing level of quality, this measure has been discarded. However, this wait for the outcome of this measure has prevented any further progress, as this outcome would have affected the implementation of the new procedure and the training.

- **Countermeasure 3**

The purpose of this countermeasure is to act as a support tool for the implementation of the new procedure, providing the necessary competences to selected operators so that they can be more helpful and distribute the tasks evenly during both batch and SKU changes.

The first step in implementing this measure has been to identify which activities are most critical for the "fondo linea" operators, either because they are too complex or because they have never performed them because they are the responsibility of the "macchinista". These activities are, as explained in the Countermeasure development section, the *Material counting* and the *Cases sampling for batch record and picking of 10 cases and leaflets for tare*, as well as the introduction of the new procedure. This selection of the activities was done between the 11th and the 12th of January, and the planned deployment of the training should have been between the 31st of January and the 8th of February.

The time in between was dedicated to the formal drafting of the procedures to be taught in the training. Thus, the first step was to follow these activities closely in order to note down, from an external perspective, all those details that could be complex to explain, to the extent that the activity's execution was thoroughly understood. Once the activity was clear and pictures were taken, an operational instruction was drafted.

In these operational instructions, all the necessary steps that must be followed in order to perform a certain activity are explained. In this way, the training handbook included, with a high level of detail, the activities that would be taught in the subsequent training. The new batch change procedure was also included in the operational instruction, so that all documentation would be compliant and there would be no doubts about the process.

Due to the postponement of the decision for Countermeasure 2, the implementation of this countermeasure had to be delayed, which finally started on the 21st of February and lasted until the 25th of February. During that week, for each production shift, the operators were brought together for a brief training. On these days, it was identified which "fondo linea" had not yet been trained, and they were explained the new procedure that would be introduced and taught how to perform the tasks that would be their responsibility. With the "macchinistas" it was only necessary to explain the new procedure to them. To ensure that the training was well received, they were asked to sign the operational instruction.

To summarize, it is safe to conclude that the implementation of Countermeasure 3 has been successful, as all operator agreed that it was important to provide this help, and during the training it was seen that new activities were being easily understood by all operators, and with practice, they would be achieving faster times to complete them.

- **Countermeasure 4**

This last countermeasure is focused in eliminating one of the causes of a lengthy SKU change, which is *Wrong reel sensor mark*. When the previous and following reels have the sensor mark in opposite parts, it is necessary to change the position of the sensors, which are shown in *Figure 42*. This is a lengthy activity that does not add any value for the customer, and it can be easily removed as it will be shown.

Figure 42. External sensor reading a contrast mark

The first stepped that was carried out, between the 17th and 18th of January, was to preparate an estimate of the budget necessary to implement any of the two options available to solve this problem.

First option was to install another two sensors (external and internal) plus a switch button, so operators could switch from one sensor to the other by just pressing one button, therefore removing the time needed to move all the sensors of the machinery. An estimated cost of this installation was made by considering the acquisition of 2 new sensors and a switch, which was approximately 890 €. This figure was obtained by benchmarking within the same brand sensors similar to the ones already available. Installation costs and costs associated to the stoppage of the line were not considered, as it was not possible to know how much time it would be needed to perform this operation.

The second option was to negotiate with the reel suppliers to inform them that it is very important to always produce the reels with the contrast mark always on the same side. Although this option seemed to be the most complex to achieve, due to the fact of having to deal with several different stakeholders, in the end it was the decision that was taken. As a result, once the problem was exposed, Production immediately adopted the necessary measures, contacted all the suppliers, and requested that the reels always had the contrast mark on the right-hand side of the reels. All customers were notified of the modification to make them fully aware of the new measure that was going to be adopted.

After the contact with the suppliers, it was agreed to continue using the reels still present in the warehouse, which were prior to the modification, until they ran out. The plan was to be done with the old reels by mid-February. From that point on, it is an event that will not repeat itself, so the countermeasure has been successfully implemented.

10.2 Overall implementation plan

The entire implementation period has lasted from the 11th of January, when the company resumed activity after the Christmas break, until the 4th of March, when the introduction of the new standard procedure for the batch change was completed. The whole timeframe can be found in the following Gantt chart in *Figure 43*, in which the most significant activities of each countermeasure have been included.

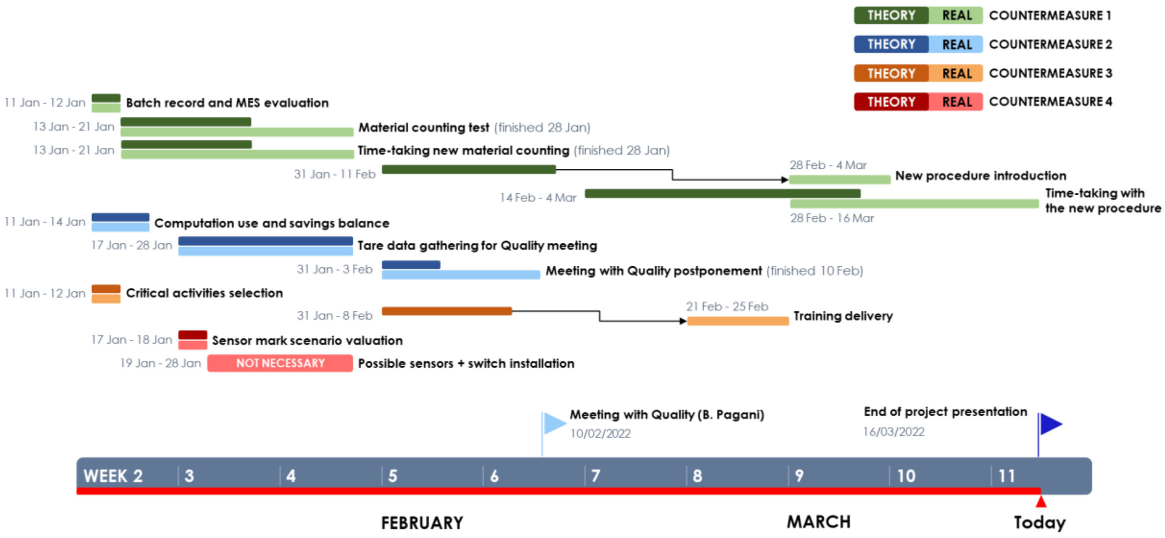

Figure 43. Gantt chart for the overall implementation of the countermeasures

In darker colours, the theoretical duration of the activities is displayed, with their start and ending dates, while in lighter colours, the actual length of the activities can be seen. In some cases, the theoretical duration matches perfectly with the real one, when it has been on schedule, but there are others in which it does not. In those cases where it does not, there are two situations. The first is that the activity has started when it was supposed to, but the time devoted to it has been extended because it has coincided with weeks with not much activity. The other situation is when the activity has directly started after the scheduled date, due to specific events such as those already detailed in the Countermeasure implementation section. The activity corresponding with the sensors and switch installation has not been necessary, however it was planned in case it was needed.

The time-taking for the new procedure, which will be explained more thoroughly in the Monitoring chapter, has started the 28th of February, along with the introduction of the new standard procedure for the batch change, and has lasted until the 16th of March. The ending of the monitoring phase corresponds with the last day in the company, in which the end of project meeting was held with the presence of all the stakeholders involved.

