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Applying lean methodologies to improve the OEE of a manufacturing line : a case study in a pharmaceutical company

Authors :

MARIA GIULIA PERRONE 976710

MASSIMILIANO MAIOCCHI 965120

Advisor :

Matteo Rossini

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Abstract

In the Pharmaceutical industry, especially for injectables, there is a high focus on the production processes. The focus of this study is the improvement of the OEE of a strategic automated filling line in a medium sized Pharmaceutical company through the use of Lean techniques.

In order to do so we were supported by a team that provided the knowledge and the skills required for the project development.

The use of the A3 logic allowed us to methodologically develop the project starting from a detailed measurement of the processes and gradually narrowing our focus until we were able to find the main root causes and we were able to assess them with the most effective countermeasures. This allowed us to achieve the results set for the project.

The solutions implemented then became company standards and, thanks to strategies developed for their sustaining, will allow continuous improvement and a higher control over the processes for the managerial level in the long period.

The countermeasures impacted both the machine hardware and the operator's organization: the hardware improvements required onerous measuring and a long process of root cause identification, while the managerial practices such as visual management and 5S have been proposed and validated multiple times, and thanks to the multiple feedbacks received by the operators and production managers we were able to find the most fitting solutions.

To make sure that the achieved results became the new standard for the processes, we developed KPIs and also a monitoring system able to quickly detect any deviations from the reached condition and act accordingly to avoid returning to the initial situation.

In conclusion, we can say that especially for outdated automated lines, focused and effective hardware changes allow to obtain considerable improvements in productivity. For what concerns the managerial aspect instead, a more standardized operations management and the transmission of the right values leads to a higher awareness of the operator's role inside the department and a higher attention to the line performance which is then translated into a higher OEE.

Estratto

Nel settore farmaceutico, specialmente quando si tratta di iniettabili, è presente un alto livello di attenzione verso i processi produttivi. Il focus di questo studio è il miglioramento dell' OEE di una linea automatica di produzione strategica all'interno di un azienda farmaceutica di medie dimensioni tramite l'utilizzo di tecniche Lean.

Durante lo svolgimento del progetto siamo stati supportati da un team che ci ha fornito la conoscenza e le capacità necessarie.

L'uso della struttura A3 ci ha permesso di sviluppare il progetto in maniera metodologica, cominciando da una misurazione dettagliata dei processi e un graduale aumento del focus sui problemi fino a quando non siamo riusciti a trovare le cause radice e a eliminarle con le contromisure più efficaci possibili. Questo ci ha permesso di raggiungere gli obbiettivi prefissati.

Le soluzioni implementate sono poi diventate lo standard dell' azienda, le strategie sviluppate per favorire il sostenimento nel tempo, permetteranno il miglioramento continuo e un maggior controllo sui processi da parte dei capi reparto.

Le soluzioni sviluppate hanno avuto effetto sia sul macchinario che l'organizzazione degli operatori : i miglioramenti hardware hanno richiesto un grande sforzo di studio della linea e di identificazione delle cause radice, mentre le pratiche manageriali come 5s e Visual Management sono state proposte agli operatori e ai capi reparto e validate più volte, e grazie ai feedback ricevuti siamo riusciti a trovare le soluzioni più adatte.

Per assicurarci che i risultati raggiunti diventino il nuovo standard dei processi, abbiamo sviluppato degli indicatori di performance e un sistema di monitoraggio capace di trovare velocemente dei discostamenti dalla condizione raggiunta e permettere di reagire prontamente per evitare la deriva dei processi.

Per concludere possiamo dire che specialmente per linee automatiche datate, degli interventi concentrati ed efficaci possono permettere di ottenere miglioramenti considerevoli della produttività. Per quanto riguarda l'aspetto manageriale invece, una gestione delle operazioni più standardizzata e la trasmissione dei giusti valori porta ad una maggiore consapevolezza da parte dell'operatore riguardo al suo ruolo nel dipartimento e un attenzione maggiore rispetto alla performance della linea, che viene poi tradotta in OEE.

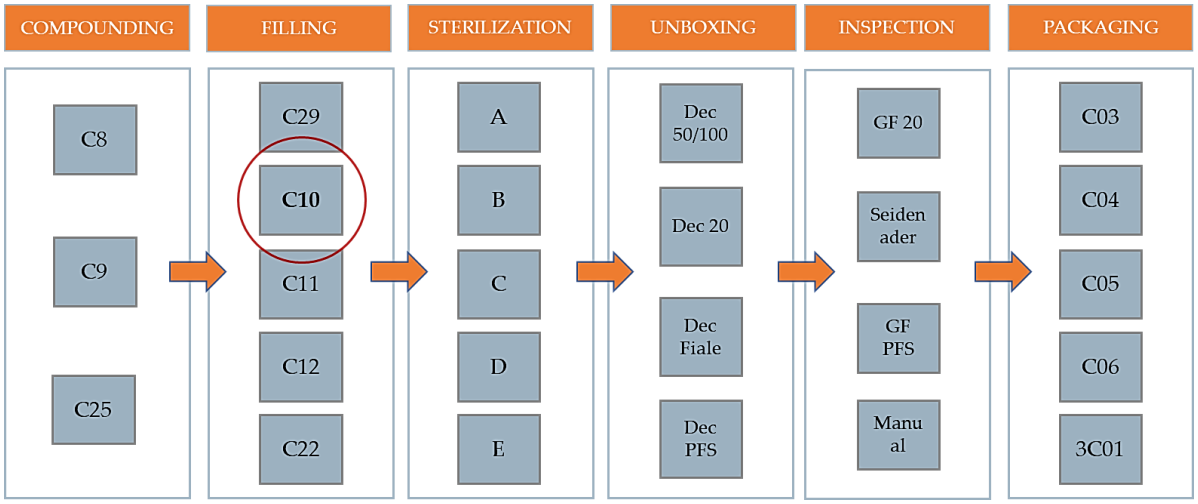
Executive Summary

Corden Pharma is an international pharmaceutical manufacturing company. The Caponago site, the plant in which the project was carried out, produces injectables for the B2B market. Most of the production volumes are represented by an anesthetic formula used in the hospitals.

The aim of the thesis is to **improve the productivity of a filling line** of great strategic importance for the company through the application of **Lean Manufacturing techniques** such as 5S, SMED and Visual Management. In particular, the indicator used by the company to measure the efficiency of the line is the Overall Equipment Effectiveness (**OEE**), which will then be used to define the starting condition and monitor the project results.

The structure of the thesis follows the steps of the **A3 Thinking methodology**, which is a problem solving methodology which supports a structured approach to improvement projects.

So, starting from the **Problem Background**, the filling line on which the project is centred is the C10. On this line vials are filled with the product that constitute the majority of the company's production volumes.



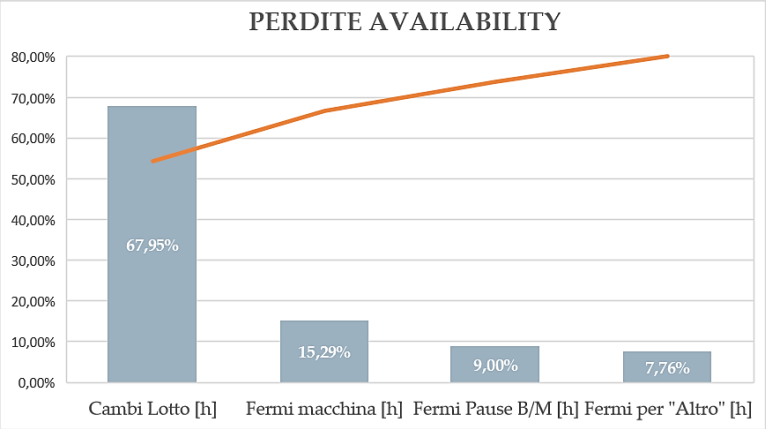
Despite its strategic importance, the C10 filling line is the one with the lowest average **OEE value, equal to 28.6%** at the beginning of the project in October. For this reason, our contribution was requested to support a dedicated team created for the productivity improvement of the line in question.

To describe in detail the current situation and fully understand where to focus our attention on, it was necessary to **breakdown the problem** as much as possible. So, after breaking down the OEE indicator into its components, the current average

Availability resulted to be equal to 66.2%, the current average Quality 95.2% and the current average Performance 45.5%.

Having realized that **most of the losses of the line are due to Performance and Availability losses**, the next step was to further breakdown the problem focusing on those two component.

For what regards the **Availability problem**, detailed data were already available from which it was possible to perform a Pareto analysis. Results show that most availability losses (68.0%) are attributable to time spent for **Changeovers.**



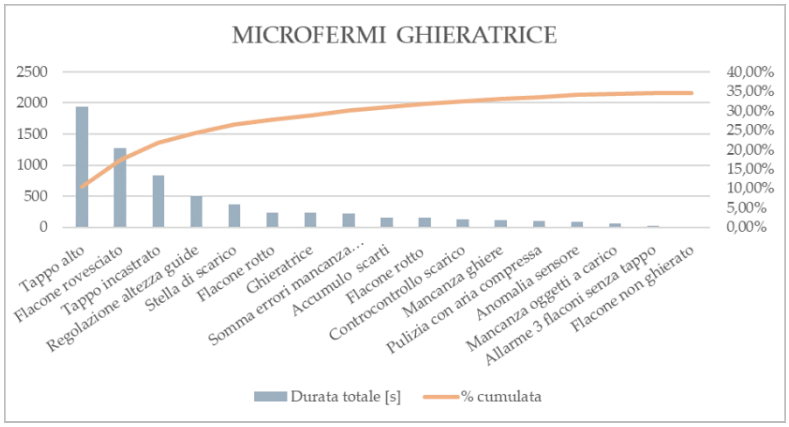
Analyzing the data related to changeovers, it was found that 89% of these are complete cleaning (compared to 11% of reduced cleaning). For this reason, we decided to focus our efforts towards the **analysis and the optimization of the complete cleaning process**.

Talking about the **Performance problem**, which turned out to be the lowest component of the OEE, it will be impacted mainly by discontinuous productions due to minor stoppages (duration less than 10 min). However, the company did not envisage a data collection method for this type of losses, so it was not possible to break down the performance issue. For this reason, a sample **data collection campaign** was carried out directly at the workshop, during which all the minor stoppages were registered together with the indication of the their duration and the reason why they happened.

TOTAL DURATION OF MICRO-STOPPAGES FOR EACH MACHINE			
Macchina interessata	**Durata totale microfermi [s]**	**% fermo**	**% cumulata**
Ghieratrice	6448	34.51%	34.51%
Incassettatrice	5780	30.93%	65.44%
Clean	3435	18.38%	83.83%
Lavatrice	1802	9.64%	93.47%
Tunnel	1220	6.53%	100.00%
Totale	18685	100%	

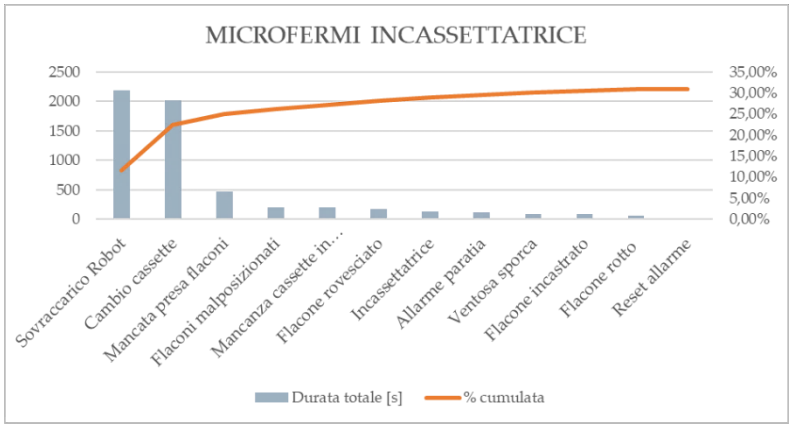
From the results of the Pareto analysis it is concluded that the biggest problems in terms of micro stoppages occur on the **Crimping Machine (35%)** and on the **Encasing Machine (31%)**.

Having realized which machines have the greatest impact on the Performance losses, a detailed analysis has been carried out with regard to CR511 and ME511 in order to identify the types of micro stops that occur most frequently on the latter. The result of the detailed Pareto analysis is shown below.



As for the **Crimping Machine**, the three main categories of micro stoppages are "**High Cap**", "**Spilled Vial**" and "**Stucked Cap**".

Together, these three categories of micro stops are responsible for **21.69% of the performance losses of the entire line**.



As for the **Encasing Machine**, the results of the analysis show that the most frequent categories of micro stops are "**Robot Overload**" and "**Cases Change**".

Together, these two categories of micro stops are responsible for **22.5% of the performance losses of the entire line.**

Having broken down and quantified the problem in detail, it was possible to **set the target** to be achieved. It was decided to set two types of target : a "must to have" target, needed to declare the project successful, and a "nice to have" target, higher than the previous one that represents more of an ambition of the project.

The **must to have target** was defined on the basis of a goal set at a managerial level :

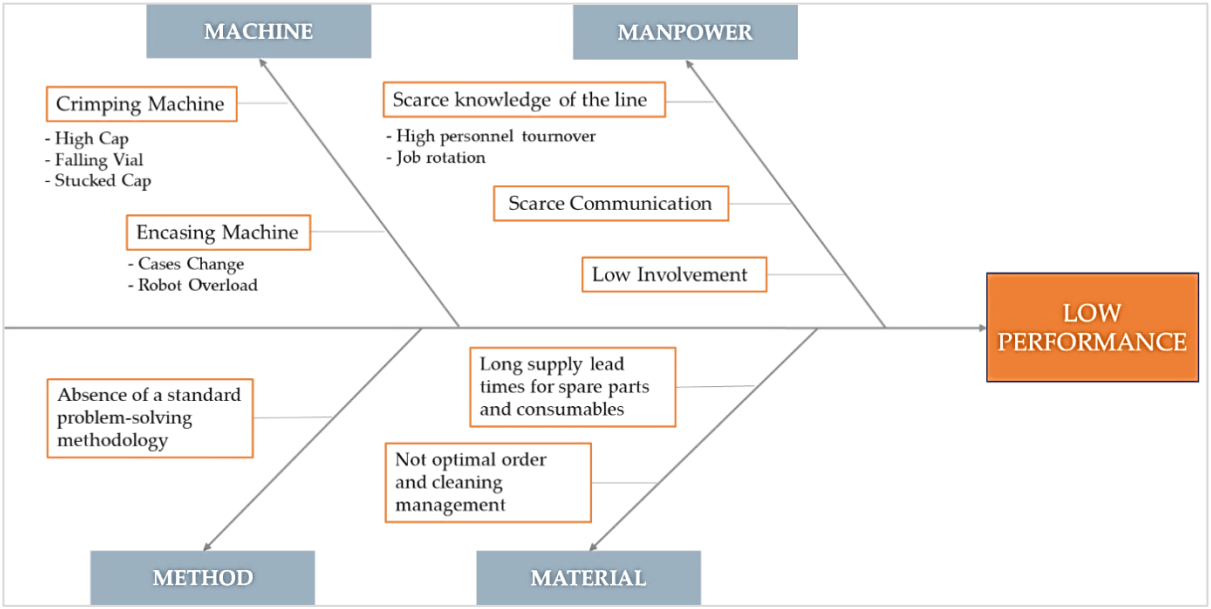
"Increase OEE measurement from 28.6% to 34.5% by Week 10 of 2023"

On the other hand, the **nice to have target** was defined following a data-based approach. So, starting from the data collected, the target was estimated assuming to eliminate the main micro-stoppages of the crimping machine :

"Increase the OEE measure from 28.6% to 36.0% by Week 10 of 2023"

At this point, to understand the root causes behind the problems brought to light, a **root cause analysis** was carried out both on the Performance side and on the Availability side.

Starting from the low **performance** problem, the macro causes identified are summarized and illustrated in the Ishikawa diagram :

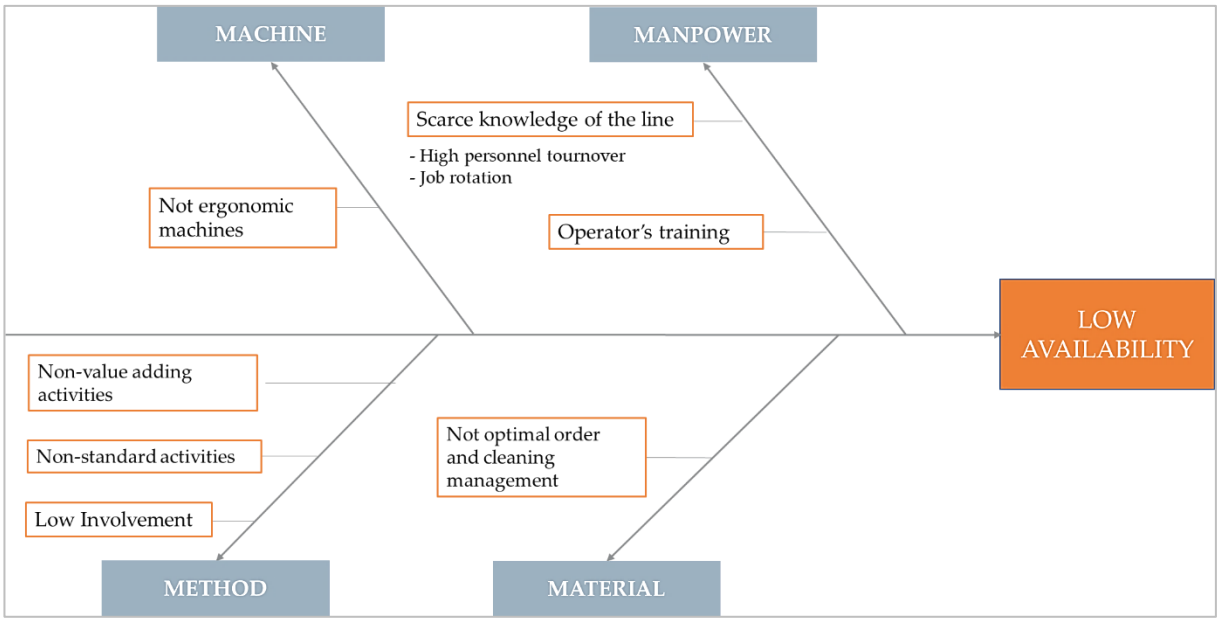


As for the category "Machine", being the most impactful category, a **5 Whys analysis** was carried out on each of the most relevant micro stops of the Crimping and Encasing Machine. The results of the analysis led us to conclude that:

- The root cause of all the main micro-stops of the **Crimping** Machine lies in the worn-out of the transport system guides together with the misalignment and damaging of the transport cells that guide the vials throughout their journey from the filler to the output of the **Capping Machine**

- The root cause of both of the **Encasing Machine** most common micro stops are the Cases which are too deformed and have too thick side rails that do not allow the correct alignment of the vials inside

With regard to the **Availability problem**, the macro causes of inefficiency identified are summarized in the following Ishikawa diagram:



After identifying the root causes of the Performance and Availability problems, the relative **countermeasures have been developed**, summarized in the following Table.

PROBLEM	CATEGORY	ROOT CAUSE	COUNTER MEASURE	DUE DATE	RESPONSIBLE
LOW PERFORMANCE	**MACHINE** (Capping Machine)	Transport cells misalignement	Transport cells replacement	Week 12, 2023	Maintenance Manager
		Guides Worn-out	Guides replacement and cells realignement	Week 2, 2023	Maintenance Manager
	MACHINE (Encasing Machine)	Old cases	Purchase and use of new dedicated cases	Week 12, 2023	Maintenance Manager
	MANPOWER	Low involvement	Visual Board	Week 7, 2023	Visual Board dedicated team
		Scarce communication			
		Scarce Knowledge of the line	Dedicated Team	Week 5, 2023	Production Manager

	METHOD	Absence of a standard problem-solving methodology	Creation of a standard problem-solving methodology	Week 20	Maintenance Manager
	MATERIAL	Not optimal order and cleaning management	5S	Week 2, 2023	5S dedicated team
LOW AVAILABILITY	**METHOD**	Non standard activities	Standard work	proposal	TBD
		Operators' organization	Third person inside the clean area	proposal	TBD
		Non value adding activities	SMED	Week 5	Project team
	MANPOWER	High turnover, too quick training	Standard work	proposal	TBD
		Scarce knowledge of the line	Dedicated team	Week 5	Production manager
	MATERIAL	Material management, disorder	5s	Week 15	Project team

As for the actual **implementation phase**, the countermeasures that have actually been implemented by the end of our project are highlighted with the **green** colour. As for the countermeasures highlighted in **orange**, these were only partially implemented or will be implemented after the end of the project.

Finally, the only countermeasure highlighted in **red** is the **SMED**. Indeed, after defining the activities that could be externalised and the potential benefit we developed a proposal in which the assembling and disassembling phase of the reservoir and of the pump system were performed outside of the machine downtime. The proposal for the future state was submitted to the validation department and quality department. However, the feedback from their evaluation was negative and **the company rejected our proposal** since the implementation of the SMED involved too many quality risks.

The countermeasures actually implemented are briefly described below.

Guides replacement and cells realignment：The cause of the most frequent micro stoppages on the Crimping Machine lies in a problem at the Capping Machine. To solve this problem, in Week 2 of 2023 a maintenance intervention was carried out for the replacement of all the 4 guides of the vials transport system in the Clean area. This represents the countermeasure from which it is expected to have the greater results in the short period. Moreover, all the 120 transport cells have been realigned as well as possible, waiting for the new cells to arrive at Week 12.