11. MONITORING

Simultaneously to the introduction of the new standard procedure for the batch change, the monitoring of the times for both the batch change and the SKU change was launched. The period in which the time monitoring was conducted was therefore between the 28th of February and the 16th of March, when the very last measures were taken. Although initially the goal was to be able to monitor for a longer time period, to achieve more accurate and reliable results, it had to be shortened due to the reported difficulties encountered during implementation. Nevertheless, in the 3 weeks of monitoring, it was possible to see several events, thus obtaining sufficient data.

This is one of the most important stages of the project, since it can determine if the project has had an important impact on the original problem, and if it has been possible to reach an improvement from the initial scenario. Thus, it can certify that the proposed targets have been reached, making it a success, or it can provide the keys to find the direction in which to keep improving if the goals are not met.

In order to conduct the monitoring, it was performed in a very similar way to the data gathering carried out to quantify the initial scenario. Thus, the managers of the manufacturing area were made aware of the tasks to be done, and they put their resources in helping me to do it. This included informing the operators that I was going to be collecting time data, and also giving me a daily schedule of the batch and SKU changes that were going to occur, giving me a few hours' notice to ensure I would not miss them.

Whenever there was a batch or SKU change, it was required to head down to the manufacturing area about half an hour in advance to ensure that the new procedure was being followed, especially for those activities in which part of the activity had been transferred from internal set-up to external set-up.

Once the batch change or SKU change began, the start and end time of each activity was noted, as had been done previously. In this way, it is possible to determine the durations of each activity, and at the same time, it allows to see how the activities overlap in order to better understand the process. Since with the new procedure some of the activities were performed in a different order, and some activities were grouped together, the durations were taken using a template adapted to the new working procedure.

At the conclusion of the monitoring period, it was possible to follow 6 batch changes and 5 SKU changes, which will be detailed in the following subsections. These monitoring operations were conducted on both stick-pack lines, 2 and 3, and in different shifts and with various combinations of operators, whether it was two “macchinistas” or one “macchinista” and one “fondo linea”. It has been done in this way in order to have as much variability as possible, to resemble the real working scenario.

11.1 Batch change monitoring

- **Detailed time taking broken down by activity and total duration**

For the batch change monitoring, the times were measured following the template in accordance with the new procedure, broken down by activity, as shown in *Table 7*.

	ACTIVITIES	AVERAGE (min) or COMPLIANCE (%)
Previous batch	Preparation of the deposit sheet	**DONE 100%**
	Send sorting balance and process balance printouts + retrieval of the printouts and batch record	**2,4**
	Document closure	**16**
	Material counting (written part)	**DONE 50%**
	Material counting (quantities)	**14,67**
	Waste removal and weighing	**5,33**
Following batch	Material control for new work order ("Buono di lavoro")	**1,4**
	Sticks' and cases' coding change (MES)	**1**
	Cases sampling for batch record and picking of 10 cases and leaflets for tare	**1,6**
	Sticks sampling for batch record and picking of 20 sticks for tare	**2,2**
	Variable data setting of process balance + sticks' tare + printout	**4,6**
	Cases and leaflets' tare	**1,8**
	Document compilation	**26,8**
	Variable data setting for the sorting scale + initial printout	**2,6**
	Retrieval of the initial printout of the sorting scale	**1,2**
	Deposit change + new deposit inspection (double check)	**14**
	Batch record double check	**4**
	Checklist + production start	**1,5**

Table 7. Average times and compliance collected for the final situation of the batch change

As displayed in *Table 7*, while the preparation of the deposit sheet is always done, the new measure of writing the informative data of the raw materials prior to the end of the current batch has been done only 50% of the time.

However, looking at the individual data for each batch change observation, the average time spent during the material count drops when the measure is applied. In cases where the raw material information is not written prior to the end of the batch, the average time for the material count is 15,67 minutes, whereas when the specified procedure is rigorously followed, the average drops to 12,67 minutes. This reduction corresponds to approximately the 3 minutes that can be moved from internal set-up to external set-up.

If compared with the previous scenario, the time needed for the material counting has increased, due to the fact that before it was performed by highly skilled “macchinistas”, while now is being performed by “fondo lineas”. As it is a new activity for them, they are taking more time, but with practice, they will be reduced to the original duration or less.

Once the breakdown of the activities of the batch change has been analysed, *Table 8* provides the total durations of all the 6 measurements that were taken.

Day	Code	Product	Batch	Stick	Duration (min)
28/02/2022	700404A	MLV STICKS	F00326 → F00327	2	**60**
01/03/2022	400647A	MULTI ESSENCE	F00295 → F00296	3	**57**
02/03/2022	400647A	MULTI ESSENCE	F00296 → F00297	3	**54**
03/03/2022	400647A → 400455A	MAGNESIUM	F00297 → F00329	3	**71**
04/03/2022	400455A → 400647A	MULTI ESSENCE	F00329 → F00330	3	**52**
15/03/2022	700601	POLIMAG FAST	F00532 → F00533	3	**54**

Table 8. Total duration of the batch changes followed

The average duration has dropped significantly to 58 minutes, with a range of 19 minutes, which is also much lower than originally. Most of the batch changes have fallen between 52 and 60 minutes, with only one exception at 71 minutes. For this data, as in the initial situation, only the time spent on the batch change is considered. If there are pauses or technical problems not related to the batch change, these have been deducted from the total time.

These results can be seen in *Figure 44*, which, following the same approach as in the initial situation, reveals how the times fluctuate in comparison with their average. All the observations are very close to the average, in contrast to the initial situation.

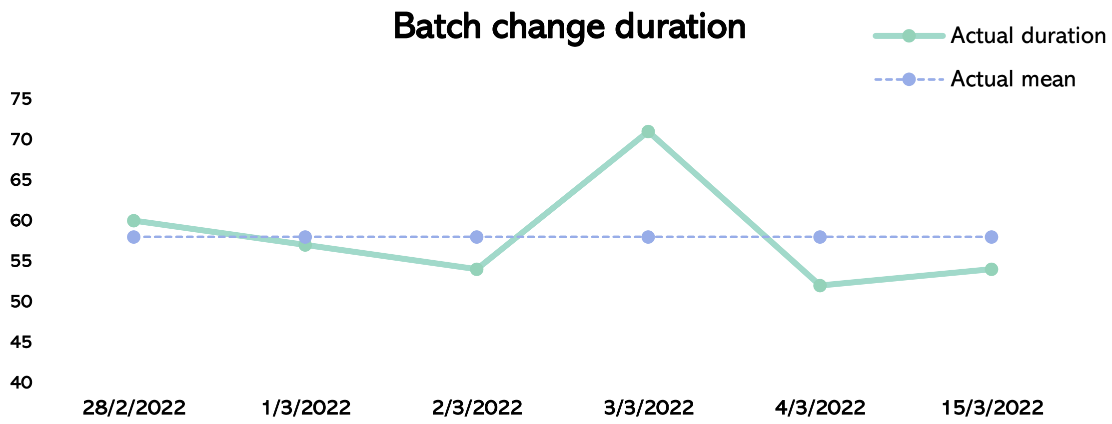

Figure 44. Time series plot of the data collected for the final situation of the batch change

- **Target achievement and comparison between initial and final scenario**

Considering the results obtained in the monitoring, it is very important to make a comparison with the targets set at the beginning of the project, to see if they have been achieved and to what extent. In the case of the batch change, the must-have objective called for a 10% reduction in the time spent on batch change within March, and the nice-to-have objective required a 15% reduction. Translated into minutes, this implied going from around 72 minutes to 64,8 minutes for the must-have objective, and to 61,2 minutes for the nice-to-have one.