Visual Board implementation : The Visual Board Project officially began in Week 48 and in the upcoming weeks interviews were conducted with all those who would actively use the board. The whiteboard was installed in the White Area of the line, while it was not possible to install one in the Clean Area due to environmental sterility constraints. After implementing the first visual board proposal, we tested it in practice. So, the first step was to carry out a training to all the stakeholders of the board, who were asked to start using it in the following days. However, the most important thing was the **establishment of a daily meeting** to be held directly on the board. After collecting feedback and suggestions for improvement from all concerned, we arrived at the definition of the final layout of the Visual Board, which was implemented at week 6 of 2023, one week ahead of schedule

5S : One of the problems contributing to the inefficiency of the production line lies in the poor organization of the material used on line and in the not optimal management of cleaning. To solve this problem, it was decided to implement a 5S project on the production line in question, involving a dedicated team starting from Week 48. The team followed the 5 steps of the methodology and the project was completed in week 51 of 2022, ahead of the planned due date.

Dedicated Team : This countermeasure has been implemented to improve both the Performance and the Availability of the line**.** Together with the production line-heads we defined the set of operators, for all the 3 shifts, that would just operate on the C10 filling line. This countermeasure was implemented in week 5.

After the implementation of the countermeasure, we **monitored the results**. Despite all the countermeasures implemented had a positive impact on the problem at local level, the only countermeasure for which an immediate feedback on the final target of OEE improvement was expected is the **intervention** carried out **on the Capping machine**. Indeed, as regards 5S, the Visual Board and the Dedicated team, the impact on the OEE is difficult to be directly traced and quantified. However, the positive impact of the latter will certainly be appreciable in the long term.

In the table below a direct comparison is made between the average condition at the beginning of the project and the average condition at the end of it.

	PROJECT START Week 25-43, 2022	PROJECT END Week 3-10, 2023	DELTA
Avg Performance	45.5%	50.8%	**+ 11.7%**
Avg Quality	95.2%	97.8%	**+ 2.7%**
Avg Availability	66.2%	72.5%	**+ 9.5%**
Avg OEE	**28.6%**	**36.0%**	**+ 25.9%**

From these results we can therefore say that **both the must to have target and the nice to have target of the project have been fully achieved**.

Having quantified the obtained results, we enter the last phase of the A3 Thinking methodology : **standardize and share success**. For this purpose, we developed a continuous monitoring system that the company can use to make sure that the achieved results become the new standard for the process.

Regarding the sustaining of the **5S** countermeasure, we implemented a system of regular audits that allowed us to review the data collected from the check forms and verify that the standards were being met.

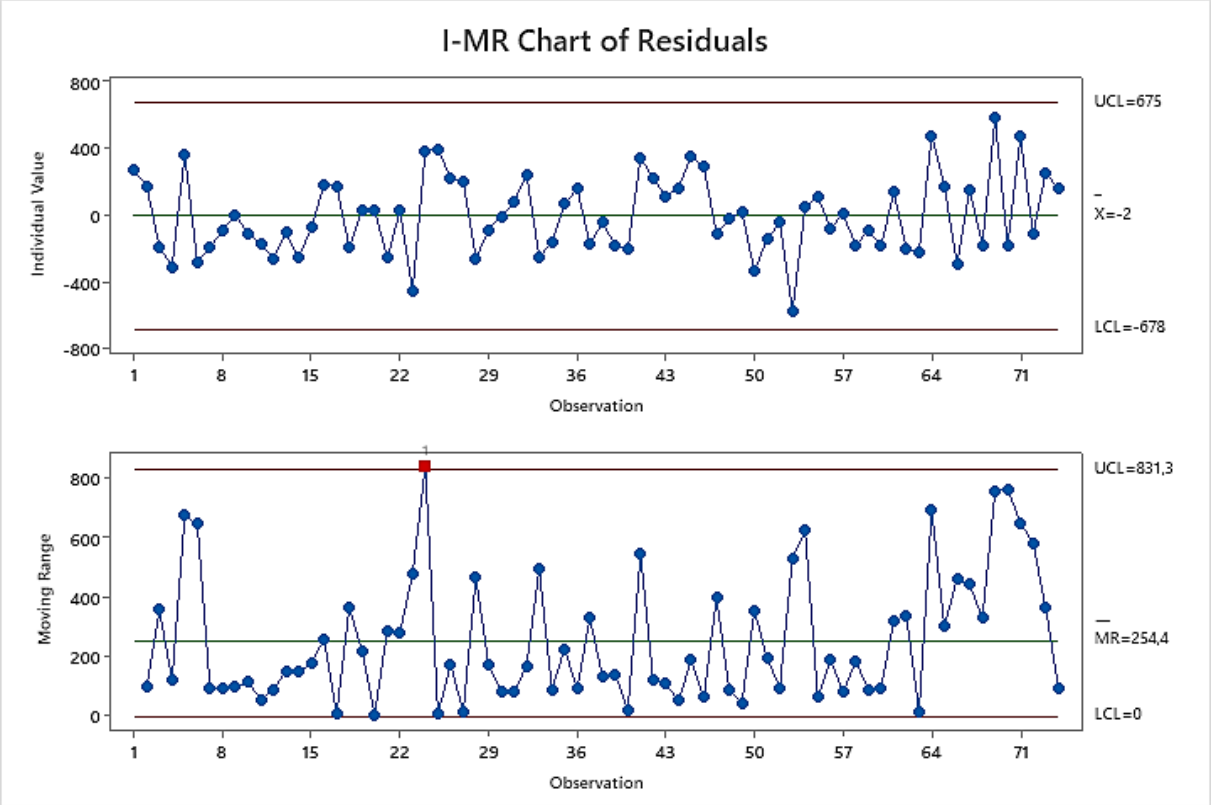
As for sustaining the improvements on the **Capping Machine**, it was decided to create a Control Chart on the production Scraps. The latter are in fact a good indicator of the health of the capping machine as most of the scraps are caused by vials with high or no cap.

For the design of the control chart, the production scraps data recorded between Week 3 and Week 10 were used, as this coincides with the period following the intervention on the Capping Machine and with the period in which the machine was expected to be in the "target" conditions that we want to maintain.

Having established that the assumptions of normality and independence of the data were not respected, we had to consider statistical methods to describe or “model” the nature of the process behaviour and so to find a model that “fits“ our data.

After snooping the data and making the necessary considerations, the proposed data model was found thanks to the use of **Minitab** software, namely an ARIMA(1,0,0). The check of the iid assumptions on the Residuals confirms that the model used to represent our data is correct. At this point, an I-MR control chart will be created on the residuals.

As shown in figure , only one point appears beyond the control limits of the Moving Range CC. However, no special causes have been found to justify the outlier. For this reason, the Design phase of the Control Chart can be considered concluded and consequently both the model parameters and the CC limits will be kept fixed for the "Usage" phase.



For the Usage phase of the Control Chart, an Excel file has been created in which every time a new observation is inserted, the "Residual" to be added to the Individual chart and the Moving Range to be added to the MR chart will be automatically calculated. The I-MR can indicate a situation of out of control both when one or more points fall beyond the control limits or when the course described by the points, even if inside the limits, is not random.

1 Introduction

For the development of this thesis, an internship was carried out at the production plant of Corden Pharma S.p.A. located in Caponago (MB). In particular, we were assigned to a project for which a dedicated team was built.

The purpose of this project was to improve the **Overall Equipment Effectiveness** of a filling line which has an important strategic role for the company.

Corden pharma had already started a journey to implement lean techniques with the Operational Excellence department in all its plants, and more in particular the Caponago site had already carried out OPEX projects with the partnership of Politecnico di Milano.

The **team** selected by the company to support us in the project was composed by:

- One representative of the production department, that could provide its expertise on what was the focus of our project.
- A maintenance coordinator, that provided the technical support needed since the focus of the project was an automated filling line.
- One employer of the supply chain department, with a Green Belt certification that supported the strategic development of the activities.
- One representative of the inspection department also with a green belt certification.
- An Engineering department employer who provided technical support and managed the investments needed for countermeasures implementation

The team then was coordinated by a master belt employee with high expertise in the OPEX and our thesis supervisor Matteo Rossini from Politecnico di Milano in the role of consultant for the company.

The project was carried out from October 2022 to march 2023. The project was developed through weekly meetings, where the team presented all the activities performed and together with the two coordinators discussed the next steps.

This document starts with a brief introduction to the company and a theoretical description of the tools that supported us during the project. The project then is presented with a structure that follows the **A3 methodology**:

In the first section we will introduce the company and a theoretical analysis of the tools and methods used in this project.

The following chapters will be focused on providing the problem background through a description of the plant, and then, in the problem breakdown we will focus on the object of our project: the C10 filling line.

After the breakdown we will explain how we defined our targets, in the root cause analysis we will identify the main causes of the problems individuated and in the Countermeasure development we will explain what are the solutions we proposed.

Finally, in the Implement countermeasures chapter, we will show how the countermeasures have been implemented and their impact in the Monitor results and process.

In the Standardize and share success there is an explanation of what are the solutions implemented to make continuous monitoring system that the company can use to make sure that the achieved results become the new standard for the process.

Lastly we will express our thoughts concerning the project in the conclusions.

2 The Company

Corden Pharma was created in 2006 as a privately held pharmaceutical brand of International Chemical Investors Group (ICIG). With 11 current manufacturing Plants across Europe and the United States, Corden Pharma is able to provide an integrated service to its customers, from the early stages of product development to the commercial production.

The group's mission is to provide customers high quality products and services in order to guarantee the well-being of patients. Corden Pharma was created in 2006 as a privately held pharmaceutical brand of International Chemical Investors Group (ICIG). With 11 current production plants across Europe and the United States.

Corden Pharma has a common vision and mission, aiming as vision is to be trusted, reliable and highly respected Contract Development and Manufacturing Company (CDMC) to pharmaceutical & Biotechnology companies by providing industry-leading Integrated Product Solutions with integrity, transparency & flexibility on all levels of the organizations.

Core values: Accountability, Collaboration, Integrity, Trust, Reliability

Key pillars: customer service, operational excellence, collaborative partnership, people & culture.

Technology platforms

Corden Pharma Caponago is one of the most strategic facilities of Corden Group and is the plant in which the projects took place.

The Corden Pharma Caponago plant is specialized in injectable manufacturing with both Terminal Sterilization and Aseptic Filling Technologies. The main product is used in hospitals for anesthesia, but also many other formulas are produced within the plant.

Figure 1 - Corden Pharma Caponago plant

Furthermore the manufacturing lines allow a variety of containers for its products: Pre-filled Syringes (PFS), Vials, Ampules and Lyophilized Vials, with a range of filling volumes.

With multiple process and filling lines the plant is able to produce more than 100.000 units every day, hence the productivity is a key factor for the plant.

3 Theoretical Background

Over the decades, the manufacturing system has made a transition from a craft system to a mass and then further a lean system. The first system focused on production based mainly on the workers skillset. A few product variants were produced in limited geographical areas. The transition to mass manufacturing has led to an increase in the volumes produced by using dedicated assembly and production lines. This allowed to achieve important economies of scale at the expense of a very limited flexibility. However, over the last few years, market needs have forced companies to be more flexible and ready to respond to increasingly wide and disparate needs. The concept of **lean manufacturing** was born to meet this need and ensure both flexibility of processes and low manufacturing costs. It has its origins in the Toyota Production System (TPS) based on JIT (Just In Time) principles which combines the best features of both mass production and craft production : the ability to reduce costs per unit and dramatically improve quality while at the same time providing an ever wider range of products (*Womack et al. 1990*). In this section we will deepen the concept of lean manufacturing together with its principles and its main practices and techniques.

3.1 Introduction to Lean

Lean is considered as a concept which integrates manufacturing system, comprise of principles, practices and techniques (*Karlsson & Ahlstrom 1997*). It is based on the Kaizen philosophy of continuous improvement (CI), standardization of work procedures, and sustaining the achieved improvements (*Womack et al. 1990*).

The five key principles of the lean philosophy are highlighted by Womack & Jones in their book, namely:

Value : define the value from the customer perspective.

Value streamline : map the value stream including all the steps describing the flow of material/product through the process. The goal is to identify and eliminate all the non-value adding activities.

Continuous flow : introducing flow in the remaining value-adding activities after eliminating the wastes in a value stream.

Pull system : work only when there is demand for it and avoid overproduction by producing only the value that is actually needed by your customer.

Perfection : closely related to the concept of continuous improvement, constantly improve every process by focusing on the activities that generates the most value.

The objective of lean is to ensure streamlined processes, waste elimination and value addition. Indeed, lean manufacturing is known as manufacturing without waste (*Taj*

2005), where wastes are non value added activities categorized as : overproduction, waiting time, transportation, inventory, inappropriate processing, excess motion and product defects (*Melton 2005; Womack & Jones 2003; Ohno 1988*).

3.2 Lean Practices and Techniques

The practical implementation of lean concept focuses on implementing and using different principles, tools, and method. The following will describe the **main lean techniques and concepts used for the development of the project**.

3.2.1 5S

To lay the foundation for a solid lean implementation it's convenient to start with some basic tools. Among the simplest tools to use in the first phase of a lean implementation we find 5S. It is a technique which provides a disciplined approach to increase the efficiency of the workplace organization by reducing wastes and contributing to the improvement of the workplace safety. The words that make up the 5S are all Japanese and coined by Toyota :

1. *Seiri* (**Sort**) : The first concerns the identification and removal of all those objects that are not used on a regular base (e.g. once a month). At the end of this first phase, only the most frequently used objects will be left in the workplace, while those labelled as not in use will be stored in a special area previously identified.
2. *Seiton* (**Set in order**) : has to do with assigning a place to each entity, as any object that is important enough to be in the workplace must also be designated to a certain place. The location of each entity must be indicated also with the help of space delimiters (e.g. coloured adhesive tapes).
3. *Seiso* (**Shine**) : The third element regards routine cleaning and inspections to analyze work conditions. Items must be clean enough to be ready for immediate usage.
4. *Seiketsu* (**Standardize**) : It is concerned with standardizing all the actions implemented in the previous stages. To do that, an audit with quantitative and qualitative expectations for each area could be conducted regularly and scores displayed in a point visible to all.
5. *Shitsuke* (**Sustain**) : The last one regards the commitment to make 5S a way of life. Routine checks are analyzed and continuous improvement is planned. The workforce is trained on self-discipline and self-awareness and the procedures are sustainedthanks to the commitment of management which must demonstrate leadership by follow-through and walking the talk (*S.Vinodh, 2023*).

3.2.2 Visual Management

Lean emphasizes on visual management as a comprehensive system to facilitate an effective understanding and immediate feedback by means of displaying trend charts of the most significant indicators, work schedules, problem areas, material flow and status of the operation. It includes techniques to enable *visual communication* and *visual control* to uncover hidden aspects and reveal bottlenecks (*S.Vinodh, 2023*).

A key aspect of visual management is that of workplace performance measurement. This can be possible through the establishment of a handful of measures (up to 5) exposed directly at the shopfloor and clearly visible and accessible to all. The latter must be strictly measured, owned, monitored and controlled by those working in the area. For this system to succeed, it is essential that individuals understand the importance of visual communication and recognize its usefulness, since they will be responsible for updating and maintaining visual communication tools. It's important for them to understand how they're performing compared to the plan and to highlight the main issues in order to arouse the attention of those who can give support and have the power to change things.

Typically, the communication board is divided into two sections. The first one contains the shopfloor measures of performance (e.g., schedule adherence, quality, cycle time, etc.), while the second one contains a problem section, where the operators can document problems they are having (*William M.Field, 2014*).

3.2.3 Value Stream Mapping

Among the principles underlying lean philosophy there is the mapping of the value stream of the process under analysis. For this reason, a tool called Value Stream Mapping has been developed as a functional method aimed at reorganizing production processes with a lean perspective. Regarding the construction of the VSM, Rother and Shook (1998) identifies five fundamental phases:

1. selection of a product family;
2. current state mapping;
3. future state mapping;
4. defining a working plan;
5. achieving the working plan.

The main elements that make up the VSM are process icons containing data boxes that denote information such as the number of operators, cycle time (C/T), changeover time (C/O), and other relevant information about the process. The processes are connected between them through arrows and include icons representing the inventory and the waiting time between them. A stepped timeline of metrics placed under the process flow separates value-added from non-value added time or resources, providing a basis for the improvement actions and for the construction of the future state map (*S.Russell, 2010*).

Moreover, Rother and Shook (1998) together with Marchwinski and Shook (2003) also proposed a list of guidelines necessary for the definition of the future state map, summarized below:

- Establish a **continuous flow** where possible
- Use **pull systems** between different work centres where a continuous flow cannot be established
- Define a **Takt Time**, which is a measure of the production rate strictly imposed by the product demand.
- The Process that dictates the pace of the entire value stream will be called the **pacemaker process**. Downstream of this point the elements would flow in a First In First Out (FIFO) sequence; upstream, production will be triggered by pull signals.
- When scheduling the pacemaker process deal with the **maximization of production levelling on mix and volume**.
- Try to **improve** as much as possible the **overall process efficiency** by cycle time improvements, changeover time reduction (SMED), work methods improvements

3.2.4 SMED

Single Minute Exchange of Die (SMED) is a lean methodology used to systematically analyze, reduce and standardize changeover time, which is considered a non value added activity (*Naboureh & Safari, 2016*). Changeover time has a direct impact on total lead time, production capacity and flexibility. For this reason, among the benefits of implementing SMED we find a waste reduction, an increased production capacity and flexibility of the equipment, an increased customer satisfaction and, more generally, an increase in machine efficiency (*P.Ondra, 2022*). Moreover, thanks to the increase of equipment Availability due to the reduction of changeover time, SMED allows for improving a fundamental indicator that will be deepened in the next paragraph, called Overall Equipment Effectiveness (*Otero & Lopes, 2018; Pattaro Jr. et al., 2022*).

The methodology consists of **three essential steps**:

Segregate the activities : very often the primary cause of high changeover times are non-standard or completely absent procedures for which activities are not clearly identified. For this reason, the first step consists in identifying all the activities of which the process is composed up to a certain level of detail. The best way to do this is to definitely make *Gemba Walk.* Once all the activities have been identified, they will be divided into two categories. The first category covers all activities that can be performed only when the machine is down, called *internal activities*. The second, on the contrary, concerns all the activities executable while the machine is running, which will be called *external activities*.

Re-arrange and Recategorize : after having defined and categorized the activities, the next step is the rearrangement and the re-integration of the latter. Indeed, the activities will have to be firstly rearranged so that all the external activities are concentrated at the beginning and at the end of the set-up process. In addition, efforts should be made to re-categorize as much activity as possible by shifting them from internal to external. This will drastically reduce the time the machine will be idle for set-up.

Simplify the process : Once setup activities have been re-arranged and re-categorized, the last step is to look at simplifying the changeover process for both internal and external activities. Try to insist on making the process as standard, repeatable and understandable as possible by the operators (*William M.Field, 2014*).

3.2.5 Focus of the project - OEE

In order to monitor the performance of the line and visualize the benefits brought by the improvement actions we used the OEE indicator.

OEE (Overall Equipment Effectiveness) is the gold standard and one of the most widely used indicators for measuring manufacturing productivity. It identifies the percentage of manufacturing time that is truly productive with respect to a given timespan.

The OEE measurement can be broken down into three metrics: Availability, Quality and Performance.

These three indicators allow to allocate the " Six Major Losses " identified and measured in the OEE computation:

- **Availability**: Breakdowns; Setup times
- **Quality**: Scraps and rework; Startup scraps
- **Performance**: shutdowns due to minor inconveniences; reduced processing speed

By measuring OEE and the time losses, it is possible to gain important insights on the areas that need to be assessed in order to improve the manufacturing process. The Breakdown of the OEE into Availability, Quality and Performance allows for a higher level of detail of analysis and a more focused and effective actions.

We will now see with more detail how the OEE is computed in Corden Pharma

3.3 OEE Calculation

For what concerns the monitoring of the filling line, Corden pharma had already started to implement the OEE calculation in the first semester of 2022, through an operational excellence project and was already running at the beginning of our experience in the company.

The measurement of the OEE only relies on data taken by the operators, since all the stations of the filling line are old and are not able to process these type of data. On the other hand, the company couldn't give a higher workload to the operators that were already in charge of too many activities. For this reason, the company decided to rely only on the data that was already taken and collected inside the FLP.

The FLP is the documentation that must follow every batch that is produced inside the plant: It tracks all the needed information concerning the activities carried out in all the departments of the company in order to ensure that the Quality Assurance department is able to verify that all the activities had been carried out and whether they are compliant to regulations or not.

In particular, the information that are written inside the FLP that concern the Filling stage are sufficient to compute the OEE of the line.

In order to understand how the file works we need to understand how operations take place in the filling line.

The line is planned to operate 3 shifts per day for 7 days a week continuously: the filling of a batch is followed by the dismantling and cleaning of some components inside the filling line, their reinstallation inside the line, and a transitory phase needed for the set-up of the filling line. Then the filling of a new batch can start.

Changeovers are not frequent on the line since they are required only in case of a production campaign of the 10 ml format (which takes place 2 - 4 times every year).

Once the Batch is filled, the batch record is collected and stored waiting to be sent to the inspection department. Here the employee in charge of the data entry collects them and inserts the data into the file that calculates the OEE.

3.3.1 The File

The file consists in an excel that automatically calculates the OEE of the single batch.

The data is typed in 3 different pages:

1. **File monitor**: Here the operator inserts the batches in the same sequence of the Filling line indicating the day and hour of the start and of the end of the filling activities.

	RIEMPIMENTO CLEAN AREA				
LOTTO	LOCALE	DATA di INIZIO	ORA di INIZIO	DATA di FINE	ORA di FINE
23R060	C10	2/25/2023	4:00	2/25/2023	15:10
23R061	C10	2/25/2023	15:50	2/26/2023	3:45
23R062	C10	2/26/2023	6:55	2/26/2023	18:30
23R063	C10	2/26/2023	21:55	2/27/2023	8:40
23R064	C10	2/27/2023	9:30	2/27/2023	22:45
23R065	C10	2/28/2023	2:45	2/28/2023	14:10
23R066	C10	2/28/2023	17:20	3/1/2023	5:35
23R067	C10	3/1/2023	10:05	3/1/2023	23:01
23R068	C10	3/1/2023	23:40	3/2/2023	10:40
23R069	C10	3/2/2023	13:20	3/3/2023	0:10
23D023	C10	3/3/2023	3:15	3/3/2023	12:40
23D024	C10	3/3/2023	16:35	3/4/2023	6:45
23D025	C10	3/4/2023	14:00	3/5/2023	7:35
23D026	C10	3/5/2023	9:50	3/6/2023	1:05
23R070	C10	3/6/2023	4:15	3/6/2023	16:43
23R071	C10	3/6/2023	17:35	3/7/2023	2:12

Figure 2 - File monitor

Lotto	Note del capoturno	Teorici	Sterilizzati	Settimana	Mese
23R048	NA	59214	57624	7	2
23R049	NA	59286	58016	7	2
23R050	NA	59166	57624	8	2
23R051	NA	59166	58212	8	2
22R052	NA	59262	58506	8	2
23R053	NA	59141	58408	8	2
22R054	NA	59141	58016	8	2
22R055	NA	59214	58114	8	2
23R056	NA	59190	58016	8	2
23R057	NA	59141	58212	8	2
23R058	NA	59100	58109	8	2
23R059	NA	59262	58408	8	2
23R060	NA	59262	58212	8	2
23R061	NA	59262	58016	8	2
23R062	NA	59335	58016	8	2
23R063	NA	59238	58016	8	2
23R064	NA	59166	58310	9	2
23R065	NA	59214	57624	9	2
23R066	NA	59141	58408	9	2
23R067	NA	59214	57624	9	2
23R068	NA	59359	58114	9	3
23R069	NA	59262	58408	9	3
23D023	NA	59649	57624	9	3
23D024	NA	59141	55664	9	3
23D025	NA	58770	55468	9	3
23D026	NA	58746	57428	9	3
23R070	NA	59262	58310	10	3

Figure 3 - Quality

2. **Quality**: This is the section dedicated to the data useful for the computation of the Quality parameter. In order to compute the theoretical batch size, before the filling, the emulsion (contained in a 1250 L vessel) is weighted, and then the total weight is divided by the standard amount of product in each vial, giving the theoretical number of units that can be filled with the batch. The vials, are then counted in the unboxing phase, after the sterilization, and since the two phases don't generate scraps, this number can be used for the computation of the quality parameter.

3. **Stops**: The FLP also has a section in which the operators must track all the stoppages of the line and the reason of it. The policy in the plant is to take note only of the stoppages that last more than 10 minutes.

FERMI LINEA AA511 (Flaconi 20 ml e 10 ml)										
Tipologia fermo	Macchina impattata	Dettaglio fermo macchina	Data inizio	Ora inizio	Data fine	Ora fine	Settimana	Mese	Lotto	Note
Altro	Non Compilare		2/27/2023	13:35	2/27/2023	14:25	9	2	23R064	ASSEMBLEA D REPARTO
Pausa MENSA	Non Compilare		2/28/2023	11:40	2/28/2023	12:20	9	2	23R065	
Fermo macchina	FM511		2/28/2023	7:05	2/28/2023	7:40	9	2	23R065	RIPOSIZIONAMENTO CONTENITORE TAPPI TRAMOGGIA PER ECCESSO VIBRAZIONI
Altro	Non Compilare		2/28/2023	18:20	2/28/2023	19:20	9	2	23R066	MANCANZA PERSONALE
Pausa BREAK	Non Compilare		2/28/2023	20:55	2/28/2023	21:25	9	2	23R066	E CAMBIO LINEA
Pausa BREAK	Non Compilare		3/1/2023	16:00	3/1/2023	16:15	9	3	23R067	
Pausa MENSA	Non Compilare		3/1/2023	18:40	3/1/2023	19:20	9	3	23R067	
Pausa BREAK	Non Compilare		3/1/2023	21:00	3/1/2023	21:15	9	3	23R067	
Pausa MENSA	Non Compilare		3/2/2023	1:45	3/2/2023	2:25	9	3	23R068	
Pausa BREAK	Non Compilare		3/2/2023	4:45	3/2/2023	5:00	9	3	23R068	
Pausa BREAK	Non Compilare		3/2/2023	16:15	3/2/2023	16:30	9	3	23R069	
Pausa MENSA	Non Compilare		3/2/2023	18:00	3/2/2023	18:40	9	3	23R069	
Pausa BREAK	Non Compilare		3/2/2023	20:45	3/2/2023	21:00	9	3	23R069	
Pausa MENSA	Non Compilare		3/3/2023	18:00	3/3/2023	18:40	9	3	23D024	
Fermo macchina	WM511		3/3/2023	20:45	3/3/2023	21:20	9	3	23D024	SOVRACCARICO SPINTORE
Fermo macchina	CR511		3/4/2023	4:10	3/4/2023	4:20	9	3	23D024	ROTTURA FLACONI + PULIZIA
Fermo macchina	FM511		3/3/2023	19:55	3/3/2023	20:45	9	3	23D024	PULIZIA STRAORDINARIA E SANITIZZAZIONE CON IPA CAMERA AZOTATURA + STAZIONE TAPPI
Fermo macchina	FM511		3/4/2023	15:42	3/4/2023	17:35	9	3	23D025	RITROVAMENTO VIALS CON VALORI OSSIGENO SPAZIO DI TESTA FUORI LIMITE INT UT
Pausa BREAK	Non Compilare		3/4/2023	20:30	3/4/2023	20:45	9	3	23D025	
Fermo macchina	WM511		3/4/2023	23:20	3/5/2023	3:50	9	3	23D025	INTERVENTO UT PER RIPRISTINO FUNZIONALITÀ ESPULSORE FLACONI
Fermo macchina	FM511		3/5/2023	3:50	3/5/2023	4:45	9	3	23D025	ATTESA VETRO
Fermo macchina	WM511		3/5/2023	13:00	3/5/2023	13:30	9	3	23D026	RIAPETO SELETTORE A CHIAVE INT UT
Fermo macchina	WM511		3/5/2023	13:55	3/5/2023	14:20	9	3	23D026	SOVRACCARICO SPINTORE INT UT
Fermo macchina	WM511		3/5/2023	19:35	3/5/2023	19:50	9	3	23D026	RIPRISTINO ALLARME D'ARRESTO INT UT
Pausa BREAK	Non Compilare		3/5/2023	20:50	3/5/2023	21:05	9	3	23D026	
Fermo macchina	ME511		3/5/2023	22:00	3/5/2023	22:40	9	3	23D026	RIPRISTINO SENSORE RILEVAMENTO CASSETTA POS 5 INT UT
Pausa BREAK	Non Compilare		3/6/2023	0:10	3/6/2023	0:25	10	3	23D026	
Pausa BREAK	Non Compilare		3/6/2023	7:50	3/6/2023	8:05	10	3	23R070	
Pausa BREAK	Non Compilare		3/6/2023	9:50	3/6/2023	10:05	10	3	23R070	
Pausa MENSA	Non Compilare		3/6/2023	11:00	3/6/2023	11:40	10	3	23R070	
Pausa BREAK	Non Compilare		3/7/2023	8:00	3/7/2023	8:15	10	3	23R072	
Pausa BREAK	Non Compilare		3/7/2023	10:35	3/7/2023	10:50	10	3	23R072	
Pausa MENSA	Non Compilare		3/7/2023	11:00	3/7/2023	11:40	10	3	23R072	
Fermo macchina	WM511		3/7/2023	13:30	3/7/2023	13:45	10	3	23R072	GIUNTO APERTURA PINZE INT UT
Pausa MENSA	Non Compilare		3/7/2023	18:00	3/7/2023	18:40	10	3	23R072	
Fermo macchina	WM511		3/7/2023	19:25	3/7/2023	19:40	10	3	23R072	RIPRISTINO MANCATA PRESA ROB0T B

Figure 4 - Stops

All the stops that are written down specify the cause (whether it is a breakdown or a lunch break), the machine impacted (in case of breakdown), the day and time of the stop and of the resumption of activities and the batch involved in the stop. These data are then used by the file to compute the availability.

All these data are then used by the file to compute all the times for the OEE calculation

3.3.2 OEE calculation:

AVAILABILITY: $\frac{Effective\ opening\ time}{Opening\ time}$

Opening time: it is considered as the time that passes between the ending of the filling activities of two consecutive batches.

Effective opening time: it is derived by subtracting, from the opening time, all the activities that stop the line:

- Changeovers (that mostly consists in the cleaning activities between two batches) which is the time between the stop of the filling activities and the start of the following batch)

-The breakdowns.

- 15 minutes breaks and 45 minutes lunch breaks

- Other activities such as operators' training or department meetings.

PERFORMANCE: $\frac{Actual\ productivity}{Theoretical\ productivity}$

Actual productivity : It is equal to the number of vials that were processed by the line, which consists in the theoretical batch size.

Theoretical productivity : it is computed using the effective opening time. Given the theoretical pace of the machine, the file is able to compute the number of pieces that the machine would have produced, if it worked at the maximum speed the whole time.

QUALITY : $\frac{Sterilized\ units}{Theoretical\ units}$

In order to compute the quality parameter, the program simply divides the two input data.

These three parameters are then multiplied, giving the OEE of the batch.

Lotto	Note	Fine riempimento	Formato	Validazione	Settimana	Mese	Anno	Tot t riempimento [h]	Tot t fermi [h]	Tot t riemp. effettivo	t cambio lotto	t apertura	Sterilizz.	Teorici	Disponibilità	Qualità	Rendimento	OEE
22R165		11/5/2022 23:40	20 ml		44	11	2022	14.67	2.00	12.67	2.92	17.58	56252	59238	72%	96%	43%	30%
22R166		11/6/2022 15:20	20 ml		44	11	2022	13.33	1.42	11.92	2.33	15.67	56644	59504	76%	95%	46%	33%
22R167		11/7/2022 10:35	20 ml		44	11	2022	18.83	4.95	13.88	0.42	19.25	55272	59190	72%	93%	39%	27%
22R168		11/8/2022 6:25	20 ml		45	11	2022	17.33	4.08	13.25	2.50	19.83	55076	59190	67%	93%	41%	26%
22R169		11/9/2022 5:40	20 ml		45	11	2022	19.68	2.08	17.60	3.57	23.25	55762	59141	76%	94%	31%	22%
22R170		11/10/2022 4:15	20 ml		45	11	2022	19.08	3.42	15.67	3.50	22.58	54194	59166	69%	92%	35%	22%
22R171		11/10/2022 23:45	20 ml		45	11	2022	16.42	2.17	14.25	3.08	19.50	54488	58972	73%	92%	38%	26%
22R172		11/11/2022 19:00	20 ml		45	11	2022	15.83	3.00	12.83	3.42	19.25	54096	59262	67%	91%	43%	26%
22R173		11/12/2022 8:10	20 ml		45	11	2022	10.00	0.25	9.75	3.17	13.17	55860	59190	74%	94%	56%	39%
22R174		11/12/2022 21:35	20 ml		45	11	2022	12.75	0.67	12.08	0.67	13.42	56449	59238	90%	95%	45%	39%
22R175		11/13/2022 17:20	20 ml		45	11	2022	16.08	3.58	12.50	3.67	19.75	55958	59262	63%	94%	44%	26%
22R176		11/14/2022 12:15	20 ml		45	11	2022	15.67	0.33	15.33	3.25	18.92	55762	59190	81%	94%	36%	27%
22R177		11/15/2022 10:45	20 ml		46	11	2022	19.02	4.17	14.85	3.48	22.50	54978	59214	66%	93%	37%	23%
22R178		11/16/2022 1:05	20 ml		46	11	2022	11.58	0.25	11.33	2.75	14.33	57134	59141	79%	97%	48%	37%
22R179		11/16/2022 14:45	20 ml		46	11	2022	12.25	0.25	12.00	1.42	13.67	56840	59166	88%	96%	46%	39%
22R180		11/17/2022 9:35	20 ml		46	11	2022	15.17	5.00	10.17	3.67	18.83	57232	59576	54%	96%	54%	28%
22R181		11/18/2022 1:25	20 ml		46	11	2022	13.50	2.42	11.08	2.33	15.83	57036	59335	70%	96%	50%	33%
22R182		11/18/2022 15:50	20 ml		46	11	2022	11.75	0.25	11.50	2.67	14.42	55762	59093	80%	94%	48%	36%
22R183		11/19/2022 7:20	20 ml		46	11	2022	14.08	2.33	11.75	1.42	15.50	54978	59238	76%	93%	47%	33%
22R184		11/19/2022 22:55	20 ml		46	11	2022	12.17	0.25	11.92	3.42	15.58	55468	59141	76%	94%	46%	33%
22R185		11/20/2022 18:30	20 ml		46	11	2022	16.00	2.42	13.58	3.58	19.58	55762	59310	69%	94%	40%	26%
22R186		11/21/2022 17:40	20 ml		47	11	2022	16.08	2.25	13.83	7.08	23.17	56448	59190	60%	95%	40%	23%
22R187		11/23/2022 1:30	20 ml		47	11	2022	23.50	11.17	12.33	8.33	31.83	53704	59141	39%	91%	44%	16%
22R188		11/23/2022 17:00	20 ml		47	11	2022	10.42	0.00	10.42	5.08	15.50	54684	59141	67%	92%	53%	33%
22R189		11/24/2022 8:35	20 ml		47	11	2022	12.17	0.50	11.67	3.42	15.58	54390	59117	75%	92%	47%	32%
22R190		11/25/2022 5:25	20 ml		47	11	2022	17.83	5.00	12.83	3.00	20.83	54390	59383	62%	92%	43%	24%
22R191		11/25/2022 22:50	20 ml		47	11	2022	12.92	1.50	11.42	4.50	17.42	54096	59190	66%	91%	48%	29%
22R192		11/26/2022 16:10	20 ml		47	11	2022	12.33	1.58	10.75	5.00	17.33	54880	59166	62%	93%	51%	29%
22R193		11/27/2022 8:55	20 ml		47	11	2022	15.25	2.08	13.17	1.50	16.75	55762	59214	79%	94%	42%	31%
22R194		11/28/2022 3:40	20 ml		47	11	2022	15.23	2.42	12.82	3.52	18.75	55468	59190	68%	94%	43%	27%
22R195		11/28/2022 23:39	20 ml		48	11	2022	15.48	2.17	13.32	4.50	19.98	55860	59117	67%	94%	41%	26%
22R196		11/29/2022 19:25	20 ml		48	11	2022	13.87	0.25	13.62	5.90	19.77	55664	59262	69%	94%	40%	26%
22R197		11/30/2022 20:05	20 ml		48	11	2022	18.25	5.00	13.25	6.42	24.67	54684	59166	54%	92%	41%	21%
22R198		12/1/2022 20:05	20 ml		48	12	2022	19.92	6.00	13.92	4.08	24.00	55076	59431	58%	93%	40%	21%
22R199		12/2/2022 13:55	20 ml		48	12	2022	12.67	1.67	11.00	5.17	17.83	56448	59214	62%	95%	50%	29%
22R200		12/3/2022 9:35	20 ml		48	12	2022	15.42	1.83	13.58	4.25	19.67	55272	59141	69%	93%	40%	26%
22R201		12/4/2022 3:10	20 ml		48	12	2022	14.67	0.33	14.33	2.92	17.58	55370	59117	82%	94%	38%	29%
22R202		12/5/2022 1:35	20 ml		48	12	2022	20.50	4.58	15.92	1.92	22.42	55272	59286	71%	93%	34%	23%

Figure 5 - OEE per batch

This sheet is then used as database for the calculation of the weekly and monthly OEE, which are displayed in a dashboard.

3.4 PDCA

All the above mentioned techniques are fundamental elements of the Lean philosophy. However, these famous tools must be governed by a restless system that guides the problem-solving process. This system constitute the heart of the Toyota management framework and is called the **PDCA** cycle. Originally developed by Walter Shewhart in 1930 and later promoted by Edwards Deming, the Plan-Do-Check-Act cycle is a scientific problem solving method which has the goal to identify the main causes of loss/inefficiency and intervene in a structured way to solve them (*Loyd et. Al, 2010*).

The steps that compose the framework are four (*M.Kocik, 2017*) :

- **Plan** : recognize the possibility of a change and set the improvement plan in terms of scheduling and objectives. It includes the steps of problem identification, root cause analysis, solution generation and preparation of an implementation plan.
- **Do** : put the improvement implementation plan into action. To successfully do it great support of the management is required.
- **Check** : Check and test whether the solutions bring the expected and required results. At this stage it will therefore be necessary to carry out a new data collection and analysis to be compared with the data collected in the plan phase and verify the effective occurrence of the change.
- **Act** : if change actions have proven to be successful, they must be permanently applied and standardised. In addition, a monitoring plan will need to be implemented to monitor the change.

The PDCA cycle is an iterative process, so if the actions prove unsuccessful, it will be necessary to return to the first "Plan" phase and restart the cycle.

Starting from this framework, various problem solving methodologies have been developed to create a communication standard and to reinforce PDCA at all levels of the organization. Among these, the focus will be on **A3 Thinking**, one of the most important problem solving methodology as well as the one used in our project to guide the improvement process.

3.5 A3 Thinking

The A3 Thinking method is a problem solving methodology which supports a structured approach to improvement projects. It's a powerful tool that helps in streamlining the project and supporting communication (G. Oversluizen et. al, 2021). Moreover, it can also be seen as managerial approach to foster and develop a continuous improvement
culture within the company. The idea behind this approach is that any problem that organizations may encounter should be summarized and communicated in a single paper sheet, called **A3 report**. The latter owes its name to the fact that its dimensions are those of an international-size A3 piece of paper (*N. Loyd et. al, 2010*).

The seven elements of A3 Thinking

The mind-set behind the A3 system can be embodied in seven elements (*D. K. Sobek et. al, 2008*):

1. Logical thinking process : Be able to think and act rationally in decision making and problem solving. Much emphasis is placed on discerning and identifying the difference between "cause" and "effect". A proper utilization of A3 reports helps to promote a correct logical thinking processes to address all important details, anticipate possible obstacles and take into account the possible effects of corrective actions implementation.

2. Objectivity : Human thought is by nature subjective and so is his mental representation of reality. A3 thinking seeks to reconcile these multiple points of view in the search for a more common and objective vision that includes all perspectives. Problem solvers necessarily start with their view of reality, making it explicit and sharing it with others. Next, they are forced to test their vision by collecting quantitative facts and comparing it with other problem solvers until it is found that the "picture" is accurate. In other words, it is a co-constructed representation of a co-constructed reality.

3. Results and process : Achieving goals using inefficient process is as much unacceptable as following the process and not achieving results. Toyota mentors want their workers to really understand the problem, investigate all the alternatives and know how the proposal fits into a larger vision. So, the PDCA process together

with the A3 approach is applied until are achieved the results that reflect an acceptable level of understanding.

4. Synthesis, distillation, and visualization : As its name suggests, the A3 report is synthetic by nature. The added value of synthesis is to force a certain way of thinking and organize the knowledge acquired during the process of solving the problem. This exercise allows to put together pieces of multiple information and acquired at various times of the process in a single "picture". Moreover, very often the most efficient way to divulge and share information is that of graphic representation. For this reason, A3 Thinking encourages the visualization of the most important information to communicate the message clearly and efficiently.

5. Alignment : The fifth element of the A3 Thinking highlights the value of developing the consensus of all parties involved in the improvement process. This includes a 3D type of communication : horizontally between the various organizational functions, vertically with respect to hierarchies and back and forth with respect to time.

6. Coherence within and consistency across : One of the fundamental points of the A3 report is to establish a connection and a logical thread between its sections. Very often we can't see the efficiency of a solution just because the problem solver is not coherent. Moreover, the issue to be tackled must be consistent with the organization's goals and values.

7. Systems viewpoint : The last element of A3 Thinking highlight the importance of considering the whole system and not focus on the single part of it. Indeed, solving a problem in one part of the system doesn't have to worsen another one, otherwise the problem will only be shifted. The problem solver must therefore maintain a broader overview to promote the good of the entire organization.

Conceptually, the A3 is divided into a series of boxes that "tell" the evolution of the improvement process starting from the problem statement, going through the definition of the current condition and the targets, continuing with the root cause analysis and the development of countermeasures to finally reach the phase of monitoring and standardization of results. The sequence of the A3 forces a certain logical flow of thought when implementing improvements; nevertheless various iterations will be required since usually it is not a linear process (*G. Oversluizen et. al, 2021*).
Going more specifically into the methodology, the elements that constitute the A3 report are described in detail below.