The outcome achieved has been that the batch change time has been reduced to an average of 58 minutes, far exceeding the targets set, both for the must-have and the nice-to-have. Thus, the reduction has been approximately a 19%, along with the decrease in variability, which has dropped from around 63 minutes to 19 minutes, less than a third of the original.

Translated into economic terms, this reduction of 14 minutes on average in batch changes, taking into account that during 2021 there have been 311 batch changes, represents an annual saving of about 72 hours. Considering the cost of €53,2 €/hour, already mentioned in previous sections, this results in an annual saving of roughly €3,800.

In the graphic in *Figure 45*, it is possible to appreciate this decrease in both average time and variability between batch changes. The same scaling has been used for the vertical axis as in the original scenario, in order to provide a truthful comparison without distorting the shape of the graph. Thus, it can be seen that the average line has descended, as well as that the new observations fit into a much more contained space.

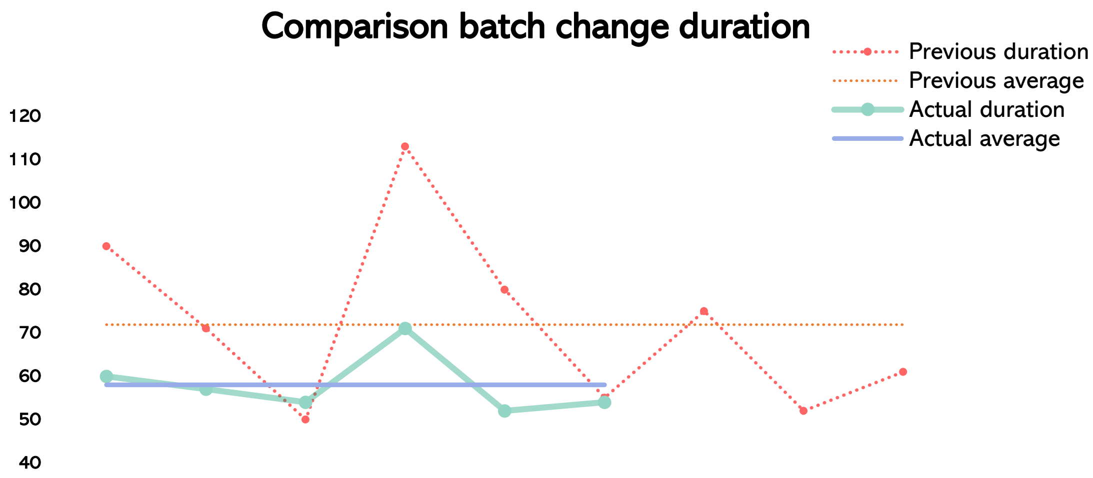

Figure 45. Comparison between the original and final scenario for the batch change

11.2 SKU change monitoring

- **Detailed time taking broken down by activity and total duration**

In the case of the SKU change, the times were monitored following the template in accordance with the activities that conform it, as shown in *Table 9*.

As seen in *Table 9,* the percentage of compliance with the measure on streamlining the material counting is still less than 100%, being in this case 60%. Although it is higher than in the batch change situation, it is still important to insist that it continues to be done because it reduces activities during machine stoppage and also facilitates the work of the "fondo linea" by stating which materials are to be used in the next batch.

For the cases in which this improvement in the counting of materials has not been performed, the average time spent on these has been 14,5 minutes, while in the cases in which it has been done, it has been 10,33 minutes, with a more significant gap than in the case of the batch change.

Time needed for the completion of the material counting is still higher than in the initial situation, for the same reason as with the batch change. As it is now performed by "fondo linea", which did not have any prior experience on this activity, they need more time to get used to the procedure of the activity. With time and experience, they will for sure reach the same time as when it was performed by the "macchinista".

It can be also observed that the time needed for the compilation and the closure of the documentation is shorter than with the batch change, as one of the main characteristics of the SKU changes relies on the fact that the documents that must be filled are simpler.

	ACTIVITIES	AVERAGE (min) or COMPLIANCE (%)
Previous SKU	Send sorting balance and process balance printouts + retrieval of the printouts and batch record	**3,2**
	Document closure	**12,8**
	Material counting (written part)	**DONE 60%**
	Material counting (quantities)	**12**
	Waste removal and weighing	**5**
Following SKU	Material control for new work order ("Buono di lavoro")	**1,6**
	Sticks' and cases' coding change (MES)	**1,2**
	Cases' change	**7,8**
	Reel's change	**-**
	Cases sampling for batch record and picking of 10 cases and leaflets for tare	**4**
	Sticks sampling for batch record and picking of 20 sticks for tare	**2,2**
	Variable data setting of process balance + sticks' tare + printout	**5,6**
	Cases and leaflets' tare	**2**
	Document compilation	**21,6**
	Variable data setting for the sorting scale + initial printout	**2,2**
	Retrieval of the initial printout of the sorting scale	**1,2**
	Batch record double check	**3**
	Checklist + production start	**1**

Table 9. Average times and compliance collected for the final situation of the SKU change

Once the breakdown of the activities of the SKU change has been analysed, *Table 10* provides the total durations of all the 5 measurements that were taken. As all the measures regarding the SKU change were finished with the application of the training, and not with the new standard procedure (which is only for batch change), monitoring could start one week before. Therefore, it went from the 22nd of February to the 16th of March.

Day	Code	Product	Batch	Stick	Duration (min)
22/02/2022	2273A	IMMUNE BOOSTER	1922452D	2	**40**
24/02/2022	700502A	FERMENTIFAST	F001207	2	**44**
02/03/2022	173K	MULTIBIOTIC	1922460D	2	**44**
16/03/2022	400776 → 400755	FEROZOMAL	F02040	2	**42**
16/03/2022	173K	MULTIBIOTIC	1922475D	3	**39**

Table 10. Total duration of the SKU changes followed

The average duration of the activity has been reduced to 41,8 minutes, with a narrow range of only 5 minutes. As with the initial situation, and as with the batch change, only the time dedicated to the SKU change was considered, and the time spent on scheduled breaks or technical interventions unrelated to the SKU change was deducted.

These results can be seen in *Figure 46*, which, following the same approach as in the initial situation, reveals how the times fluctuate in comparison with their average. All the observations are extremely close to the average, improving the initial situation.

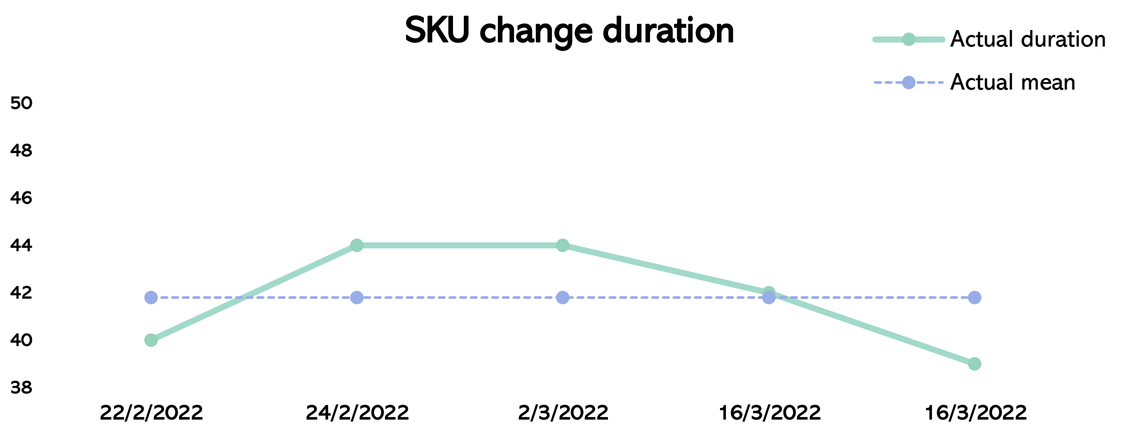

Figure 46. Time series plot of the data collected for the final situation of the SKU change

- **Target achievement and comparison between initial and final scenario**

Considering the results obtained in the monitoring, it was needed to compare them with the targets set at the beginning of the project, to determine if they have been achieved and to what extent. For the SKU change, the must-have objective called for a 10% reduction in the time spent on SKU change within March, and the nice-to-have objective required a 15% reduction. These objectives implied going from around 46,4 minutes to 41,8 minutes for the must-have objective, and to 39,4 minutes for the nice-to-have one.