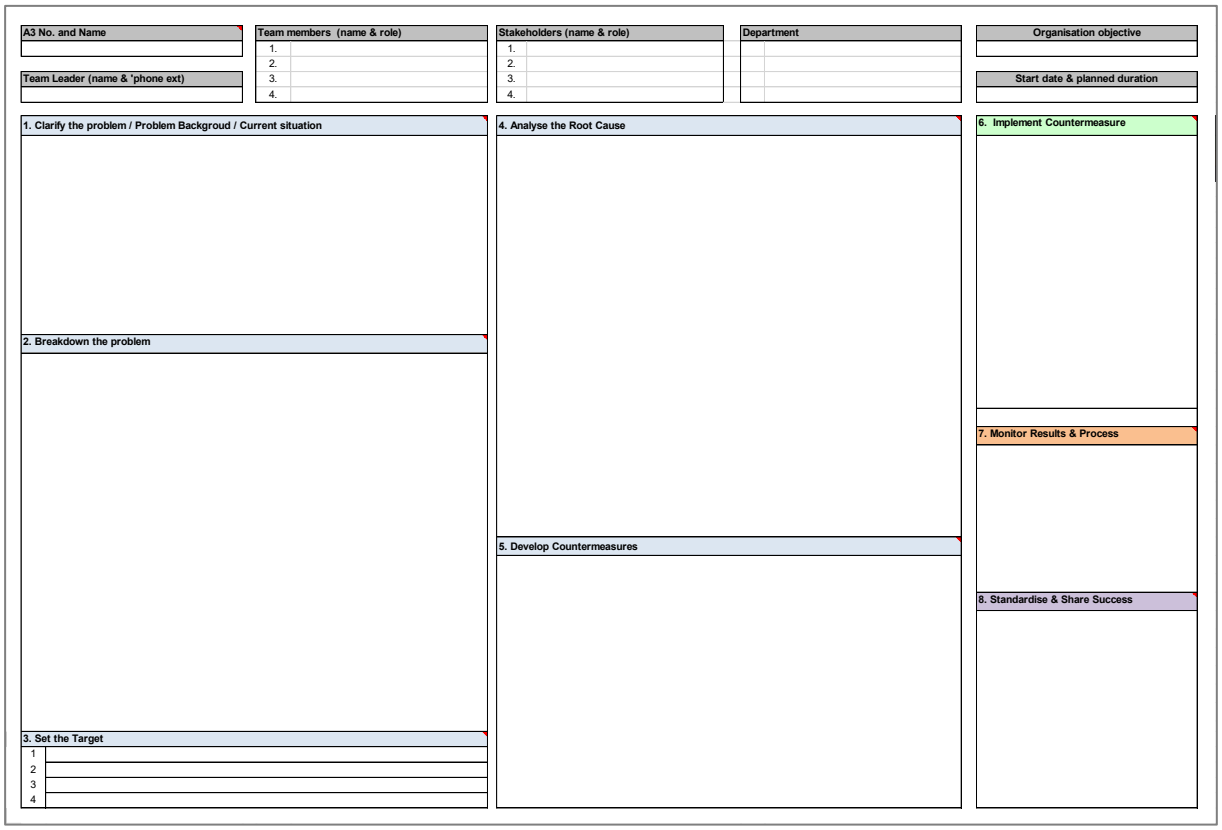


Figure 6 - A3 Thinking Report

First of all, underlined at the top of the report, is the **title** of the project. The title must be clear and explanatory of the purpose of the project to immediately capture the attention of the stakeholders. Next to the title are usually indicated the names of the members responsible for the A3 and the date.
The first box of the A3 is represented by the **Problem Background**. In this section the problem is clarified and presented in all its aspects, answering questions such as What is the problem? What is the current performance that needs to be improved? Who is interested in the problem? What benefit does solving this problem have for me? How does it help to address the goals of the business?

To follow, there is the **Problem Breakdown**, which describes in detail the current situation. At this stage, the *Value Stream Map* is often used to describe the process and highlight its criticalities. In any case, everything described in this section must be strictly quantified and supported by operational evidence (*Gemba Walk*).
After highlighting the current situation, the project team together with stakeholders define the **Targets/Goals**. In this section, the main objective of the project, previously specified in the background, is deepened in quantitative detail. To be complete, the goal statement must be composed of: Action verb + object of the action + from "current state" + to "future state" by "date".

The next step in the A3 is to **Analyse the Root Cause** of the problem detected in the current state by considering as many potential cause factors as possible. Different

techniques and methods can be used for this purpose, among the most important there are Interviews, the *Ishikawa diagram*, the *5 Whys* analysis, the *Cause and effect analysis*, *FMEA/FMECA* and *Pareto Charts*.

Root causes should then be addressed in the **Proposed Countermeasures.** Identify an effective countermeasure that directly addresses the root cause. For each countermeasure must be specified its impact on the target and the required implementation effort. They will then be prioritized considering the trade-off between implementation difficulties and final impact and included in a priority list. It will therefore be developed an implementation plan in which the estimated start and end dates of each countermeasure's implementation will be present together with its responsible.

At this point, it will be finally the time to **Implement the** selected **Countermeasures** with the definition of a detailed action plan.

Once the countermeasures are implemented, will come the time of the **Monitoring** phase. The results and the process will then be monitored through some established KPIs to determine if the desired targets have been reached and take corrective action if not. It may take several attempts to achieve the expected results, but this is part of the normal "*learning by doing*" process.

Finally, **Standardize and share success**. The new process and set as new standard will be documented. In addition, it will be crucial to share success with all members of the organization to increase the level of involvement and confidence in the process. Examples of actions that can be done to succeed in this last phase are implementing *visual management*, use *control charts* to test results, present the results to senior management and recognise and reward the team.

As pointed out in the previous paragraph, the A3 Thinking methodology derives and develops from the PDCA. In fact, each phase of the A3 report can be traced back to the corresponding phases of Plan-Do-Check-Act, as highlighted in Figure 7.

A3 Thinking is the methodology that **guided the development of our project**, providing a structured approach to the problem-solving process.

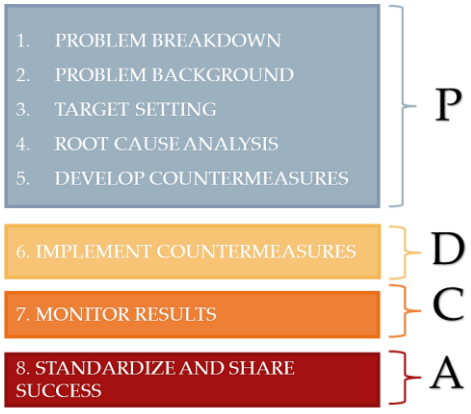


Figure 7 - Link between A3 Thinking and PDCA cycle

For this reason, the following paragraphs will follow the A3 Report structure, starting from the Problem Background to the last phase of Standardization and Sharing of successes.

4 Problem Background

The Caponago manufacturing plant is separated into 2 main areas:

- **Terminal sterilization**, where the product is filled in a controlled environment and then is sterilized.
- **Asepsi**, where the product is filled in an aseptic environment and doesn't need a terminal sterilization.

Our project focused on the "terminal sterilization" production area of the plant, which is responsible for the most of the plant's output.

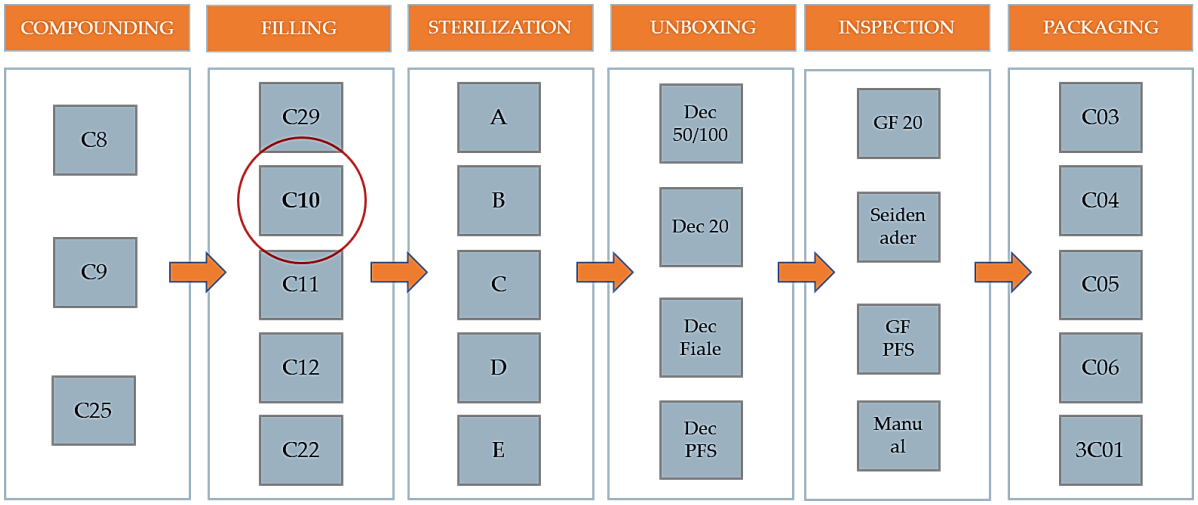


Figure 8 - Terminal sterilization plant scheme

This area is composed of :

- **3 compounding rooms**: in this area all the ingredients are weighted and mixed into a vessel (generally of 1250L of volume) in order to create the formula of the product.
- **5 filling lines**: where the containers are filled with the product, then are capped, sealed with a crimp and then put into metal boxes, that will protect the product during the sterilization phase.
- **5 autoclaves**: these are used for the sterilization of the product. After the filling phase, the metal boxes are put in a chart that enters the autoclave, which makes it rotate for a predetermined cycle time at particular temperature and ensures the sterilization of the product.
- **4 Unboxing lines**: where the product is taken out of the metal boxes and is put into cardboard boxes that will be later sent to the inspection department. After this phase, some samples are taken out of each batch and are sent to both a

chemical and a microbiological laboratories, that will analyze the product in order to make sure that it is safe for the customer.

- **3 automatic inspection lines and 3 manual inspection rooms:** Here each single unit produced is carefully inspected for a wide range of defects, according to regulations and customer requirements. If a batch is non-compliant it has to be further inspected until all the defective units are removed, otherwise the batch is rejected.
- **5 packing lines:** where the batches that have been inspected and were analyzed in the laboratories can finally be packed and labelled, ready for shipping.

The project was carried out within the filling department as it is the department that was pointed out as the most critical and the one that would benefit the most from OPEX projects.

As previously said, the filling department is composed of 5 filling lines: W10, W11, W12,W22 and W29.

Among all the 5 filling lines the most strategic is the W10 since the current demand leans towards the product and the format filled in this line and as a consequence the line operates 3 shifts per day 7 days a week.

Despite the strategic relevance of this filling line, **its performance in terms of productivity got worse during the years** reaching an unacceptable level.

For all these reasons, the W10 filling line was the perfect candidate for the Operational Excellence projects that the company has been carrying on in order to establish a lean culture.

5 Problem Breakdown

To understand which are the component parts of the problem it is necessary to firstly realise what is the starting situation. For this reason, a detailed description of the operation of the line C10/W10 will be firstly presented in this paragraph. Then, the quantitative analysis intended to deeply describe the starting condition and identify the areas of interest for the focus of the project will be shown.

5.1 Process Description

All the 5 filling lines have a similar structure in terms of main components, but they all differ in some details. They are all fully automated lines and each one requires 4 operators: one at the input, one at the output, a third one performing in process control and the last one in the clean area and overlooks the filling machine

The W10 line is composed by 5 main parts:

Washing machine: here an operator has the job to place a box of glass vials on a rotating table that allows to open it and flip the vials (the vials in the boxes are upside down). After the vials are out of the box and flipped they are pushed by the operator into a conveyor which has the purpose to direct the vials towards 10 parallel canals in which the vials are filled with hot water and enter the machine.

Once inside the machine the vials are transported into a water tank, which has the purpose to wash the outside part of the vials. At the end of each of the 10 canals, the vials go through a gate that allows the passage of one vial at the time for each canal.

Here the 10 vials get uplifted and are grabbed by pincers that hold the vial upside down. Then the machine brings the vials through 8 consecutive stations: stations 1,3,5,7,8 inject air into the vials to dry them out while the stations 2,4,6 inject water to wash it. After the last drying station, the pincers release the vial that is taken into the second machine. The machine is able to process 180 vials per minute.

Depyrogenating tunnel: the washing machine puts the vials into a conveyor that goes through a depyrogenating tunnel. Here, the washed vials are heated at a predetermined temperature for the whole run inside the tunnel. The conveyor's pace is set in order to guarantee a minimum standard throughput time that guarantees that the vials are sterile and all microbes have been eliminated.

These first two machines (washing machine and depyrogenating tunnel) are coupled: this means that they operate at the same pace and if one of the two machines stops for any reason, the other stops as well.

Filling Machine: At the end of the tunnel, the vials are now sterile and enter inside the third phase: the filling of the vials. This is the only station where the product is exposed to the external environment, and for this reason it is located in a separated,

more controlled area: the “Clean Area”, where the vials stay constantly under laminar flow of air.

On the other hand, the first 2 machines are located in the “White Area“, where there is a lower level of cleanliness. Here the vials, are led into a rotting buffer, which has a capacity of approximately 300 vials. Sensors can detect when the buffer is full and consequently stop the Depyrogenating tunnel.

Once the vials exit the buffer, they are directed towards cells that will take the vials one by one. Here the vial is transported to the filling station which is equipped with 16 needles: the first 8 are able to inject nitrogen into the vials (it is needed to prevent the oxidation of the product), the second set of needles, fill the vials with the product, with a rate of 180 vials per minute.

After the vial is filled, it goes through another flow of nitrogen to ensure the absence of Oxygen before the vial is sealed in the capping machine:

The **Capping Machine**, has 24 separated stations which rotate and one at the time can inject once more nitrogen and immediately after put the cap on the vials, isolating the product from the outside.

Once the vial is filled and sealed it goes through a sensor that identifies the vials that had not been sealed properly or were not capped at all. If the vial is not compliant the machine automatically takes it out of the flow and leads it into a canal that makes it fall into a bin placed outside the carters.

The good vials instead go through an ”S” shaped curve that takes them outside the Clean Area and back into the white area. The machine is able to process 180 vials per minute

Crimping Machine: To ensure that the vial is sealed, the crimping machine has the purpose to cover with an aluminium foil the cap and secure it to the vial.

First the vials arrive in a conveyor that lines up the vials one by one and leads them towards the crimping machine, here, at a distance of 70 cm from the station, there is a sensor that measures the maximum queue possible: if the Crimping machine stops, the vials line up until they reach the sensor and it stops the Filling Machine. The capacity of this buffer is low and it amounts to 15 seconds of timespan between the stoppage of the crimping machine and the filling machine.

Before entering the crimping machine the vials go through another sensor that controls if the cap of the vial is properly placed. Then the vials enter into the Crimping machine: The machine has 12 stations and rotates, grabbing the vial from the conveyor and releasing it on the opposite side, with a rate of 180 units/minute.

Just before entering into the station, the crimp is placed over the cap from above. Then the vial goes into the machine: it is locked in position by two plates pressed together that rotate and also push the crimp on the vial.

Then, while the station rotates, it goes through a set of blades that bend the bottom of the crimp in order to fix it to the vial. The crimps are refilled into the machine by an operator once every 5 minutes.

After this process, the plates release the vial that is immediately checked for flaws in the crimp, if the crimp is not sealed properly or it is not present at all the vial is automatically taken out of the flow and led into a canal that makes them fall into a bin placed outside the carters.

The good vials continue their path into a conveyor that leads them into a rotating buffer, with a capacity of 300 vials, that decouples the crimping station from the Boxing station. If this buffer reaches maximum capacity, a sensor detects it and stops the crimping machine.

Encasing Machine: the buffer directs the vials into 2 parallel canals that enter the Boxing machine:

Here the vials line up in position where 2 robotic arms grab the vials with a set of 14 suction cups each and insert them in the metal boxes at a rate of 240 vials/minute that will protect them during the sterilization phase.

The two robotic arms are able to fill 2 boxes in parallel, placing 7 vials inside the boxes every cycle. Once the boxes are full (each box contains 298 vials) the machine stops and gives an alert for the operator.

The operator then manually activates a chain system that rolls the boxes outside of the carter 2 at a time. He then has to close the 2 boxes and remove them from the line, laying them on a table. In the mean time, two empty boxes that were waiting in line advance thanks to the same chain system, and they are replaced by two more empty boxes that are placed on the line through an elevator.

The operator then performs a second cycle to take out also the second set of full boxes, the four empty boxes advance in position to be filled by the two robots and another couple of empty boxes are placed by the elevator. At this point the machine can start again its cycle

The operator then can load the boxes on a metal chart that secures them and will go inside the autoclaves for the sterilization phase.

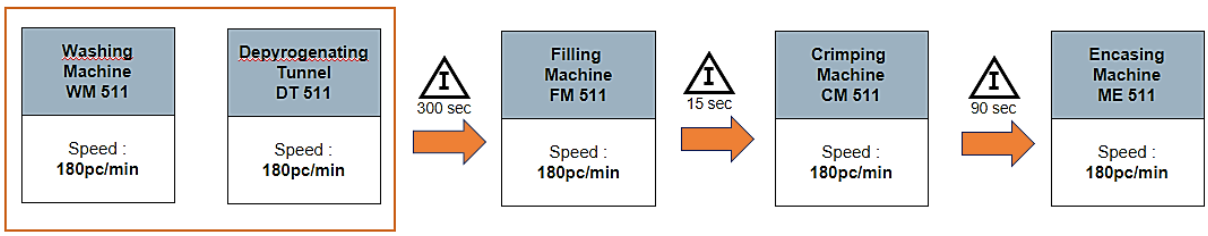


Figure 9 - C10 filling line scheme

5.2 Problem Breakdown

The first step towards the breakdown of the problem concerns the analysis of the OEE. The measurement system of the latter, as explained in the previous paragraph, has been validated and implemented since week 25 of 2022. Since then, all the data needed to calculate the indicator have been systematically collected and transcribed into a dedicated file that is continuously updated by the worker in charge.

Analysing these data, it was possible to derive the average of the Availability, Performance and Quality components of the line recorded in the **time period between week 25 and week 43**. The latter was taken as a reference since it coincides with the beginning of our project into the company.

As can be seen from the results shown in Table 1, **the average OEE of the observation period is 28.6%.**

Week	N° batches	Availability	Quality	Performance	Media OEE
25	9	65%	95.6%	44.5%	27.5%
26	10	71%	96.8%	44.3%	30.7%
27	6	53%	96.9%	48.6%	24.7%
28	5	49%	96.6%	48.7%	23.0%
29	6	60%	95.1%	42.3%	23.7%
30	11	75%	95.9%	48.7%	35.0%
31	7	76%	97.0%	47.7%	35.0%
35	8	74%	94.5%	43.2%	30.3%
36	8	60%	93.4%	41.6%	23.0%
37	9	70%	93.1%	45.5%	30.4%
38	8	66%	96.0%	45.2%	28.9%
39	4	47%	93.8%	40.5%	17.7%
40	5	47%	93.2%	53.8%	21.7%
41	10	79%	94.4%	45.3%	34.1%
43	8	64%	94.7%	44.4%	26.7%
Totale	**114**	**66%**	**95.2%**	**45.5%**	**28.6%**

Table 1 - C10 OEE from week 25 to week 43

Breaking down the indicator into its components, the current **average Availability** resulted to be equal to **66.2%**, the current **average Quality 95.2%** and the current **average Performance 45.5%.**

From what has been said it is clear that most of the losses of the line are due to Availability and Performance losses. For this reason, it was decided to focus the attention on these two components and further break down the problem in the following dedicated paragraphs.

5.2.1 Availability

As for availability, the indicator takes into account all those losses due to machine unavailability, waiting of any kind and changeovers. In our specific case, the unavailability of line AA511 can be traced back to four macro categories of losses :

- **Machine Downtime** : When the line stops due to an unplanned event and requires an intervention. The downtime, is not necessarily related to a breakdown of a machine or equipment, it can also be related to a deviation of the process from the Standard Operating Procedures.

- **Breaks** : Each shift, the operators have the right to two 15 minutes breaks, and one 45 minute lunch break. If the Filling department has enough operators, they manage the breaks in order to ensure that the line is never unsupervised hence doesn't have to stop. Although it could happen that the department is understaffed and there is not enough operators to replace the 3 people that have a break. In this case the line must stop, as it can't operate unsupervised. When the team comes back from the break, the operator in charge writes down the break in the "breakdown" section of the FLP

- **Changeovers:** These stops, include all the activities that are carried out between the filling of two batches: These are called "Cleaning activities".

There are 2 types of changeover: the "complete" and the "reduced". The complete is more accurate and has an average duration of 3.3 hours

While the "reduced" changeover allows to perform a less accurate cleaning and doesn't involve the dismantling of certain components, allowing to use them also for the following batch. In this case, the average time for the operations is 1 hour

- **Format changes** : these are activities that only occur when the line needs to switch production from 10 ml to 20. It consist in exchanging the parts that handle the vial and takes a long time to perform, although the number of 10 ml campaigns is very low (4 campaigns forecasted in 2023)

- **Others** : such as the waiting, scheduled interventions, training activities or department meetings.

As highlighted in the previous paragraph, the average line availability at project start date was 66.2%. As a result, the total loss of line availability amounts to 33.8%. By analysing the data collected between week 25 and week 43, it was possible to understand which macro categories of losses have the greatest impact on the total availability loss. The data summary is shown in Tab 2 and in Figure 10.

Week	Fermi Macchina [h]	Fermi Pause B/M [h]	Fermi per "Altro" [h]	Tempo per Cambi Lotto [h]
25	15.22	5.33	0.67	34.78
26	10.03	4.83	4.72	32.62

27	6.23	4.25	23.42	51.12
28	13.60	3.83	3.67	68.17
29	4.48	6.42	0.00	64.32
30	6.37	4.83	0.33	31.72
31	4.08	5.08	1.67	18.00
35	8.60	7.42	0.75	20.28
36	19.87	8.58	0.50	43.88
37	4.40	9.75	7.75	33.70
38	3.00	6.75	18.78	34.95
39	13.42	2.67	1.50	75.83
40	8.83	3.75	0.00	86.53
41	7.05	5.17	0.25	21.38
43	19.90	6.67	9.58	27.32
Totale	**145.08**	**85.33**	**73.58**	**644.60**

Table 2 - C10 machine stops from week 25 to week 43

In Figure x, the breakdown of Availability losses in the four macro categories for each week is shown.

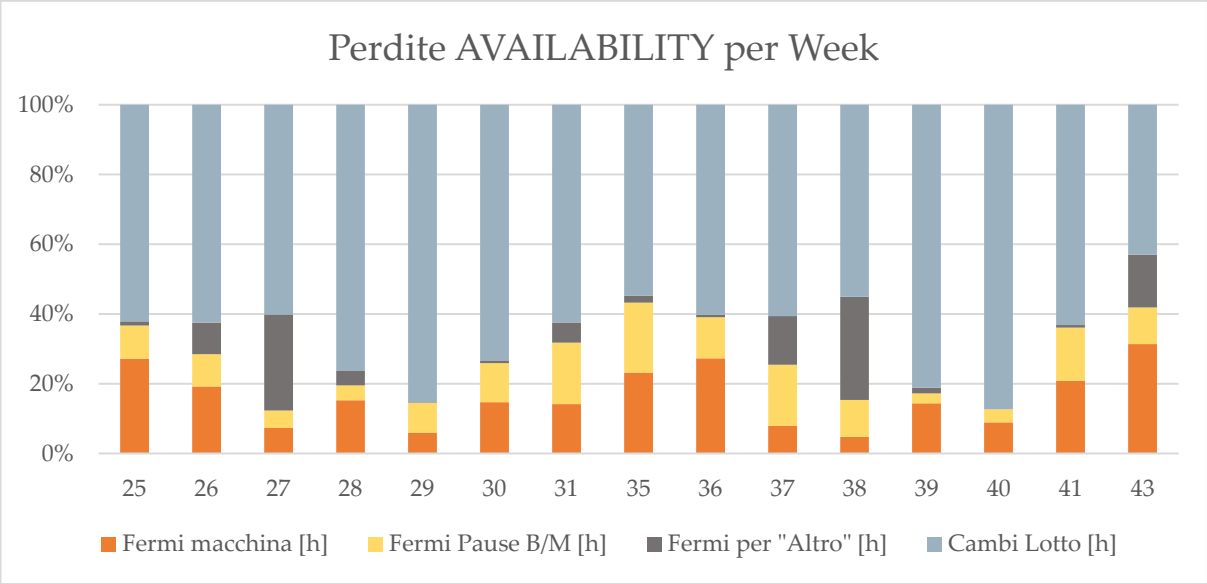


Figure 10 - Pareto analysis on Availability losses

As clearly visible, most of the losses come from the category "Changeovers", highlighted in sky blue.

Carrying out a Pareto analysis that puts together the data of all the weeks, it is concluded that **68.0% of the losses of availability is attributable to time spent for Changeovers**, 15.3% of the losses derives from machine stoppages, 9.0% from breaks and 7.8% for time spent on material waits and scheduled maintenance.

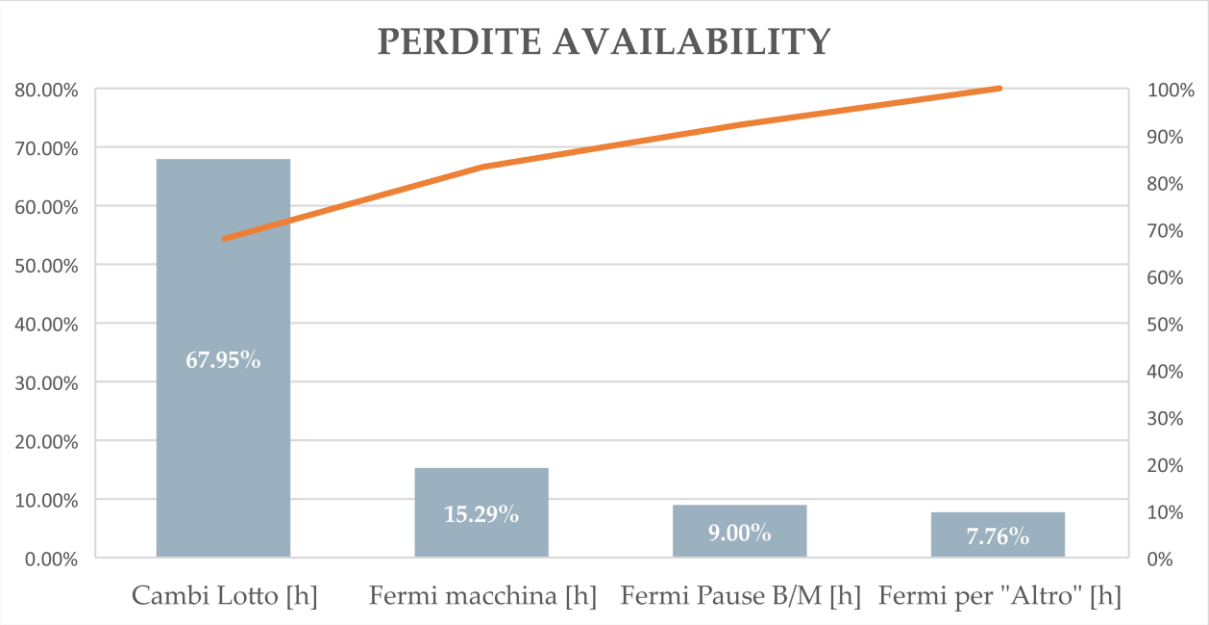


Figure 11 - Pareto analysis on Availability losses

Being the highest time loss among the ones pointed out, **we narrowed our focus on the Changeovers**.

5.2.1.1 Changeovers

As previously explained, there are 2 types of changeover activities that can be performed: a **complete cleaning** or a **reduced cleaning**.

The reduced cleaning, implies less activities and requires less time to be performed.

The quality regulations impose as a constraint, a maximum holding time that can pass between two "Complete cleaning campaigns". This holding time depends on the formula of the product: In a small percentage of the batches it amounts to 24 hours and in most cases it is 28 hours.

This means that if the line is able to fill 2 batches within the holding time, between the two, a reduced cleaning can be performed, allowing to optimize the times. Historically, **the percentage of reduced cleaning has been equal to 11%** (with a theoretical maximum of 50%). For this reason, we decided to focus our efforts towards the analysis and the optimization of the complete cleaning process.

5.2.2 Performance

As explained in the paragraph dedicated to the OEE, in calculating the **Performance** indicator are taken into account any events that prevent the process from operating

at the maximum validated speed. So, the latter will be impacted mainly by discontinuous productions due to minor stoppages (duration less than 10 min) and speed losses of any type.

In our case, the company did not envisage a data collection method for this type of losses, so it was not possible to break down the performance issue. For this reason, a sample **data collection campaign** was carried out directly at the workshop, during which all the minor stoppages were registered together with the indication of the their duration and the reason why they happened.

The data collection campaign was carried out for several days **from week 43 to week 49** and at different times of the day, in order to capture as many sources of variability as possible. The average duration of each survey was around 111 minutes, as shown in the summary table below.

Data	Lotto	T rilevazione [min]	Somma microfermi [min]	% microfermi
13/10/22	22R144	95	33.33	35%
14/10/22	22R146	165	73.92	45%
24/10/22	22R150	195	54.83	28%
26/10/22	22R152	87	22.83	26%
28/10/22	22R156	105	27.45	26%
02/11/22	22R161	95	43.88	46%
24/11/22	22R190	60	18.67	31%
30/11/22	22R197	90	31.33	35%
TOTALE		892	306.25	34%

Table 3 - Data collection campaign summary

Although the production line AA511 is running 24 hours a day, the collected sample of data has been a good starting point for the definition of the current situation and the breakdown of the problem between the various machines constituting the production line.
However, before analysing the data, it was necessary to clean and standardise them. To do so, it was necessary to lead back the different types of micro stops detected during the Gemba Walk to a certain number of standard categories of micro stops for each machine, reported below.

CATEGORIE FERMI				
WM 511	**DT 511**	**FM 511**	**CR 511**	**ME 511**
Giunto apertura pinza incastrato	Anomalia nastro	Errata presa tappo	Controcontrollo scarico	Mancata presa flaconi
Giunto chiusura pinza incastrato	Anomalia Temperatura	Nessuna inversione pompa	Tappo alto	Sovraccarico Robot
Flacone incastrato		Soma errori mancanza tappo	Tappo incastrato	Cambio cassette
Sovraccarico spintore		Controcontrollo scarti buoni	Flacone rovesciato	Reset allarme

Sovraccarico arresto al carico			Reset allarme	Flaconi malposizionati
			Flacone non ghierato	Mancanza cassette in posizione
			Accumulo scarti	Spinta in ingresso non completa
			Controcontrollo scarti buoni	
			Flacone rotto	
			Allarme paratia	
			Regolazione altezza guide	
			Mancanza ghiere	
			Stella di scarico	
			Sovraccarico contro guida coclea	
			Ghiere incastrate in lamiera tramoggia	

Table 4 - Micro-Stops categoriezation

After assigning each micro-stop to the corresponding category, we were able to proceed with the analysis. Firstly, a Pareto analysis was carried out on the total duration of the micro stops for each machine, in order to identify which machines had the major impact on the Performance indicator.

DURATA TOTALE MICROFERMI PER MACCHINA			
Macchina interessata	**Durata totale microfermi [s]**	**% fermo**	**% cumulata**
Ghieratrice	6448	34.51%	34.51%
Incassettatrice	5780	30.93%	65.44%
Clean	3435	18.38%	83.83%
Lavatrice	1802	9.64%	93.47%
Tunnel	1220	6.53%	100.00%
Totale	18685	100%	

Table 5 - Micro-stops total duration per machine

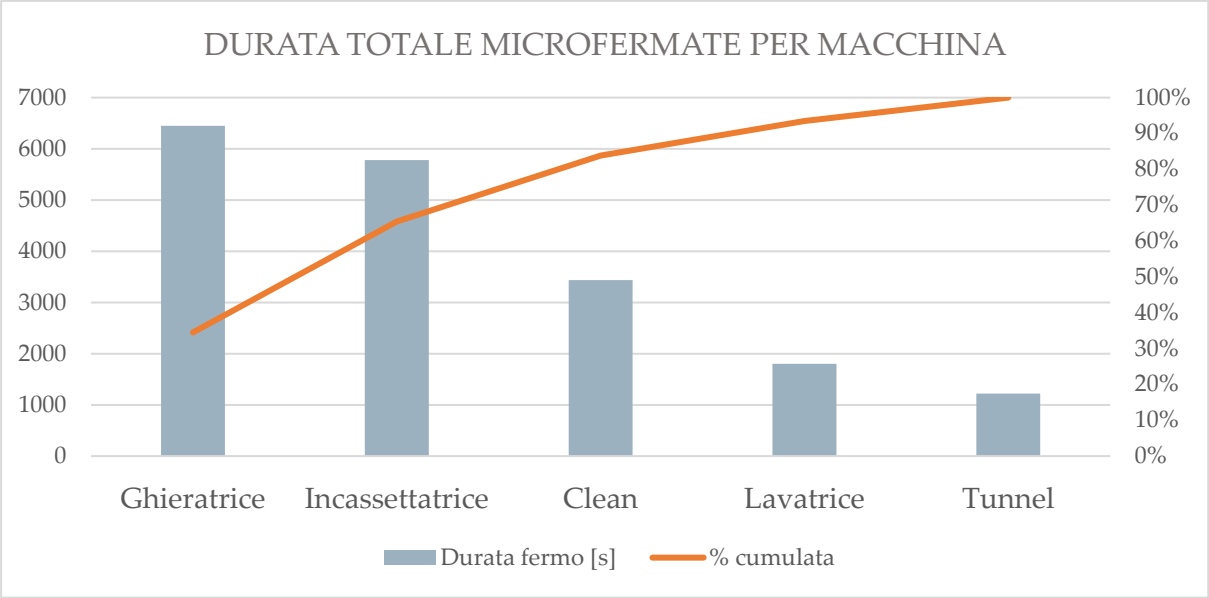


Figure 12 - Pareto Analysis on AA511 Performance losses

As can be clearly seen from the Pareto graph, the biggest problems in terms of micro stoppages occur on the **Crimping Machine (CR511)** and on the **Encasing Machine (ME511)**. In particular, **35%** of the total time lost for minor stops is attributable to the **Crimping Machine**, while **31%** is attributable to the **Encasing Machine**.

Having realized which machines have the greatest impact on the Performance losses, a detailed analysis has been carried out with regard to CR511 and ME511 in order to identify the types of micro stops that occur most frequently on the latter. The result of the detailed Pareto analysis is shown below.

MICROFERMI GHIERATRICE				
Microfermata	**Durata [s]**	**% su fermi ghieratrice**	**% su fermi totali**	**% cumulata su totale**
Tappo alto	1938	30.06%	10.37%	10.37%
Flacone rovesciato	1275	19.77%	6.82%	17.20%
Tappo incastrato	840	13.03%	4.50%	21.69%
Regolazione Altezza guide	500	7.75%	2.68%	24.37%
Stella di scarico	375	5.82%	2.01%	26.37%
Flacone rotto	240	3.72%	1.28%	27.66%
Reset allarme	230	3.57%	1.23%	28.89%
Somma errori mancanza chiusura	220	3.41%	1.18%	30.07%
Accumulo scarti	155	2.40%	0.83%	30.90%
Flacone rotto	150	2.33%	0.80%	31.70%

Controcontrollo scarico	125	1.94%	0.67%	32.37%
Mancanza ghiere	120	1.86%	0.64%	33.01%
Pulizia con aria compressa	100	1.55%	0.54%	33.55%
Anomalia sensore	90	1.40%	0.48%	34.03%
Mancanza oggetti a carico	60	0.93%	0.32%	34.35%
Allarme 3 flaconi senza tappo	20	0.31%	0.11%	34.46%
Flacone non ghierato	10	0.16%	0.05%	34.51%
Totale fermi ghieratrice	**6448**	**100.00%**	**34.51%**	

Table 6 - Micro-stops detail for the Crimping Machine

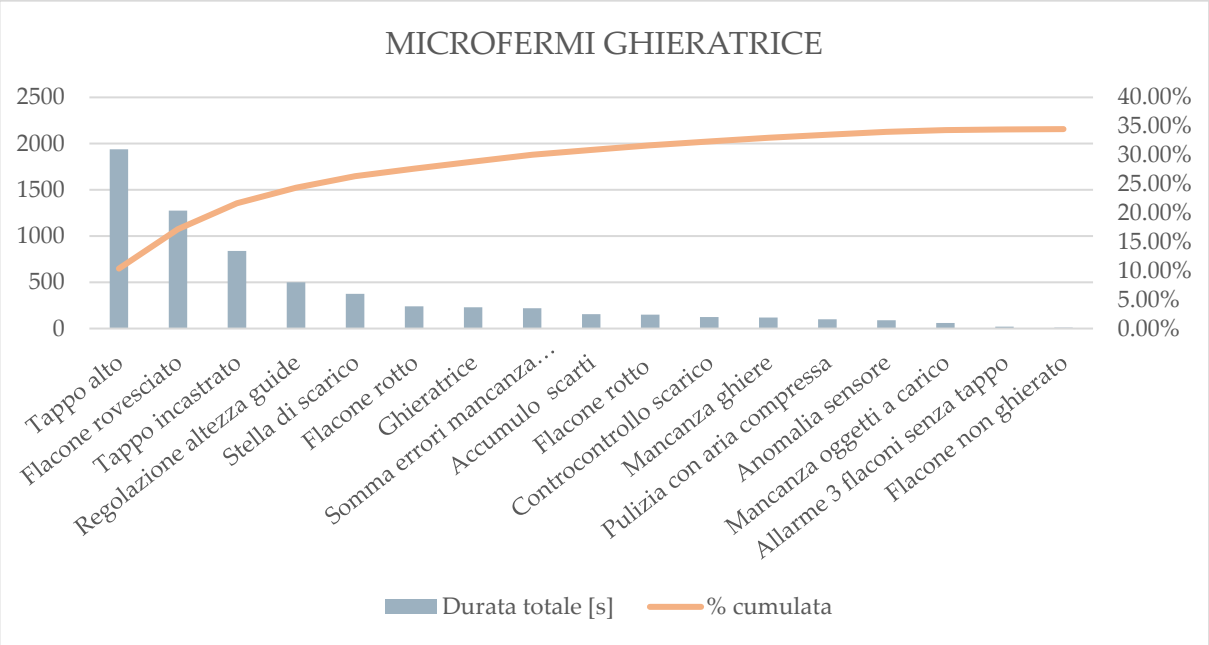


Figure 13 - Pareto Analysis on Crimping Machine Performance losses

As for the **Crimping Machine**, the three main categories of micro stoppages are "**High Cap**", "**Spilled Vial**" and "**Stucked Cap**". In particular, "High Cap" represents 30% of micro stops of the Crimping Machine and 10.37% of the micro stops of the entire line in terms of duration. On the other hand, "Spilled Vial" is responsible for 19.8% of the micro stops of the Crimping Machine and 6.8% of the micro stops of the entire line.

The micro stop "**High Cap**" occurs when the vial, coming out of the Clean area after the Capping Machine, has the cap in a higher position than expected. The vial, once entered the Crimping Machine, will cause it to stop provisionally due to the fact that the ring can not be inserted correctly. The operator must then reset the alarm and force the restart of the machine, which will discard the vial in question.

Figure 14 - Vial with high cap

Figure 15 - Spilled vial

The micro stop "**Spilled Vial**" occurs instead when the vial falls on the collection lung at the exit of the Clean Area or on the guide that precedes the Crimping Machine. When it arrives near the entrance of the Crimping Machine, a sensor detects that the vial is in a horizontal rather than vertical position and stops the machine. The operator must then lift the bottle and restart the machine.

The micro stop "**Stucked Cap**" always occurs in Chicane when the cap of a vial remains stucked between the clamps present in that area and the vial itself, not allowing its advancement. This micro stop does not bring up an alarm, therefore it can be time before the operator notices and stops the machine to manually "unlock" the vial.

Figure 16 - Stucked cap

Together, these three categories of micro stops are responsible for 21.69% of the performance losses of the entire line.

As for the **Encasing Machine**, the result of the analysis was as follows:

MICROFERMI INCASSETTATRICE				
Microfermata	**Durata [s]**	**% su fermi incassettatrice**	**% su fermi totali**	**% cumulata su totale**
Sovraccarico Robot	2185	37.80%	11.69%	11.69%
Cambio cassette	2020	34.95%	10.81%	22.50%
Mancata presa flaconi	465	8.04%	2.49%	24.99%
Flaconi malposizionati	210	3.63%	1.12%	26.12%
Mancanza cassette in posizione	210	3.63%	1.12%	27.24%
Flacone rovesciato	180	3.11%	0.96%	28.20%
Incassettatrice	135	2.34%	0.72%	28.93%
Allarme paratia	120	2.08%	0.64%	29.57%

Ventosa sporca	90	1.56%	0.48%	30.05%
Flacone incastrato	85	1.47%	0.45%	30.51%
Flacone rotto	60	1.04%	0.32%	30.83%
Reset allarme	20	0.35%	0.11%	30.93%
Totale	**5780**	**100.00%**	**30.93%**	

Table 7 - Micro-stops detail for the Encasing Machine

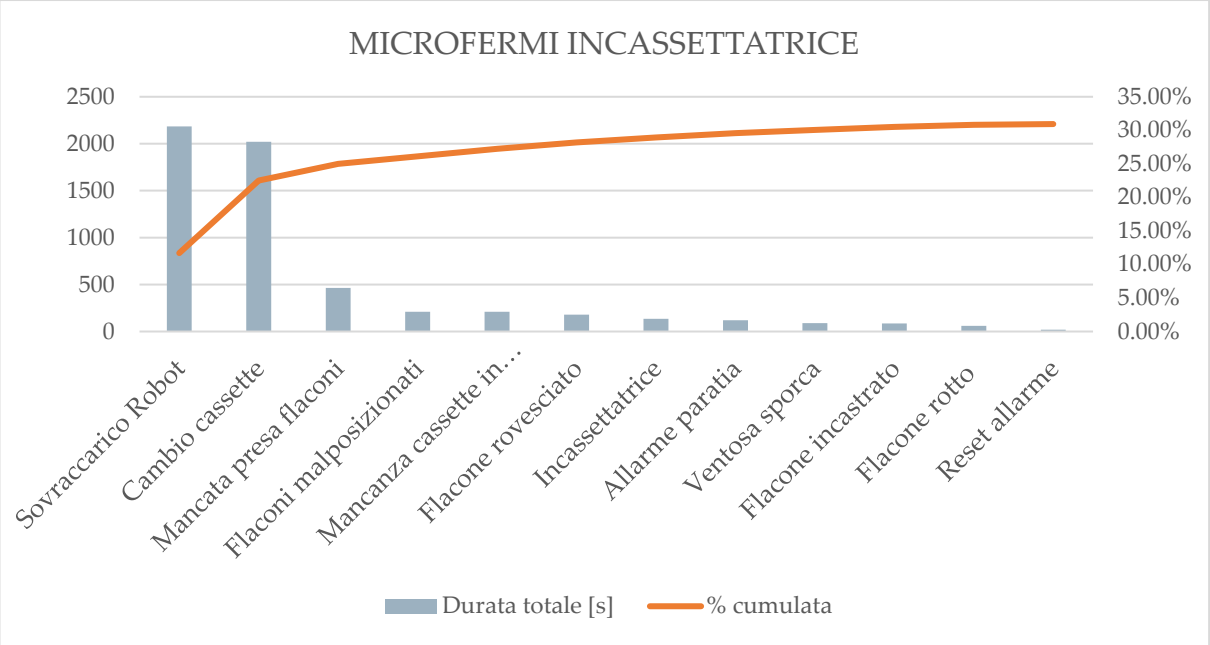


Figure 17 - Pareto Analysis on Encasing Machine Performance losses

The most frequent categories of micro stops of the Encasing Machine were "**Robot Overload**" and "**Cases Change**". In particular, the first category is responsible for 37.8% of the micro stops of the Encasing Machine and 11.7% of those of the entire line in terms of duration. The second category represents 35% of the micro stops of the Encasing Machine and 10.81% of those of the entire line.