The outcome achieved with the countermeasures has been that the SKU time has been reduced to an average of 41,8 minutes, which is exactly the must-have target proposed at the beginning of the project. What has been also remarkable has been the reduction of the variability, from a range of 14 minutes to an astonishing 5 minutes of range, nearly one third of the original one.

To understand the economic impact of this reduction of 4,6 minutes per SKU change, it is necessary to consider that there have been 213 SKU changes during the year 2021. This amounts to a total of 16,5 hours per year saved with the measures. Adding the cost of 53,2 €/hour, this reduction in the SKU change duration adds up to 875 € of yearly savings.

The *Figure 47* allows to appreciate the decrease in both the average time and variability between SKU changes. The vertical axis has been built with the same scaling as the original scenario, to provide a truthful comparison maintaining the same shape of the graph. Therefore, it can be seen that the average line has gone down, as well as that the new observations fit into a narrower space.

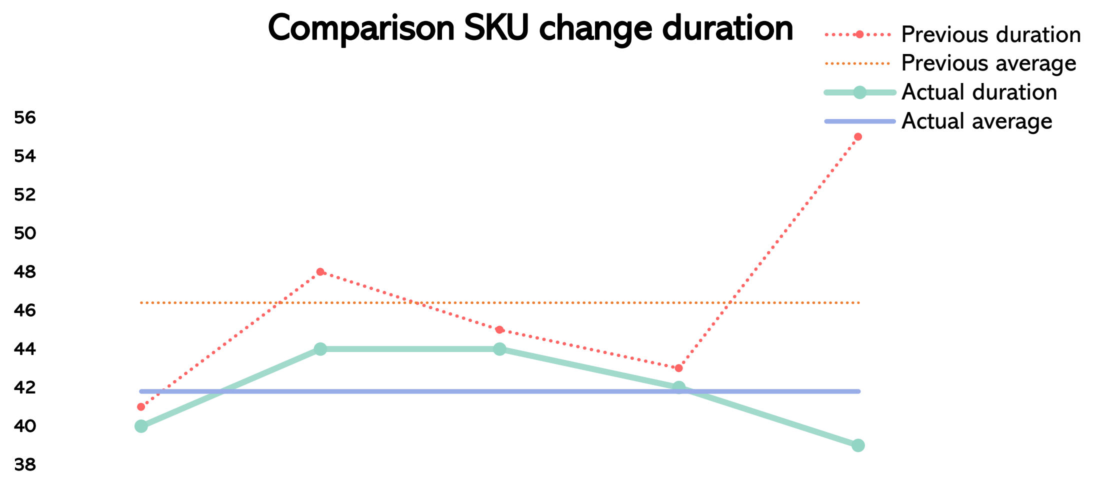

Figure 47. Comparison between the original and final scenario for the SKU change

11.3 Overall Equipment Efficiency analysis

While both of the proposed objectives for the batch change and the SKU change have been achieved, it is also necessary to check whether focusing the project efforts on improving them has yielded positive results in solving the main problem. The key problem, which was a concern for the company, was the low OEE of its stick-pack lines. Research showed that a large part of the losses was caused by batch changes, so the project was aimed at improving them to see how this would increase the OEE of the lines.

In this section, using the daily update dashboards that the company works with, it will be shown how the OEE of the stick-pack 2 and 3 lines has behaved in the weeks prior to the implementation, and during the weeks that followed, as appears in *Figures 48* and *49*.