The "**Robot Overload**" micro stop occurs when one of the two Robots fails to make the last "push" of the vials inside the cases due to lack of space. In this case the operator has to open the safety cover of the machine to try to adjust the previous vials and make room for the last row; then force the restart of the machine. In case the space is not yet sufficient, the Robot will try to place the vials in the case, but most of the time they will protrude from the edge. Then, at the time of changing cases , the bulkhead that rises to prevent the bottles from escaping during the horizontal translation of these, will meet the protrusion of the last bottles and raise the entire case, that falling during the descent of the bulkhead will make many vials come out.

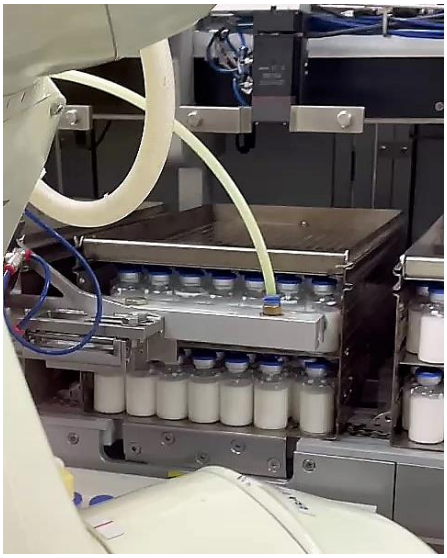


Figure 18 - "Robot Overload" micro stop

The micro stop "**Cases Change**" has been called so because it happens during the cases changeover of the machine. In this case, compared to the normal course of action, there may be problems of two types :

Figure 16 - Case embedded in input

- Incoming cases get stuck and cannot get down to the Robots. In this case, the operator will have to manually push the boxes towards the elevator that brings them down to the robots, then go back to the control centre to restart the machine.
- Operators are unable to insert the lid of the cases and are forced to waste time trying to fit it or even deform it manually.

Together, these two categories of micro stops are responsible for 22.5% of the performance losses of the entire line.

6 Target Setting

Since our first day the company has made clear and explicit what the final goal of the project was, namely to increase the OEE indicator of the Bausch AA511 line from the current 28.6% of the week 43 of 2022 to the future 45% by the end of 2023.

However, the end of our thesis project was scheduled for Week 10 of 2023, coinciding with the second week of March. For this reason, it was necessary to define together with the company the goal to be achieved by the end of our stay for the project.

It was decided to set two types of target : a "**must to have**" target, needed to declare the project successful, and a "**nice to have**" target, higher than the previous one that represents more of an ambition of the project.

6.1 Must to have Target

In order to define this target it has been decided to follow the simplest approach, that is to redefine the final objective proportionally, **assuming a constant and linear increment of the OEE from month to month.**

So, if the company wants to increase OEE from 28.6% to 45% by the end of 2023, this means that they want to earn 16.4 percentage points of productivity in 14 months (from late October 2022 to late December 2023). As a result, the OEE is expected to increase by 1.17 percentage points each month. Considering that the end of our project is scheduled for the second week of March, the increase in OEE that must be achieved is 1.17 percentage points/month for 5 months, meaning 5.85 percentage points. To conclude, **the must have target has been set as follows** :

"Increase OEE measurement from 28.6% to 34.5% by Week 10 of 2023"

6.2 Nice to have Target

Unlike the must to have targets, which was defined on the basis of a goal set at a managerial level, for the nice to have target it was decided to follow a data-based approach. For this reason, the definition of the nice to have target took place after the data collection campaign for micro stops.

To set the "nice to have" target in the most concrete and objective way, it was decided to estimate a possible increase of the OEE resulting from a Performance improvement, which represents the most impacting component in terms of losses on the indicator. Starting from the data collected, the target was estimated assuming to **eliminate the main micro-stoppages of the crimping machine** described in the

previous paragraph, since the latter turns out to be the most problematic machine and it was decided to give priority to her. Assuming to eliminate the micro stops "High Cap", "Spilled Vial" and “Stuck Cap" would lead to the elimination of 21.7% of the performance losses of the entire line. Considering that the current performance losses are equal to 55.5%, these would be reduced to 43.5%. As a result, the new **Performance** component would be **56.5% compared to the current 45.5%.**

In addition, it has been estimated that the elimination of the problem of the High Cap would also involve the elimination of about 50% of the total product waste on the line, and therefore the elimination of 50% of quality losses. Considering that the quality losses at the initial state amount to 4.8%, these would be reduced to 2.4% at after solving the “High Cap” problem, thus leading to the increase of the **Quality** indicator **from the current 95.2% to the future 97.6%.** Assuming constant the availability measure, the future OEE would become 36.4%.

Consequently, **the nice to have target has been set** rounding down the number obtained with our calculations, to account for a certain percentage of error:

“*Increase the OEE measure from 28.6% to 36.0% by Week 10 of 2023*”

In the estimation of targets the long supply lead times of any materials and spare parts by Bausch suppliers have been taken into account.

7 Root Cause Analysis

In this chapter a root cause analysis of the problem both in terms of Performance and Availability losses has been performed. First, the "**Ishikawa Diagram**" or "Fishbone Diagram" is used as a tool to identify the macro causes of the problem. So, both in terms of Performance and Availability, the main macro causes of losses have been identified based on the so-called 4M : Machine, Method, Manpower, Material. Following, for each of the macro causes for which it was deemed necessary, a **5 Whys** analysis has been carried out to go deeper and identify the so-called root cause on which to develop countermeasures.

7.1 Performance

Regarding the problem of low performance, the macro causes identified are summarized and illustrated in the Ishikawa diagram in Figure 20.

7.1.1 Ishikawa Diagram Performance Problem

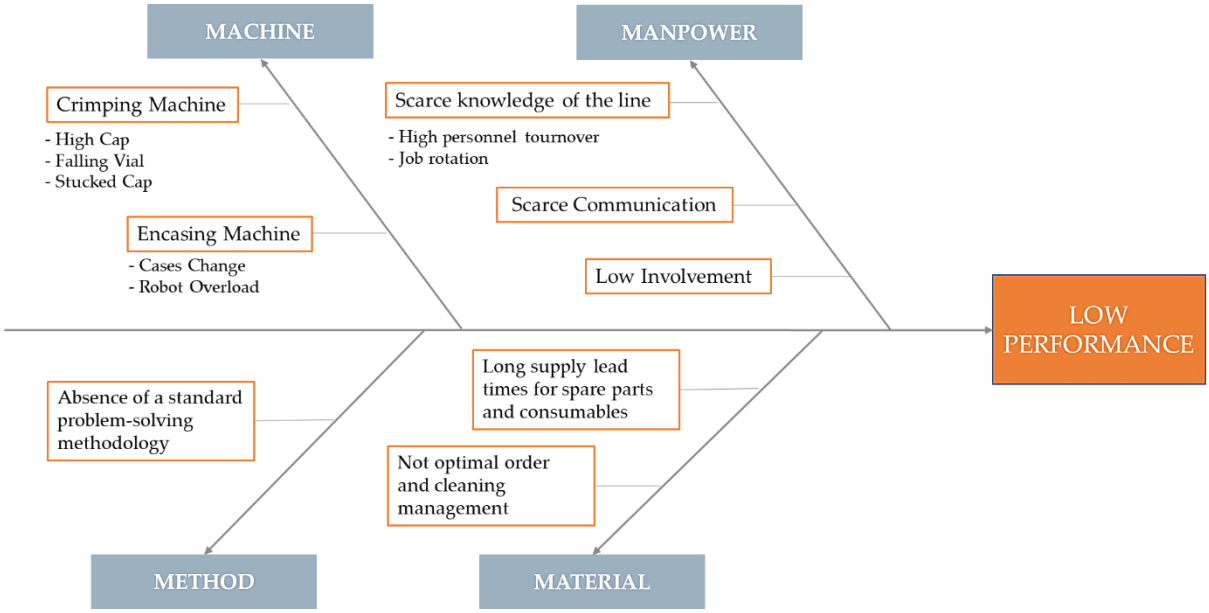


Figure 20 - Low Performance Ishikawa Diagram

Starting from the **Machine** category, the macro causes have already been identified in Paragraph 4 thanks to the detailed breakdown of the problem. The main causes of loss of performance are therefore associated with Crimping Machine and Encasing Machine. As already highlighted, the most frequent micro-stoppages of the Crimping Machine are “High Cap”, “Spilled Vial” and “Stucked Cap”, while those of the Encasing Machine are “Cases Change” and “Robot Overload”.

For what regards the **Manpower** category, the main macro-causes identified concern:

- Poor knowledge of the line by operators. This happens first of all for the high turnover of the staff and secondly because there are no dedicated teams for each line but there is a continuous rotation of the working teams on all lines. So, each operator works on the same line for a short time and does not fully master the know-how of the line. On the other hand, the strategic decision to carry out such job rotation has on its side the increase of flexibility of the operators.
- Poor communication. Both at a lower level between different shift operators and at a slightly higher level between line managers/shift managers and operators. However, the main communication problem occurs between maintenance and production departments at any level.
- Low involvement. Operators are not involved and informed about the development of the production line nor about maintenance interventions and actions carried out on it. This creates a great feeling of alienation that involves a total disinterest in the performance of the line and consequently little effort and collaboration in trying to improve it.

For the **Method** category, the main macro cause concerns the absence of a standard methodology for the resolution of the most frequent micro stoppages. Indeed, every time the machine encounters a problem of any kind, a specific alarm appears on the control panel and the operator should be trained to solve the problem in the shortest possible time. However, there is not a standard methodology of finding and solving the cause of the problem and the indications are only exchanged verbally through "word of mouth". Consequently, very often operators do not know precisely how to behave and especially where to look for the cause of the alarm when it occurs. Inevitably, the durations of the micro stoppages lengthen worsening the Performance indicator.

Lastly, regarding the category **Material** two macro causes have been identified :

- Long supply lead times for spare parts and consumables. Not all spare parts in the line can be in stock. For less critical spare parts there is a supply to order and the shipping time is very high by the official manufacturer of the production line.
- Not optimal order and cleaning management. After numerous Gemba Walk has been highlighted that on the workshop there are objects used with very low frequency and not useful for the every-day operations . In addition, even for the most frequently used materials, a well-defined position is not foreseen, which involves a waste of time by the operators in the research of them.

Among the macro causes identified, the long supply times of spare parts and consumables have not been further analysed for the purposes of the project since they exceeded our field of action.

On the other hand, it was decided to carry out a more in-depth analysis of the macro causes of the "**Machine**" category in order to identify the root causes on which to act

at the operational level. To do this, a **5 Whys analysis** was carried out on each of the most relevant micro stops of the Crimping and Encasing Machine.

7.1.2 5 Whys Crimping Machine

Starting from the Crimping Machine, below are illustrated the 5 Whys analysis on the "High Cap", "Spilled Vials" and "Stucked Cap" micro stoppages, respectively.

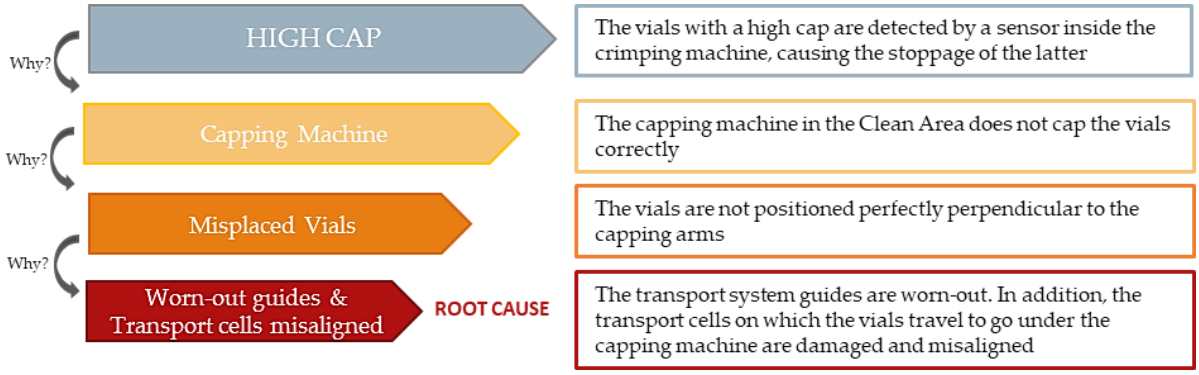


Figure 21 - 5 Whys analysis for the "High Cup" micro stop

Going ahed with the other two micro stops, the 5 Whys analysis illustrated below revealed that the root cause of both turns out to be the same as the first micro stop. In fact, both "Spilled Vial" and "Stucked Vial" are micro stops traceable to the same "High Cap".

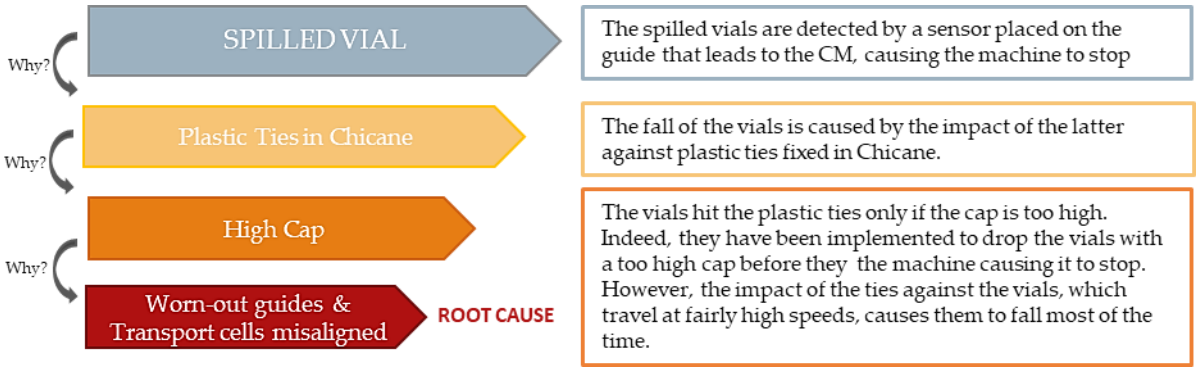


Figure 23 - 5 Whys Analysis for the "Spilled Vial" micro stop

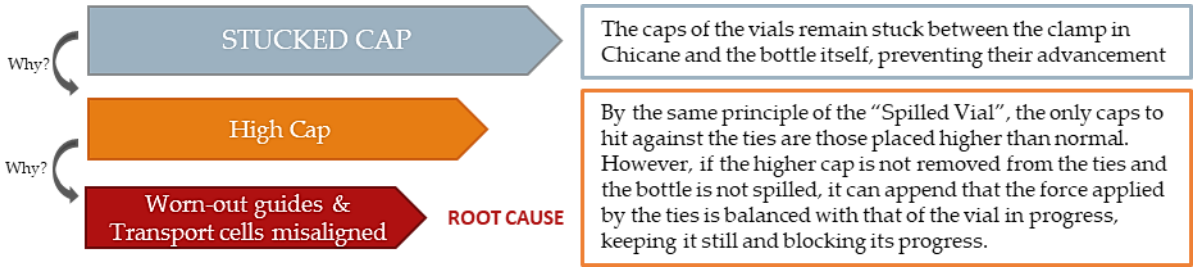


Figure 22 - 5 Whys Analysis for the "Stucked Cap" micro stop

In conclusion, it can be said that the micro stops of the Crimping Machine are not due to a problem of the machine itself but are the reflection of a problem on the Capping Machine. Indeed, **the root cause of all the main micro-stops of the Crimping Machine lies in the worn-out of the transport system guides together with the misalignment and damaging of the transport cells** that guide the vials throughout their journey from the filler to the output **of the Capping Machine**.

7.1.3 5 Whys Encasing Machine

Regarding the encasing machine, the following are the 5 Whys analysis regarding the microfermate " Cases Change" and "Robot Overload" respectively

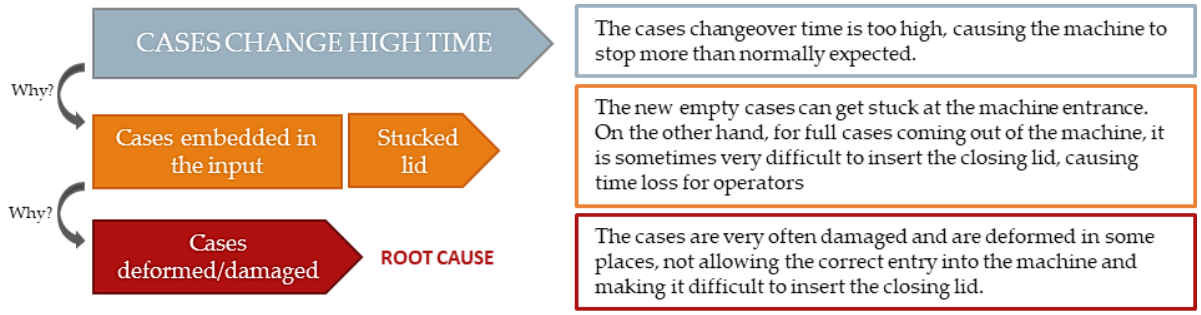


Figure 24 - 5 Whys Analysis for the "Cases Change" micro stop

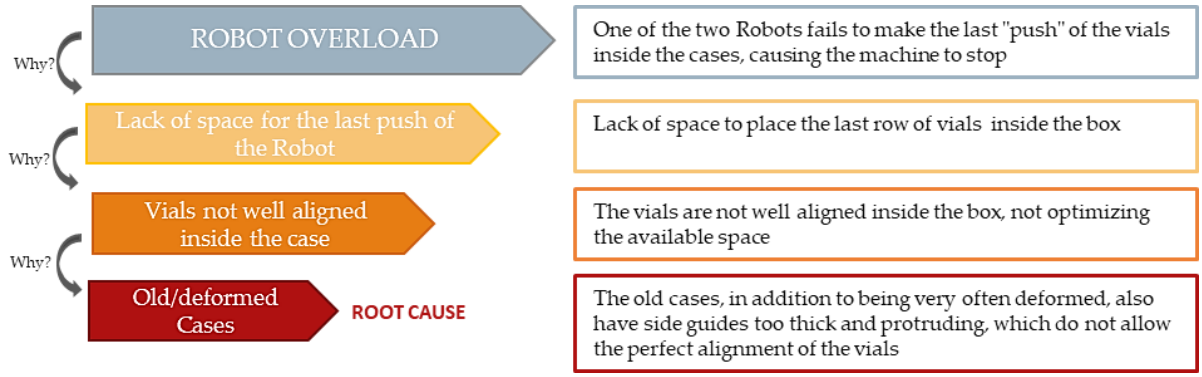


Figure 25 - 5 Whys Analysis for the "Roboto Overload" micro stop

From the analyses carried out it can be concluded that the root cause of both of the Encasing Machine's most common micro stops are the **Old Cases :**

- **Too deformed/damaged** → cause problems at the cases change
- **They have too thick side rails** → do not allow the correct alignment of the vials inside

7.2 Availability

We have concluded that the most time consuming activities that impact the availability are changeovers and that they mostly consist in cleaning activities.

In order to fully understand the real causes for such long changeover lead time, we had to start narrowing down our focus on the activities performed and the way those are carried out.

The cleaning activities are performed in parallel in both the White area, and the Clean area, but most of the workload is focused on the clean area.

-The activities in the White area (which include the Washing, Crimping and Encasing Machines) consist in the simple removal of the vials that fell inside the line floor and the cleaning of spilled product. This is an activity that is performed by the 3 operators that supervise the White area. These activities are not time consuming hence are not the bottleneck of the changeover.

-The Cleaning of the Filling line (inside the Clean area), being the most critical phase in terms of cleanliness, is a much more time consuming activity and is performed by one or maximum 2 operators:
The activities can be divided in three main sections:

- **Disassembling**: as the filling of a batch stops, the operator must remove all the used material and takes out some components of the lune in order to clean them (in some cases) or replace them with a new sterile component.
- **Cleaning:** in this phase, the operator removes all the vials that fell on the machine floor. Consequently the filling line and its components are first cleaned and then sanitized.
- **Reassembling:** where all the sterile pieces are installed back into the machine.

In order to understand better the changeover and identify the opportunities to improve the changeover Lead Time, we decided to measure the activities of the cleaning campaigns.
While measuring the activities, we were also able to study the machine and better understand the components involved in the cleaning activities.

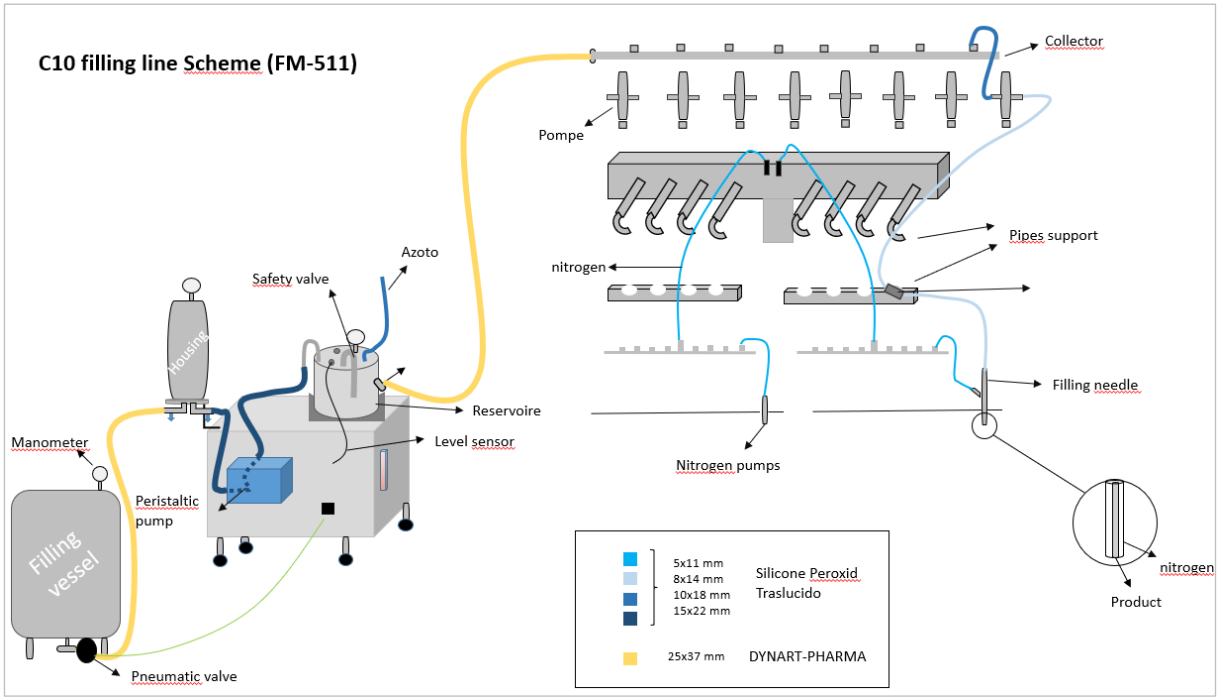


Figure 26 - C10 filling station components

As you can see in the picture, the product, which is contained in a filling vessel, is pumped into a filtering system (housing) and consequently, thanks to a peristaltic pump, into a reservoir. After the product goes through this first section, it is directed towards a collector, that receives the product and distributes to the filling pumps (one per pipe) which are connected, one by one, to the filling needles. In parallel to the product flow we can also see the nitrogen flow that, as explained in the problem breakdown, is needed to prevent the oxidation of the product.
Also next to the capping machine, there is a system that replenishes the machine with cups (not represented in the image).

At the end of the Measuring campaign we were able to tell with high detail what were the **main activities carried out during a changeover**:

7.2.1 Disassembling

The line disassembling involves 2 main systems: the pump system and the reservoir system
Reservoir system: as briefly explained, the product goes through the reservoir system first. The system is composed by 2 separate parts.

The first part is a **filter**, that makes sure that all impurities are eliminated before the product is pumped into the vials. This system is composed by a metal **housing** that contains the filter (which is single use). Then the filter is connected to a pipe, that goes through a peristaltic pump. This pump has the purpose to direct the product towards the reservoir.

Figure 27 - Reservoir : housing and filter

Figure 28 - Reservoir : structure and cover

The reservoir is needed to decrease the pressure of the product: indeed, the filling pumps are very delicate and must pump a very precise dosage in every vial. The pressure that the product has once it comes out of the filter is too high and must be decreased.

Pump system: The product goes then from the reservoir into the pump system. The collector receives the product and distributes it into 8 pipes. Each pipe is then connected to the filling pumps: these are the pumps that push the product with high precision into the filling needles, and ensure a constant and stable filling volume.

Figure 29 - Pump and pipes with filling needles

The operator must disassemble both the reservoir and pump system, since those are the components that touch the product and for this reason they must be sterile.
On top of these activities, the operator has to take out of the line the system that replenishes the cups to the capping machine (which consists in a hopper) and some boxes that are placed on the line floor as well. These boxes have the purpose to keep the line floor as clean as possible: there is one box dedicated to vials that fall into a trap placed before the filling station, two boxes placed under the pump, that collect eventual product spilling, and a last box, which collect all the cups that fall from the capping machine.

The average duration of this activity (according to our measurements) is equal to approximately 1 hour.

7.2.2 Cleaning

Once all the material is taken out the cleaning activities can begin.
In the cleaning activities two main phases can be identified: cleaning and sanitization: every component is first cleaned with alcohol and then sanitized with IPA.
The cleaning involves the whole filling line and some of the components disassembled. It starts with the removal of the scraps and of all the material that fell onto the line floor, such as cups, empty vials, and product.
After the removal of the materials the cleaning can start:
Every single surface must be cleaned with paper towel and alcohol in order to remove all the impurities that could potentially contaminate the following batch production. The same surfaces are sanitized with IPA.
Then all of the components removed during the disassembly can be cleaned: here the components separate into 2 different flows:

- some parts that do not require sterilization (according to regulations) are cleaned and then sanitized by the operator. this includes the hopper that replenishes the capping machine as well as the clamps and gaskets that are used to seal the pipes' junctions, but also some components of the reservoir system, such as the manometer and the level sensor.

- Other components, that are in contact with the product, need to go through a sterilization process. The parts, when they are disassembled, are placed on a trolley and then brought by the operator in another area, where they are first cleaned, and then sterilized in an autoclave. After this process, the parts are sterile and can be stacked in a cabinet waiting to be reinstalled onto the line.
  Being this a long process that takes hours (due to the long lead times for cleaning and sterilization), each component has a substitute. This allows to save time in the reassembly of the line as there is no need to wait for the components' sterilization.

The average duration of this activity (according to our measurements) is equal to 30 minutes

7.2.3 Reassembling

At this point the line is clean and it can be reassembled.
The cabinet containing the new sterile parts is brought inside the filling room, next to the line. Then all the parts are assembled and installed into the line.
Once the reservoir system, the pump system, the hopper and all the boxes are installed, the line is set to operate. At this point the vessel is brought from the process room (where the ingredients are mixed and create an emulsion) to the filling room.

The vessel is then connected to the filter through a "Dynart pipe", and the operator opens the valve to let the product flow into the filter.
The average duration of this activity (according to our measurements) is equal to 1 hour and 20 minutes.
The average duration of the Changeovers according to the data on the OEE file is 3 hours, which is coherent with the times we measured.
Once the valve is opened, the changeover activities can be considered finished and the filling of the new batch starts. The first phase of the filling is a transitory phase in which the line automatically sets the pumps level to the correct value in order to ensure that they fill the vials with the correct amount. During this time, the operator takes care of all the documentation relative to the activities that were performed.

The measurement of the activities and the chance to talk to the operators for long time allowed us to gain knowledge about the line components and the organization of the operations in the Clean area.
This knowledge allowed us to point out the **inefficiencies** that could be potentially assessed, and we decided to do it through an **Ishikawa diagram**:

7.2.4 Ishikawa Diagram Availability Problem

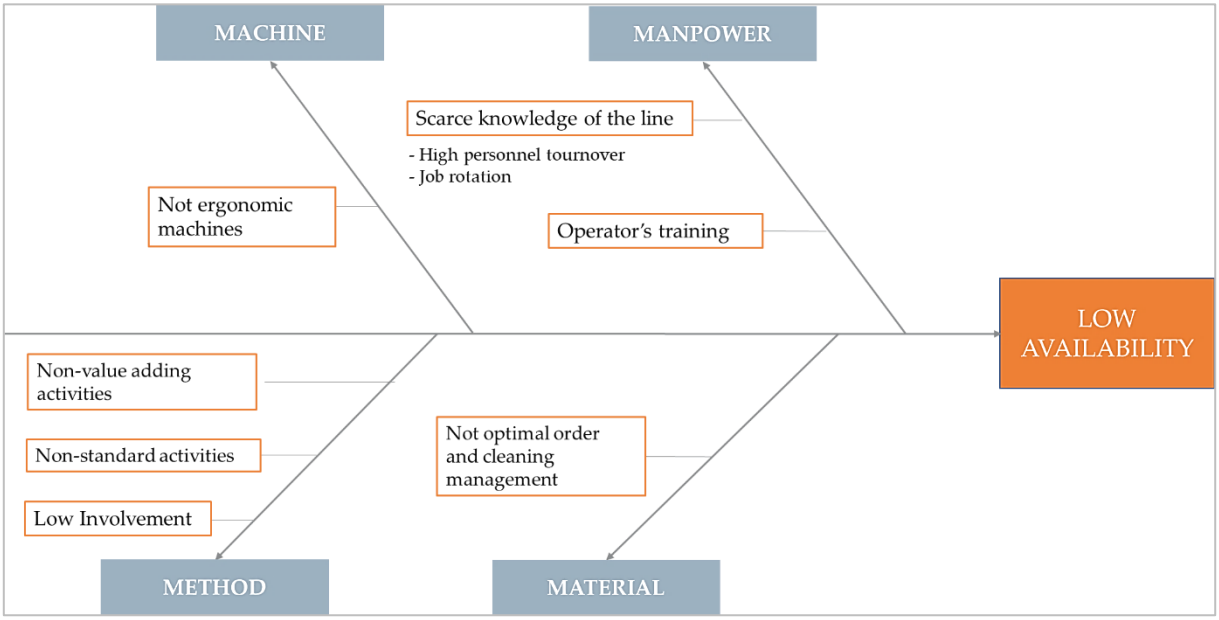


Figure 30 - Ishiwa dgram Availability problem

For the **Method** axes we observed 3 main issues:

- **Non standard activities**: despite the activities were carried out in a sensitive and controlled environment, they were not strictly standardized, especially in terms of sequence. This did not impact on the quality of the product but contributes to the variance in the changeover time: more expert operators could perform the

activities better and in a smarter sequence which allowed them to perform quicker changeovers.

- **Operators' management:** another issue regards the management of the operators during a cleaning campaign. In all our measurements we noticed that the number of operators was variable and it was not given the proper attention: in some cases the activities were carried out by two operators, but in the most of the occasions there was only one operator to perform the changeover. Instead, the operators in the white area, which had already performed the quicker changeover activities that have to be carried out on the other machines, were waiting for the line to restart the operations.

- **Non value adding activities performed during the changeover:** Some non value adding activities were performed during the cleaning campaigns such as the assembling and the dismantling of the components that could potentially be performed outside of the cleaning campaigns. We decided to investigate and go more in detail of these activities using the principles behind the **SMED** methodology.

For the **Machine** axes we were able to point out some issues that can all be reconducted to one root cause:

- **The machine is not ergonomic:** during the measurements, we noticed that the operators often struggled to reach some areas of the machine. Especially for the pump system: the pump system is placed between the main line components (needles and vials transportation system) and the wall that separates the white area from the clean area. Because of this position, the activities related to the disassembly and the reinstallation of the pumps and the collector, are critical and time consuming as the area is not easily accessible. On the wall that separates the clean area to the white area, there is a set of gloves that allow the operator in the white area to access the machine inside the clean area. These gloves were installed so that the operator in the white area could help with the operations involving the pump system. Although the gloves were not installed properly and they are useless (the operators in the white area struggle to reach certain parts of the machine). Due to this problematic, the operators in the clean area must climb inside the machine and perform all the operations on their own, in a tight space, with all the inefficiencies that come with it.
  The machine structure, is also a constraint when it comes to the cleaning activities: the operator, struggles to reach certain parts of the machine to clean them and wastes more time then it needs.

On the **Manpower** perspective, three main issues came out:

- **Operators' turnover :** as already highlighted in the previous paragraph, one of the most known issues around the company is the operators' turnover. This problem has already been noticed in the white area's operators but also in other areas of the plant other than the filling. This problematic was also experienced in the Clean area: the operators can be divided into 2 categories:

    - the first is composed by operators that were hired when the plant became property of the Astra-Zeneca group in the 90's. they are very knowledgeable and have their own methods for carrying out the activities.
    - In the second category there are all the young operators (often aged from 19 to 25 years old) that have a high turnover: they work in the company for a period that goes from 6 months to a maximum of 2 years. After two years the company policy is not to renew the contract and replace it with a new operator.

  This particular structure is not sustainable in the future and the effects are already visible: few people own the know-how and are able to perform certain activities in an efficient and optimal way. The unexpert operators on the other hand spend a lot of time, especially in the first moths in order to learn the job and really becoming a useful resource. In the end, by the time that the operator is really trained there is not much time left for him to bring any value to the company, and a trained operator is substituted with an unexpert one.

- **Operators' training:** as we have previously anticipated, being the clean area a complicate working environment, the training activities are very delicate and a proper training allows the operator to bring value to the operations.
  From the many interviews carried out during our measurements, the operators (both expert and non expert) explained us that the training activities were not made properly and often too quickly. The trained operator then has to independently perform some delicate activities and there is a much higher chance of mistakes that could cause inefficiencies.
  The most critical parts are the machine knowledge and the C5 activities:

    - The machine knowledge is very important in the supervision of the activities. If a problem occurs and the operator knows the machine, he is able to signal with precision the issue to the mechanical maintenance technician and allow a quick fix, or in some cases the operator is able to independently solve the problem, saving all the waiting for the maintenance technician who has to move from the white area to the clean area (the dressing activities require approximately 10 minutes).

    - the C5 activities are related to the cleaning and the sterilization of the line components after their dismantling and then the redistribution of the sterile

components in the cabinet of each of the 5 filling lines. This is a central activity, where a non well trained operator could cause a lot of problems such as the mix up of line components, or an incomplete set for the line reassembling activities: this issue was reported by the operators but was also experienced by us during the monitoring of the activities.

Another issue with the training of the operators is that the training is often made by the expert operators who, as pointed out earlier, develop their own methods and pass those to the trainee. This causes a variability in the operativity in the Clean area.

- **Scarce knowledge of the line:** As highlighted in the previous paragraph for the White Area, also in the Clean Area the operators have to work on a different filling line almost every day and also switch from the clean area and the white area activities.
  This high rotation allows the operators to see and operate in all the filling lines and develop a high horizontal specialization. Although this means that an operator will take much more time to become knowledgeable about the machines and the value added by the operator will be less.

Finally, regarding the **Material** macro-cause category we found two important criticalities, which are the same encountered in the White Area :

- **Material management:** As explained in the manpower axes, The materials in the Clean area are not well managed and for this reason much time is wasted during changeovers. This was reported by the operators and the supervisors, but was also noticed by us during measurements: indeed in multiple occasions the operators wasted time looking for a missing component that was not present in the cabinet. All these inefficiencies can be traced back to 2 root causes that are bounded together: the operators' training and also the lack of a unique and unanimous standard (despite the presence of the Standard Operating Procedure 245 that regulates all cleaning activities)

- **Disorder**: once we were able to enter the Clean area, one of the first problems that we noticed was the mess. Many components were not stored in an appropriate way (although still compliant to Good Manufacturing Practices) and this caused issues during the Changeover activities such as missing pieces (in one particular occasion, during a changeover the operators couldn't find the sterile housing of the filter and wasted 30 minutes looking for it to then find out that it had been left outside the autoclaves) or pieces mix-up
- (components of other filling lines that were placed in the wrong cabinet.

8 Develop Countermeasures

After identifying the main root causes of the problem both in terms of Performance and Availability, the next step was the proposal of the related countermeasures. Below are the main countermeasures that it was decided to adopt after a careful analysis and discussion with the members of the entire team. Together with the countermeasures, the implementation plan is also indicated with the associated dates of expected completion and the responsible of the action.

8.1 Performance countermeasures:

PROBLEM	CATEGORY	ROOT CAUSE	COUNTER MEASURE	DUE DATE	RESPONSIBLE
LOW PERFORMANCE	**MACHINE** (Capping Machine)	Transport cells misalignement	Transport cells replacement	Week 12, 2023	Maintenance Manager
		Guides Worn-out	Guides replacement	Week 2, 2023	Maintenance Manager
	MACHINE (Encasing Machine)	Old cases	Purchasing of new dedicated cases	Week 12, 2023	Maintenance Manager
	MANPOWER	Low involvement	Visual Board implementation	Week 7, 2023	Visual Board dedicated team
		Scarce communication			
		Scarce Knowledge of the line	Dedicated Team	Week 5, 2023	Production Manager
	METHOD	Absence of a standard problem-solving methodology	Creation of a standard problem-solving methodology	Week 20	Maintenance Manager

	MATERIAL	Not optimal order and cleaning management	5S	Week 2, 2023	5S dedicated team

Table 9 - Performance countermeasures

8.1.1 Machine

As illustrated in the summary table above, the main countermeasures that have been decided to adopt for the macro-category **Machine** are :

- Guides and transport cells replacement regarding the Capping Machine
- Purchasing of new, dedicated cases for the Encasing Machine

The due dates were decided to be Week 2 for the guides and Week 12 of 2023 for the transport cells and the new cases. Both the new transport cells and the new dedicated cases were ordered in Week 49 of 2022, while the guides were already available at the warehouse. The responsible of the actions was decided to be the Maintenance manager.

8.1.2 Manpower

As for the low involvement and poor communication of the **Manpower** category, it was decided to adopt a single important countermeasure, namely the implementation of a Visual Board directly on the line. To do this, it was decided to employ a dedicated team composed of the undersigned Maria Giulia Perrone and Massimiliano Maiocchi plus two other students of Politecnico di Milano engaged for the Industrial Management Lab and a project coordinator (Ruggiero Ludovici). The implementation due date was decided to be in Week 7 of 2023.

8.1.3 Material

The same dedicated team was commissioned to implement 5S as a countermeasure for the not optimal order and cleaning management for the **Material** category. The due date of this project was decided to be week 4 of 2023.

8.1.4 Method

Finally, for the **Method** category, it was decided to create a standard methodology for the resolution of the main micro stoppages. However, the due for the implementation of this countermeasure has been agreed for week 20 since it was decided by the team to give precedence to the other countermeasures.

8.2 Availability countermeasures:

PROBLEM	CATEGORY	ROOT CAUSE	COUNTERMEASURE	DUE DATE	RESPONSIBLE
LOW AVAILABILITY	METHOD	Non standard activities	Standard work	proposal	TBD
		Operators' organization	Third person inside the clean area	proposal	TBD
		Non value adding activities	SMED	Week 5	Project team
	MANPOWER	High turnover, too quick training	Standard work	proposal	TBD
		Scarce knowledge of the line	Dedicated team	Week 5	Production manager
	MATERIAL	Material management, disorder	5s	Week 15	Project team

Table 10 - Availability countermeasures

The countermeasures developed to improve the changeover lead time are targeting all the issues that arise during the project except for the machine axis: The constraints were imbedded within the machine structure and could not be assessed without major changes.

8.2.1 Method

SMED

The first countermeasure developed was the SMED. In order to define all the single activities that were performed during both the dismantling and assembling of the reservoir and the pump system we used the Standard Operating Procedure. This SOP regulates all the activities in the Clean area with high detail and allowed us to define a standard. We then proceeded to take detailed measurements for each activity.
Then, we exploited the help of a shift head and the filling department head to examine all the single activities listed and define, considering all the GMP constraints, whether or not it was possible to modify the current practice and

perform these operations in a more efficient way. The target of this activity was to validate the process, and later implement it into the procedure.

The output of this activity was a detailed sequence of actions that could possibly be carried out outside the machine stoppage time, alongside their respective durations.

SMED proposal:

The assembling activities, for quality reasons, must be performed under laminar flow and there was not enough space in the C10 room. For this reason we wanted to exploit a station (next to an unactive autoclave exit) in a different room of the Clean area. This location was chosen just for the proposal, in case of a positive feedback we would have proceeded with the purchase of a dedicated laminar flow rack. The activities that must be performed under the laminar flow are the ones identified in the root cause analysis and will be performed by the c5 operator.

After the assembling, the two systems wait (still under laminar flow) for the batch filling to end, and the assembling activities to start. Then, when needed, the two systems are transported to the C10 room to be installed.

After the filling then, the disassembling activities are delegated to the C5 operator. In this case, being already dirty material, the disassembly can be done within the C5 room.

SMONTAGGIO RESERVOIRE	
Attività	**Tempo [s]**
Recupero carrello per movimentazione Vessel	90
Movimentazione Vessel verso locale lavaggio	120
Recupero carrello con vasche dove depositare pezzi da lavare in C5	70
Smontaggio housing + filtro + campana	180
Smontaggio sonda + sfiato + manometri + guarnizioni e clamp + clamp reservoire + coperchio	200
Posizionamento panni antipelo su tavolo +Trasferimento pezzi smontati Reservoire da Carrello a tavolo	200
Movimentazione carrello con pezzi sporchi verso C5	100
MONTAGGIO RESERVOIRE	
Attività	**Tempo [s]**
Trasferimento pezzi da Armadio e da locale C14 a tavolo	180
Sanitizzazione pezzi smontati RESERVOIRE su tavolo	600
Montaggio coperchio + guarnizione + clamp reservoire	90
Montaggio sonda	70
Montaggio manometro reservoire	30

Montaggio sfiato di sicurezza + guarnizioni degli altri componenti	60
Montaggio adattatore + tubo dynart Reservoire-Collettore	45
Montaggio Housing + filtro + campana + manometro	540
Montaggio pescante + altri pezzi minori su coperchio	75
Totale (s)	**2650**

Table 11 - Reservoir activities externalization

SMONTAGGIO POMPE	
Attività	**Tempo [s]**
Smontaggio pompe di dosaggio dopo averle scollegate dalla linea	240
Raccolta di tutti gli strumenti in una o più vaschette	90
Movimentazione carrello con pezzi sporchi verso C5	100
MONTAGGIO POMPE	
Attività	**Tempo [s]**
Trasferimento pezzi da armadio e da locale C14 a tavolo	30
Apertura sacchetti con materiali sterilizzati	60
Assemblaggio pompe di dosaggio	450
Assemblaggio collettore con tubi	120
Collegamento tubi a pompe	200
Collegamento aghi riempimento a pompe	250
Collegamento aghi riempimento a flusso azoto	60
Totale (s)	**1600**

Table 12 - Pump System activities externalization

The externalization of these activities is estimated to bring a benefit of about 70 minutes of manpower per changeover. Considering that the Changeover activity is supposed to be performed by two operators and that the disassembly/assembly of the pumps and the reservoir can be carried out in parallel, **the externalization of these activities would lead to a reduction of the total changeover time of about 35 min.**

Third person inside the clean area

To both support the operator that performs a changeover and also to support the extra activities that we allocated to the c5 operator in the SMED proposal, we thought to bring inside Clean area one of the 3 operators of the White area.

Indeed, when the line stops at the end of a batch, the changeover activities for the white area are much less and could easily be performed by 2 operators.