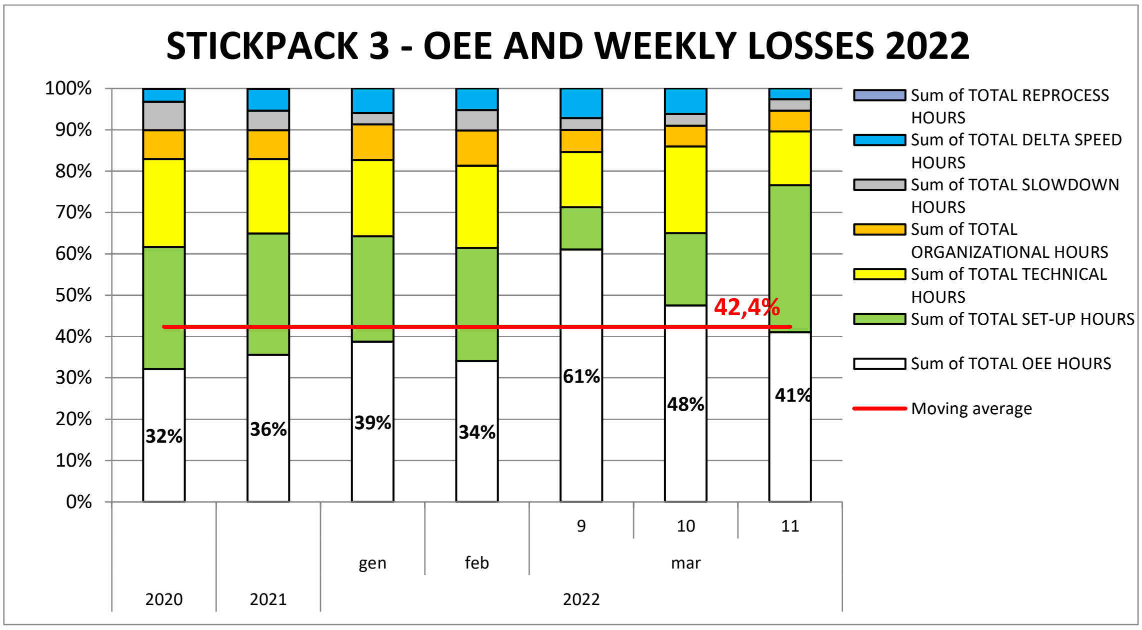

Figure 48. OEE dashboard for stick-pack 3 line

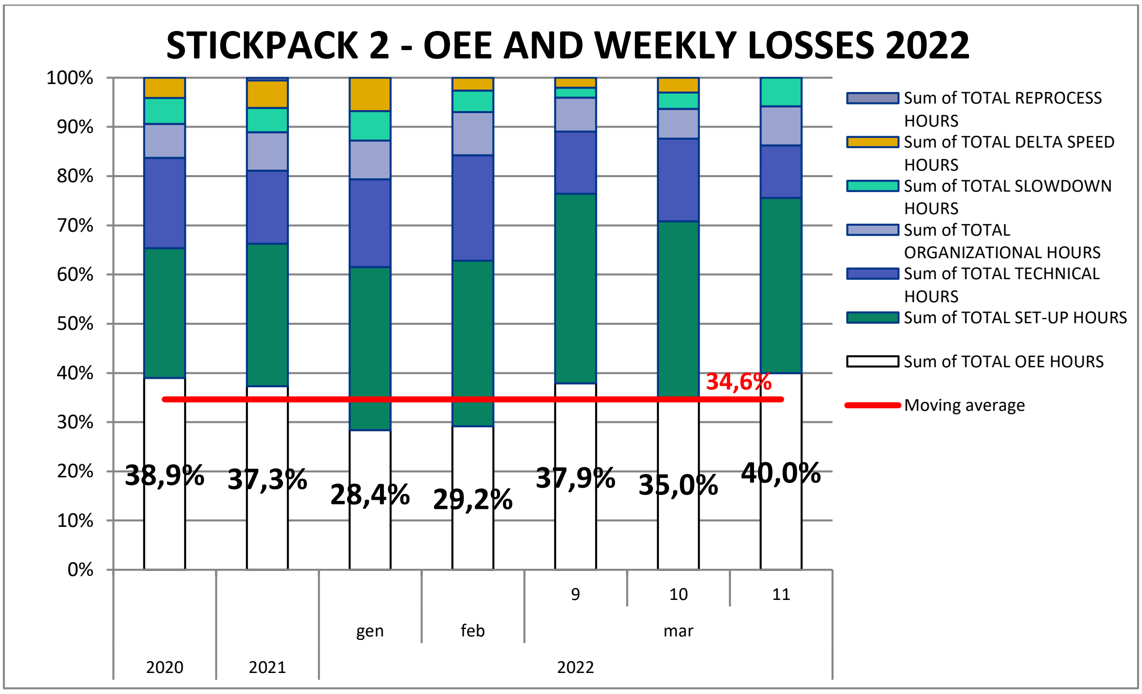

Figure 49. OEE dashboard for stick-pack 2 line

As it can be seen in both *Figures 48* and *49*, all the losses have been plotted so that the OEE for the stick-pack 3 and stick-pack 2 lines, respectively, is visible. Thus, during the last weeks of presence in the company, after the implementation of the standard procedure in week 9, the OEE of both lines 3 and 2 has been higher than in the previous months. As line 2 typically performs more SKU changes, the improvement is slightly lower than that of line 3, which typically performs batch changes.

12. STANDARDIZATION AND FUTURE DEVELOPMENT

12.1 Standardization of the new situation

To be able to keep control over the measures that have been implemented, and thus to avoid reverting back to the original situation over time, it is necessary to establish a standard or continuous monitoring to be able to see when the situation is deviating and to be able to promptly react to it.

This continuous monitoring can only take place for the batch change, because it is the only one that is recorded in the database as such. If SKU changes are also included in the dataset in the future, they can also be continuously monitored.

Thus, for the batch change, a control chart has been made with the observations that have been collected during the monitoring phase in order to understand what the limits for the duration of a batch change should be, either upper or lower limits. To do so, with the software *Minitab*, the control chart of *Figure 50* has been created.

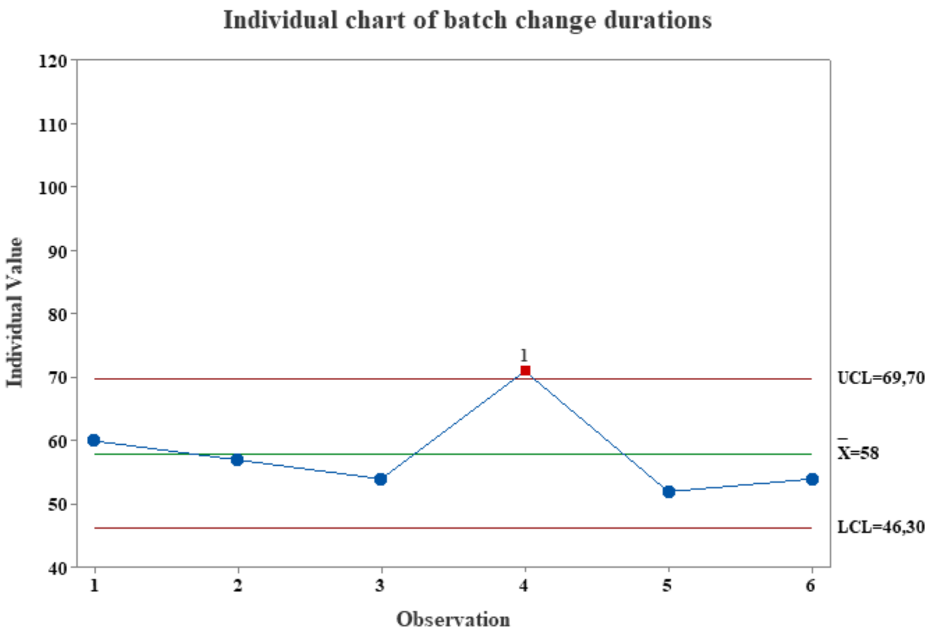

Figure 50. Control chart with the limits for the durations of the batch changes

For the creation of this control chart, all the observations collected have been used, and a K of 1,5 has been established to define the limits of the control chart. Although the typical value for K is close to 3, the limits would have been too narrow for a process that can have more variability than that, due to the great importance of the human factor. The limits with K equal to 3 would have been useless as most of the observations would have fallen in the out-of-control zone for natural variability causes.

With these limits adapted to the characteristics of the process, the in-control zone is placed between 46,3 and 69,7 minutes. To simplify and make these numbers more user-friendly, the control zone can be considered to lie between 46 and 70 minutes. Any observation that falls between the limits will be considered in-control, and anything above or below them, will be out-of-control.

For those observations in-control it is not necessary to perform any further action as they have a duration similar to what it is supposed to be. However, for those out-of-control, it will be necessary to analyse what has caused that batch change to go beyond the limits. The causes will have to be asked and collected, and during time, those that repeat more often will emerge, thus giving room for improvement by focusing on eliminating them.

Although these control limits are designed especially for the actual situation, they will have to be revised every time there are improvements performed on the line. One of the projects Production is now focusing on, the introduction of a new batch record to reduce the time spent in writing documentation to open and close the batch, will for sure be beneficial to reduce the total duration of the batch change. However, it will require to re-design the control chart limits as the in-control conditions will be completely different.

As the input data for this continuous monitoring will come from the dataset which is filled with the durations handed by the workers, it is important to check if those are trustworthy, as they now make a rough estimate on the time spent to perform the activity. To do so, the data collected in presence was compared with the same events registered in the dataset, and the results are shown in *Table 11*.

Day	**Batch**	**Stick**	**Duration collected (min)**	**Duration registered (min)**
28/02/2022	F00326 → F00327	2	**60**	**60**
01/03/2022	F00295 → F00296	3	**57**	**50**
02/03/2022	F00296 → F00297	3	**54**	**55**
03/03/2022	F00297 → F00329	3	**71**	**60**
04/03/2022	F00329 → F00330	3	**52**	**50**
15/03/2022	F00532 → F00533	3	**54**	**60**

Table 11. Comparison between the collected and the registered durations

As it can be seen most of the observations are very close, but they lack precision as operators only write durations as multiples of 5, without controlling the exact time dedicated. However, it is safe to say that, without considering the exception of the fourth observation, the data present in the dataset could be a reliable source to control the situation and perform further investigations when it goes beyond the established limits.

12.2 Next steps for future development

- **Integration of process scale and sorting scale to the MES system**

Due to the failed implementation of the second countermeasure, which was intended to improve the tare activities of sticks, cases and leaflets, another solution has been elaborated and proposed that could be very useful to improve the batch change time, as well as the SKU change. This solution includes the integration of both the process scale and the sorting scale into the MES system, taking a step further in the digitalisation of the whole process. Currently the system is as in *Figure 51 (left)*, and what is proposed is to upgrade it to the one in *Figure 51 (right)*.

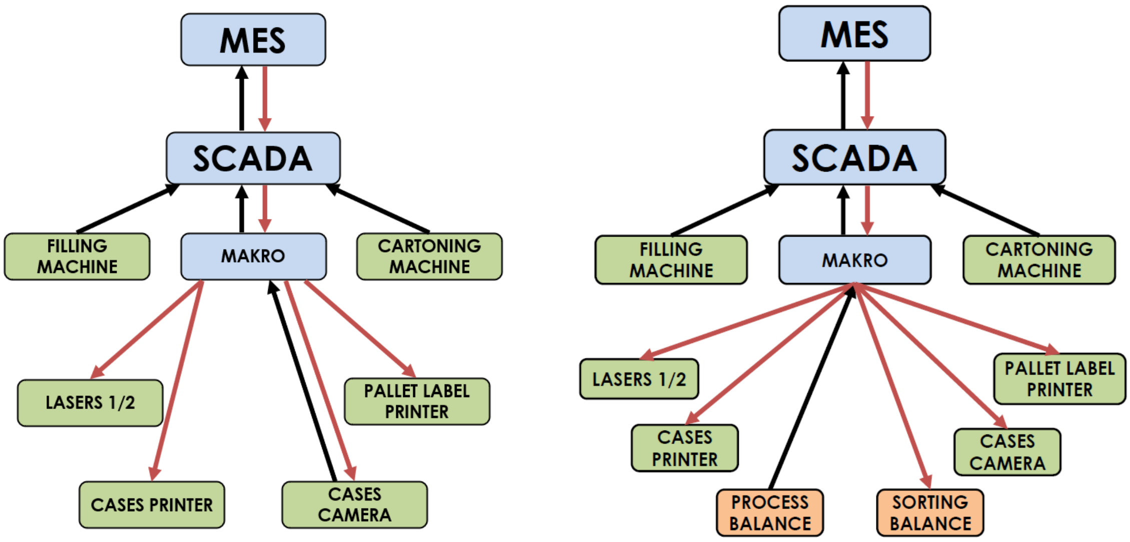

Figure 51. Comparison between the current system (left) and the proposed one (right)

The process would be as follows:

1. The operator will perform the tare as always, and each stick weighed will be registered in the system.
2. Once all 20 sticks have been weighed, the MES system will perform all the calculations. The printout will also be done to be attached to the documentation.
3. The tare calculated by the MES system will be sent directly to the sorting balance.

With this system therefore, it is possible to cut the *Variable data setting of process balance + sticks' tare + printout + cases and leaflets' tare* by 2 minutes, which is the time that the “macchinista” spends writing and performing the calculations for the tare. The activities *Variable data setting for the sorting scale + initial printout* and *Retrieval of the initial printout of the sorting scale* would be completely removed, as it would no longer be necessary to move to the sorting balance to introduce the tare. This would help in removing possible human error and reducing by 3 more minutes the batch change.

This measure, which would provide a theoretical reduction of 5 minutes per batch change, would have an effect of nearly 26 hours saved per year, which equals to nearly 1.400 € per year. It has been discussed its feasibility with the Automation team, responsible of the MES system, and the outcome has been very positive.

Although Production holds the position that the scales are ready to be integrated into the MES, it will be necessary to check the suitability of the balances present on the line and, if they are unsuitable, to assess whether upgrading the existing ones or purchasing new ones would be a cost-effective operation.

- **New standard procedure for the SKU change**

As with the batch change, a standard procedure has also been designed for the SKU change, which would help to streamline the change procedure in order to improve efficiency and reduce variability. The SKU change, despite having a documentation that is quicker to complete, is a more complex activity, as the materials must be changed. Although replacing the cases is easy and does not take long, it can also happen that the reel also needs to be changed, which is where the activity becomes more time-consuming. For these reasons, this procedure has not been implemented for the SKU change, as the complexity of its application is higher and would have required more time than the project could have taken.

Nevertheless, the procedure that has been prepared and has been left ready to be implemented, on behalf of the company, will be presented in this document. For the SKU change there are two main scenarios. The first one does not require to change the reel, only replaces the cases, and the second one requires performing a reel change, regardless of whether the cases need to be changed or not. The Gantt diagram prepared for the first scenario can be found in *Figure 52*, while *Figure 53* will show the diagram for the second one. In both diagrams it is possible to see the precedence of all the activities and also to appreciate in which moments there is an overlap of activities.

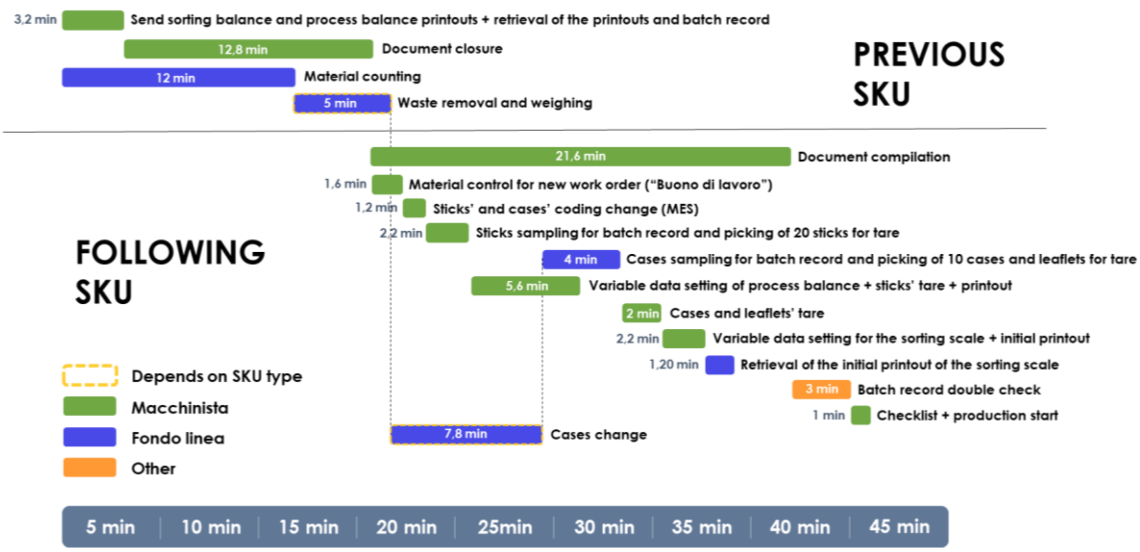

Figure 52. Gantt chart for the first scenario of the SKU change

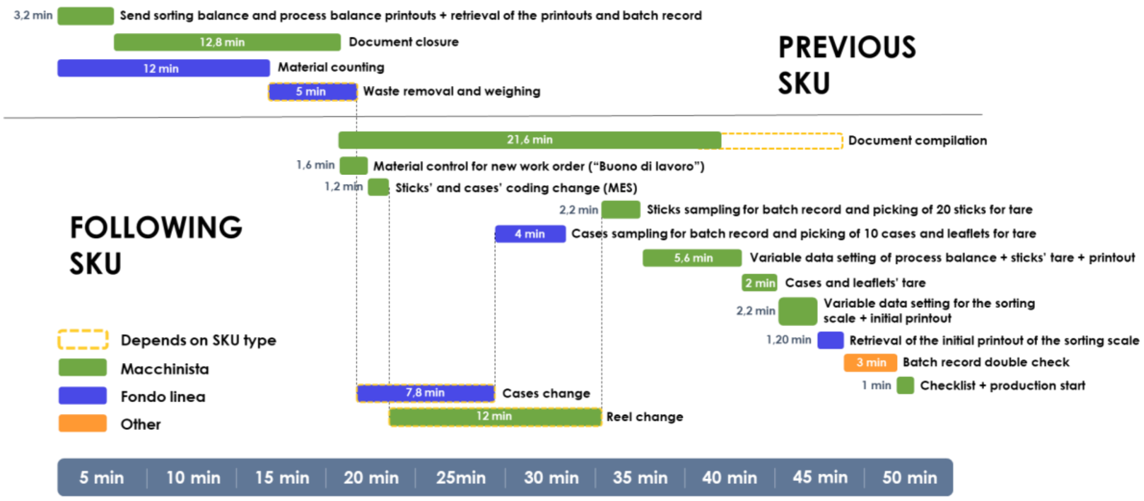

Figure 53. Gantt chart for the second scenario of the SKU change

For the *Figure 52*, the one that corresponds to the scenario where only the cases need to be changed, the expected duration of the SKU change just be, on average, around 41,6 minutes. In this, the waste removal has been highlighted in yellow as sometimes the sticks produced that are still on the line are not removed, as if the coding does not change, they can be introduced in the new cases for the following SKU. However, if the coding does change, it will be necessary to remove them from the line. The *Cases change* activity has also been highlighted in yellow as it could happen that they did not change, although it is not the most usual.

For what regards the *Figure 53*, the reel change has been added to the whole procedure. It is mandatory to change the reel before the *Sticks sampling for batch record and picking of 20 sticks for tare* activity, as it must be done with the reel that will be used for production. As the reel change can only be performed by the "macchinista", he must stop the *Document compilation* activity, elongating the whole activity as shown in yellow. Once the new reel is in place, the procedure follows as usual. During the reel change, the "fondo linea" must work in parallel performing the *Cases change* and the *Cases sampling for batch record and picking of 10 cases and leaflets for tare* activities. Thus, having this extra activity to carry out increases the theoretical duration to 48 minutes.

Although the overall reduction in time is not very high, it does allow establishing a standard for the activity in order to reduce its variability, and to be able to optimally plan the rest of the activities that surround it. If this measure can be carried out in combination with training of the operators, it will be possible to reduce times even further, as they will be more experienced and will have greater capabilities to carry out their activities in a faster and more dynamic way.

13. CONCLUSION

During the course of this project, the A3 methodology has been rigorously followed in order to achieve an improvement from the initial situation to the actual scenario. It has been very helpful to provide the working guidelines with which to direct the whole project, in order to provide a scientific approach to solve one of the company's concerns.

For what regards one of the stick-pack packaging line main issues, the time lost in the batch change, it has been successfully approached, reaching an important improvement that has increased the efficiency of all the line. Batch changes, as demonstrated during the data analysis of the initial situation, are one of the most impactful activities during the year, as they occur with a high frequency and require a great investment of time. The first objective, which was divided into must-have and nice-to-have targets, has been achieved beyond the expected goal. Therefore, the average for the batch change has been reduced from 72 minutes, into 58 minutes, and most importantly, the variability has been lowered to less than a third of the original one. This has allowed saving up to 3.800 € yearly.

This has only been possible thanks to the application of multiple countermeasures, which have helped in dividing in a more evenly way the tasks required, trying to maximise working in parallel by providing all operators with the necessary competences.

The other issue that also affected the efficiency and was closely related to the batch change, which is the so-called SKU change, has also been tackled, in order to reduce the time spent on them, and to increase the overall efficiency. The outcome of the countermeasures on the SKU change has been positive, however, it has not been as successful as with the batch change, by only reaching slightly the must-have objective. Therefore, the improvement has gone from an average time of 46,4 minutes to 41,8 minutes, providing up to 875 € of yearly savings.

Even though the results have been beneficial, there are multiple reasons for which the SKU change has shown lower signs of improvement. As the project was more focused on the batch change, the procedure for the SKU change has been prepared but not implemented due to lack of time, so when in the future it is introduced, durations will be reduced. Also, one of the activities that would have affected the SKU change duration, which was Countermeasure 2, was eventually not implemented, preventing from a further improvement. The last cause is related with Countermeasure 4, which was designed specifically for the SKU change. Although it was successfully applied, there has not been any occasion to see the results it yields, so it has not been possible to observe its impact in the monitoring performed, but it is safe to say that it will have a great impact on a yearly scale, as it completely eliminates a waste. The time required to move the sensors was close to 20 minutes, and since the beginning of the project to the end of 2021 it happened 4 times. With this countermeasure, it will not repeat ever again.

For what regards the future, this is a project of continuous improvement, and it is needed to keep striving for perfection. That is why the countermeasures proposed in the future development and the continuous monitoring are very important to ensure the well-functioning of the process and to avoid reverting to the original situation.

Throughout the course of this project, I have been able to learn many valuable lessons that will be very relevant for my future life, both in my professional and personal life. This project has encouraged me to work autonomously rather than depending on a group, and despite having the support of my company and academic tutors, I took many decisions on my own and managed the directions it had to take.

Working with all the operators in the manufacturing area has taught me that the most hands-on knowledge is there, and that if you never go down to the productive area and you always stay in the office, it is impossible to truly understand how things really work. This contrast between theory and practice is what has provided me with a big picture of the whole process and has given me very valuable insights.

I feel very satisfied with the outcome of the project that I have been involved with the company, as according to the described results it has been beneficial for both parties.

Finally, I also feel very grateful for all the support I have received, which has undoubtedly been very valuable to push the whole project forward.

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15. ANNEXES

- A3 Framework for Fine Foods & Pharmaceuticals N.T.M. S.p.A.

Project name

OEE improvement in a nutraceutical stick-pack packaging line

Responsible student

Ignasi Greoles

Stakeholders

Luca Garghentini – Continuous Improvement Specialist
Andrea Sacchi – Food Supplements Plant Director
Mauro Rocca – Production Execution Manager

Academic tutor: Miguel Martin Cortez Aguilar
Company tutor: Luca Garghentini

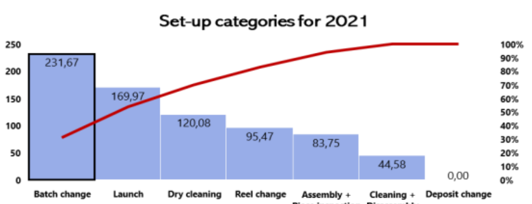
Start date: 25/10/2021
Planned duration: 5 months

1. Problem background

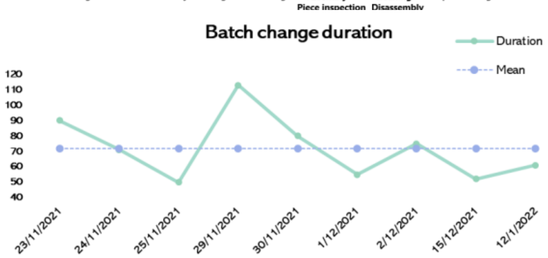
PROBLEM: The OEE of the lines that produce sticks (stick-pack 2 and 3) is low as they are performing under the target assigned. The total resources lost in inefficiencies during 2021 (set-up, technical, organizational…) for both lines sum up to:

TIME	RESOURCES	MONEY
3.946 hours	2 FTE per line	210.000 €

2. Problem breakdown



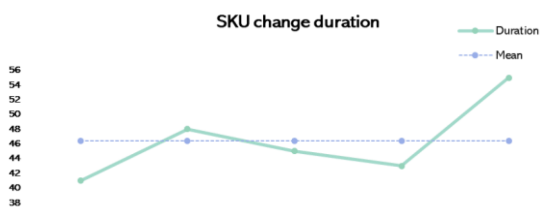
Entering inside the set-up, there are multiple activities, from which the one in which more time is dedicated is the **BATCH CHANGE.**



Batch change durations have been collected to quantify the original situation

Average = 72 minutes
Range = 63 minutes

Variability is very high



SKU change durations have been collected to quantify the original situation

Average = 46,4 minutes
Range = 14 minutes

3. Target setting

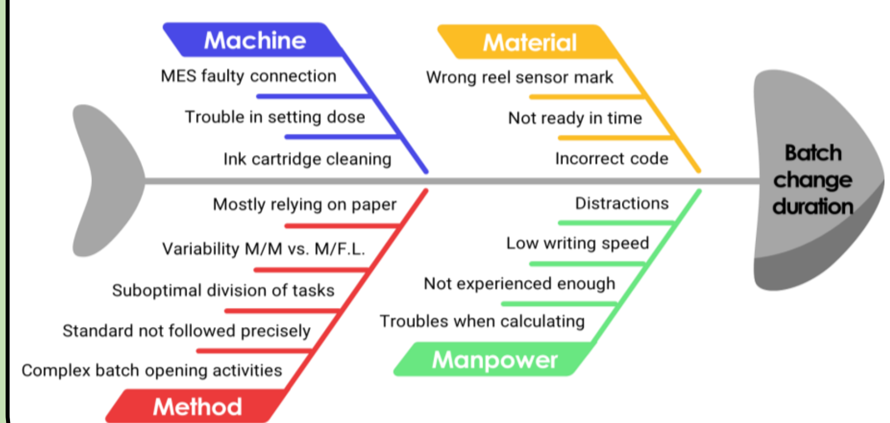
MUST-HAVE → To reduce by a **10%** the time dedicated to the batch change by March.
NICE-TO-HAVE → To reduce by a **15%** the time dedicated to the batch change by March.

MUST-HAVE → To reduce by a **10%** the time dedicated to the SKU change by March.
NICE-TO-HAVE → To reduce by a **15%** the time dedicated to the SKU change by March.

4. Root cause analysis

- **Why 1** – It is mainly because **set-up times have increased 561 hours between 2020 and 2021.**
- **Why 2** – All the categories of the set-up have increased, specially the batch change, because **batch change is the most time-consuming activity.**
- **Why 3** – Because **it has many activities that take a long time and most of them are performed only by the «macchinista».**
- **Why 4** – The «fondo linea» can only help with basic activities, so they take a lot of time because **most of them involve hand-writing a lot of documentation and depend on the «macchinista's» speed.**
- **Why 5** – Because **digitalisation is still being applied, and most of the «fondo linea» are not prepared to do more complex activities(*), so the «macchinista» must do them to be sure they are performed correctly and faster.**

(*) «Fondo linea» do not receive specific training for one manufacturing line, as they have a high rotation around the plant.

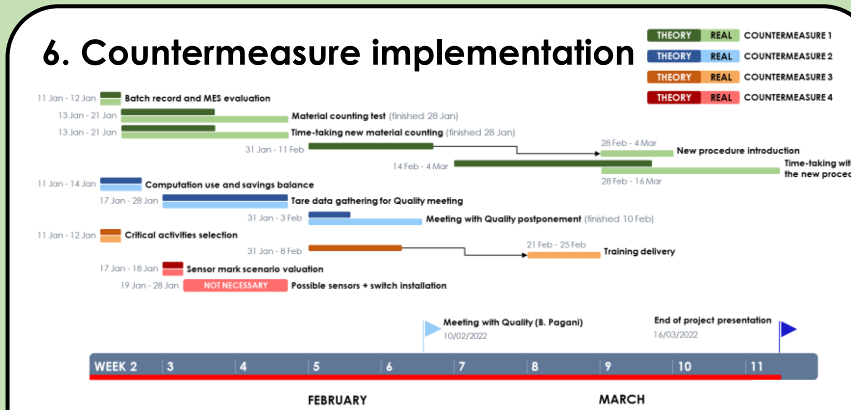


5. Countermeasure development

Countermeasure		Type	Time	Cost	Impact KPI 1	Impact KPI 2	TOTAL
CM1	New procedure	Light investment	6	10	10	6	32
CM2	Batch opening activities	Quick win	8	10	5	5	28
CM3	Training	Light investment	7	8	8	8	31
CM4	Wrong reel sensor mark	Quick win	8	9	0	9	26

	Description	Root causes affected
CM1	Establishing a new procedure to perform the batch change activities in a more efficient way.	• Distractions • Variability M/M vs. M/F.L. • Suboptimal division of tasks • Standard not followed precisely
CM2	Simplify the batch opening activities.	• Complex batch opening activities.
CM3	Provide a training to "fondo linea" operators to increase their capabilities and to introduce the new procedure. Tasks will be more evenly distributed.	• Not experienced enough • Troubles when calculating • "Fondo linea" operators do not receive effective training so they cannot perform many activities
CM4	Place the sensor mark on the same side.	• Wrong reel sensor mark

6. Countermeasure implementation

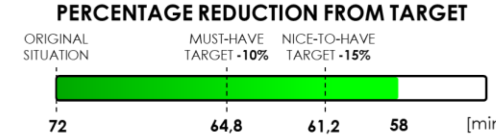


Countermeasure			
Team support Countermeasure 1	PRODUCTION	CONTINUOUS IMPROVEMENT	
Team support Countermeasure 2	PRODUCTION	CONTINUOUS IMPROVEMENT	QUALITY
Team support Countermeasure 3	PRODUCTION	CONTINUOUS IMPROVEMENT	
Team support Countermeasure 4	PRODUCTION	CONTINUOUS IMPROVEMENT	

7. Monitoring results

OLD AVERAGE **72 min** → ACTUAL AVERAGE **58 min**

PERCENTAGE REDUCTION FROM TARGET

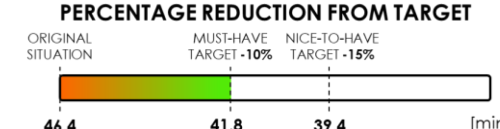


BATCH CHANGE

The countermeasures applied have had a very positive effect, reaching the nice-to-have target and beyond.

OLD AVERAGE **46,4 min** → ACTUAL AVERAGE **41,8 min**

PERCENTAGE REDUCTION FROM TARGET



SKU CHANGE

The countermeasures applied have had a positive effect, only reaching the must-have target.

Standardization and future development

	Action	RESPONSIBLES
Future actions	INTEGRATION OF THE PROCESS SCALE AND THE SORTING SCALE TO THE MES SYSTEM	PRODUCTION
	NEW STANDARD PROCEDURE FOR THE SKU CHANGE	CONTINUOUS IMPROVEMENT AUTOMATION
Standard actions	CONTINUOUS MONITORING OF THE BATCH CHANGES DURATIONS	CONTINUOUS IMPROVEMENT