Standard work

Also, due to all the problems that concerned the operators' training, the team also thought that the standardization of the changeover activities would help to reduce the variability of the processes and decrease the overall lead time.

8.2.2 Manpower

Dedicated team

To assess the job turnover problem, but also to support the project in the countermeasures implementation phase, the team decided to define a set of operators (enough to ensure all the 3 shifts) that would only work on the C10 line.

8.2.3 Material

5S

Due to all the issues we noticed concerning the material management, we also decided to perform a 5s activity on all the areas that involve the components of the filling lines:

- Room c10
- Room c5 (where pieces are cleaned)
- Room C6 (where pieces are sterilized)
- Room c14 (where sterilized parts exit the autoclave and some components are stocked)

Once we developed the countermeasures we could then move to their implementation.

9 Implement Countermeasures

After developing the countermeasures and the associated action plan, it's time to actually implement them. This chapter will illustrate the **countermeasures implemented until** the closing date of our thesis project in **Week 10**.

9.1 Countermeasures for the Capping Machine

As previously explained, the cause of the most frequent micro stoppages on the Crimping Machine lies in a problem at the Capping Machine. In particular, the problem concerns the wear of the guides together with the misalignment and damaging of the transport cells. To solve this problem, in **Week 2** of 2023 **a maintenance intervention** was carried out **for the replacement of all the 4 guides of the vials transport system in the Clean area**, already available in the warehouse. Moreover, all the 120 transport cells have been realigned as well as possible, waiting for the new cells to arrive at Week 12. This intervention, which caused the line to stop for two entire working days, represents the **countermeasure from which is expected to have the greater results in the short period.**

Since the closing date of our thesis project was set for week 10 of 2023, it was not possible to see the implementation of the new transport cells at the time of writing.

9.2 Countermeasure for the Encasing Machine

As for the Encasing Machine, the main countermeasure concerns the purchase of new cases dedicated to the line. In particular, these boxes have much thinner side guides that increase the space inside the box and facilitate the alignment of the vials inside.

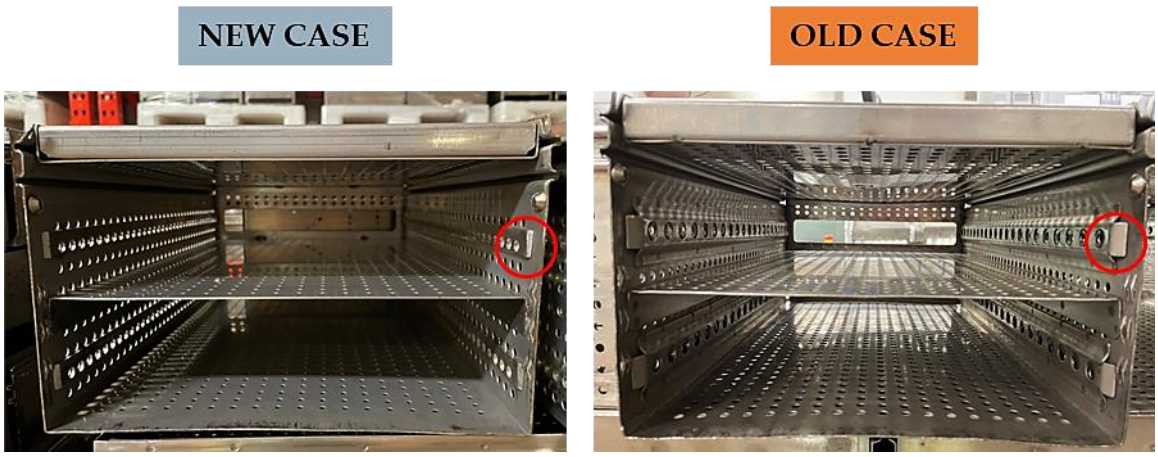


Figure 31 - New VS Old Cases for the Encasing Machine

This, together with the resolution of the deformation problem, should solve in large part the problems of both "Robot Overload" and high "Cases Change" time. The

new cases, of which a small sample was already present in the company, were ordered during Week 49 of 2022 and their arrival is scheduled for Week 12 of 2023. Consequently, **it was not possible to see the Encasing Machine working continuously with the new cases**.

9.3 5S white area

As pointed out in paragraph 2.1.1, to lay the foundation for a solid Lean Implementation it is convenient to start from the basics. Among the easiest tools to use in the first phase of a lean implementation there is **5S**, which is a technique used to provide a disciplined approach to the maintaining of an orderly, organized and clean work environment.

Indeed, one of the problems contributing to the inefficiency of the production line lies in the poor organization of the material used on line and in the not optimal management of cleaning. To solve this problem, it was decided to implement a 5S project on the production line in question, involving a dedicated team **starting from Week 48.** The team followed the 5 steps of the methodology, the progress of which will be shown below.

9.3.1 Sort

In this first phase, the project group inspected all the material that was next to the filling line and, together with an operator and a production assistant, evaluated whether it was useful to the operations or not. Being a pharmaceutical context, we did not find any useless material except for some components of the line, that were used for a 10ml format that had not been used for years. We proceeded to move it to the warehouse and replaced it with the 10ml format that is used periodically and was instead stocked on a pallet and placed under the line.

Figure 32 - Old 10ml format

9.3.2 Set in Order

Also in this phase we had to deal with few materials, most of which was stored in a cabinet next to the line. So, following the 5s methodology we identified a place for all the material and equipment stocked and proceeded to label each position.

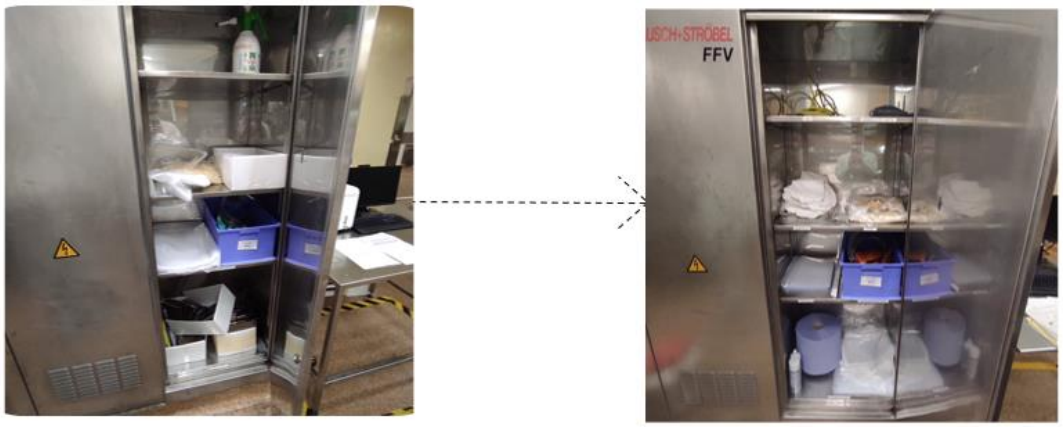


Figure 33 - Cabinet set in order

9.3.3 Shine

The w10 line was already significantly clean when we began our project, as it was already required to adhere to strict standards of cleanliness. However, we inspected the area for any issues and took steps to ensure that the area was in compliance with the necessary safety and cleanliness standards.

The only space that required our attention was the area beneath the washing machine, which had an unresolved leaking issue. To solve this problem, a maintenance intervention was required to insert ducts under the washing machine, in order to collect the water losses of the machine and convey them to a single collection point.

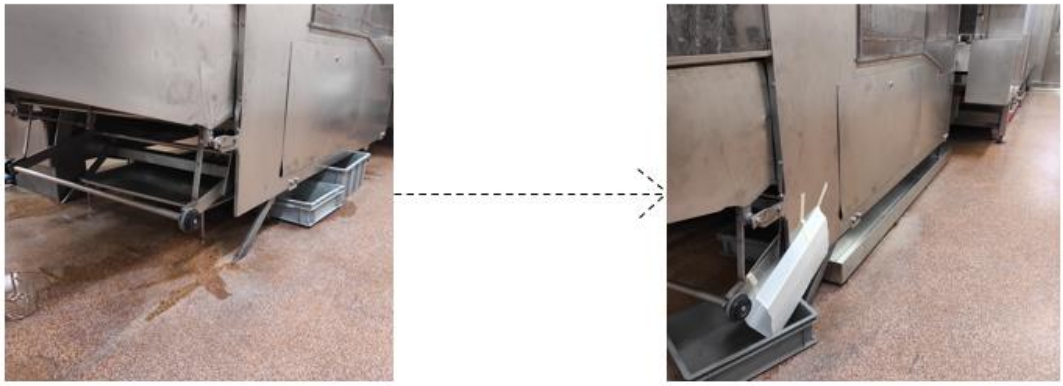


Figure 34 - Washing Machine Shine

9.3.4 Standardize

The standardization phase was not implemented since we did not perform 5s in the other lines and inside the line floor there was no opportunity to replicate positions standardization.

9.3.5 Sustain

To ensure that the 5S project standards were being met, we developed a series of **check forms** to be filled each week, for every section of the w10 line :

- Left Hall
- Right Hall
- Centre Hall
- Input-Output Area
- Tools Cabinet

These forms provided a detailed overview of the areas and allowed us to track any discrepancies or issues that needed to be addressed.

CORDENPHARMA
EXPERTS TAKING CARE

Data: _____ Responsabili: _____

Area: linea W10 (**corridoio dx**)

	SI	NO
Le norme di sicurezza sono rispettate per quanto riguarda materiali ed attrezzature? Note:		
C'è solo il materiale che ci serve? Note:		
L'ambiente di lavoro risulta pulito? Note:		
Ci sono tutte le attrezzature che servono e nulla di più? Note:		
L'attrezzatura è in ordine? Note:		
Punteggio totale (SI = 1, NO = 0)		

Figure 35 - 5S audit form

To monitor the results, we also implemented a system of regular audits that allowed us to review the data collected from the check forms and verify that the standards were being met: a "yes" answer to each question equals to 1 point, a "no" answer 0 points. The proportion of the points with the maximum is then translated in percentage in the "voto" section. This system of monitoring will allow also in the future to quickly identify any potential issues and take corrective action, if necessary.

2023								TABELLONE 5S									linea AA511									
settimana	51	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
responsabili	SP			SP		SP	SP		SP	SP	SP															
data	23/12			20/01		02/02	09/02		23/02	02/03	09/03															
corridoio sx	5			5		5	5		5	5	5															
corridoio centrale	5			5		5	5		4	4	5															
corridoio dx	4			5		5	5		4	4	5															
area I/O	5			4		5	5		5	5	5															
armadio	5			4		4	4		5	5	5															
totale	24			23		23	24		23	23	25															
voto	96%			92%		92%	96%		92%	92%	100%															
N°segnalazioni	2			3		2	1		2	1	0															

Figure 36 - 5S board

Project 5S was completed in week 51 of 2022, ahead of the planned due date.

9.4 Visual Board

As mentioned in the previous paragraph, it was decided to start a project for the implementation of a visual board as a countermeasure to the poor communication between the maintenance and production departments and between the production operators themselves. The Visual Board Project officially began in Week 48 and in the upcoming weeks interviews were conducted with all those who would actively use the board, namely heads of the production line, heads of production shift and operators. In particular, we carried on interviews to 5 head of the production line, 3 head of production shift, 3 skilled operators and 4 operators.

During the interviews, we asked to each of them what would actually be useful to have on the board, leaving them free to express any idea/thought without any kind of conditioning. After listening and taking note, we also tried to propose our ideas to test if they could be valid or if they could add something useful to theirs. The objective was to find out which was the possible value adding information they could find on the Visual Board and how they could be represented and collected in a sustainable way. It was immediately evident the **strong scepticism** of the operators about the usefulness of the visual board, but despite this they were still collaborative and willing to dialogue.

After having completed all the interviews, the team gathered to put together all the information and decide what to introduce on the Visual Board. To do this, a qualitative approach was followed giving priority to the ideas which has been proposed by the majority of the respondents or which found the highest percentage of consensus when proposed by us. From this was derived the first layout implemented in Week 3 of 2023 and illustrated in figure x.

9.4.1 First implementation proposal

The whiteboard was installed in the White Area of the line, while it was not possible to install one in the Clean Area due to environmental sterility constraints.

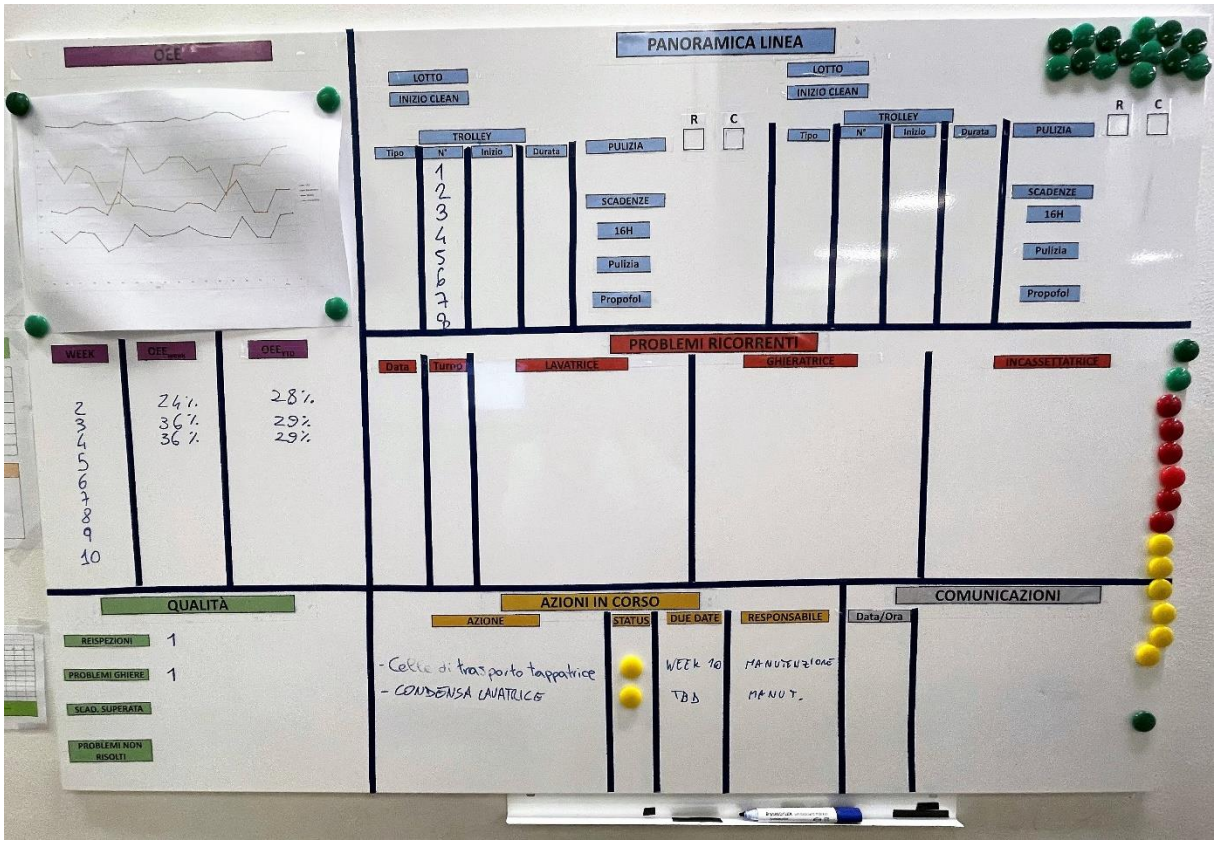


Figure 37 - Visual board

The whiteboard was installed in the White Area of the line, while it was not possible to install one in the Clean Area due to environmental sterility constraints.

The first part of the whiteboard in the upper right consists of all the necessary information to monitor the **general trend of the line**.

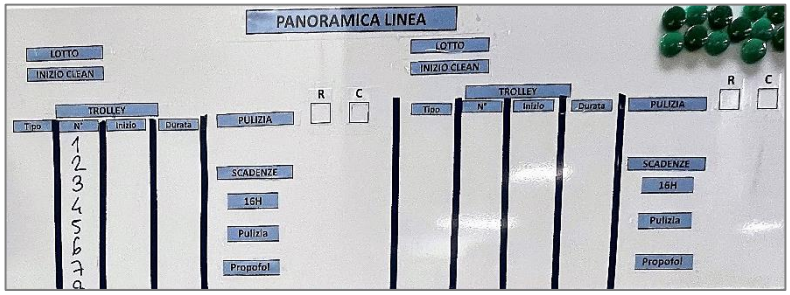


Figure 38 - Visual Board General Trend section

In particular, from the various conducted interviews it has been found that the most used unit of measurement to immediately understand how the line is performing are the filled trolleys. For this reason it was decided to introduce a simple table indicating the type of trolley (if single or double layer), its number (from 1 to 8 as a maximum), the start time of

filling the trolley (since the first box is inserted) and the duration of filling. Together with these data is obviously reported the lot you are referring to in the table.

Other important information included in this whiteboard part is about **expiries**. In particular, the time of the product filling start is reported in the clean area (from which the deadlines are derived), the expiration of the product and the expiration of the cleaning. The deadlines are variable depending on the type of product and the type of cleaning carried out (if complete or reduced) according to standards and fixed constraints.

The second macro area of the board, immediately below the previous one, concerns the **most common micro-stops**.

Figure 39 - Visual Board "Micro Stops" section

This area has been divided into five columns : three concern the machines in the white area, namely the Washing Machine, the Crimping Machine and the Encasing Machine, while the other two concern the indication of the date and the shift in which the information is inserted. The idea is that the operator, at the end of the work shift, reports on the board the description of the most frequent micro stops on each machine, if present.

Directly connected to the area of the most frequent micro stops, there is the area of **ongoing actions**.

Unlike the two areas described whose maintenance responsibility is entrusted to operators, this area is the responsibility of maintenance. Indeed, here will be inserted all the le established countermeasures to solve the most frequent micro stops mentioned above. Together with the description of the corrective action, it will be indicated the status, the due date and the responsible of it. The status will be highlighted by a red,

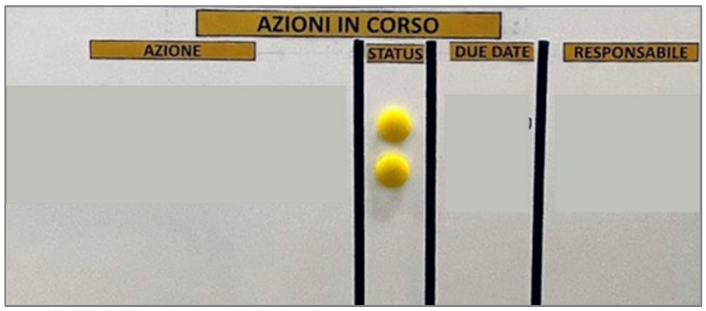


Figure 41 - Visual Board "Ongoing Actions" section

Figure 40 - Visual Board "Communication" section

yellow or green magnet depending on whether the action is respectively “not started”, “ongoing” or “completed”. This will be a fundamental part to make the operators more involved in the operations performed on the line and aware that their efforts have a practical response in the continuous search for the improvement of the production line.

The lower right area is dedicated to **communications** of any kind. Here production operators will find any information useful or necessary for the daily operations by line managers or by maintenance operators.

Moving towards the left area of the blackboard, we find respectively the part dedicated to the **OEE** trend of the line and the one dedicated to **Quality** .

The first shows the graph of the **OEE** with the details of the performance of its three components (Availability, Yield and Quality). The persons responsible for the update of this area are.... who provide the new data on a weekly basis.

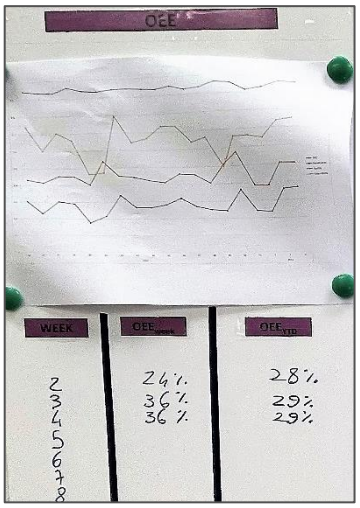


Figure 43 - Visual Board "OEE" section

Figure 42 - Visual Board "Quality" section

The second regards the area dedicated to **quality**, this provides an indication of the cumulative number of re-inspections, problems on dials, deadlines exceeded and problems not solved on a monthly basis.

9.4.2 Test and Feedback collection

After implementing the first visual board proposal, it’s time to test it in practice. So, the first step was to carry out a training to all the stakeholders of the board, who were asked to start using it in the following days.

However, the most important thing was the **establishment of a daily meeting** to be held directly on the board. The scheduled time for the meeting has been decided to be at the shift change at 14:00 o’clock. The participants of the meeting will be the same who will have to use it daily, that is, heads of shift, heads of line, operators and maintenance. In particular, there will be :

- 2 head of the production line or 2 head of production shift depending on the availability, one of the previous shift and one of the following

- 1 operator representing the previous shift plus all the 3 operators of the next shift

- 1 maintenance representative

The meeting follows the logic of the board. They start by analysing the line performance through the filling time of the trolleys. If this deviates from the average standard duration, the next section is followed by an analysis of the most frequent micro stops with the operator of the previous shift. At this point the maintenance representative takes note of the information received in order to reason about the countermeasure to be implemented and gives practical advice to operators on how to intervene to solve the micro-stop as soon as possible or limit its occurrence. The total duration of the meeting must not exceed 10 min.

During the first week of using the whiteboard we carried out many Gemba Walk monitoring. In particular, we attended the meetings held at 14:00 and gathered feedback from all concerned.

9.4.3 Final Visual Board

After collecting feedback and suggestions for improvement from all concerned, we arrived at the definition of the final layout of the Visual Board, shown in Figure 44.

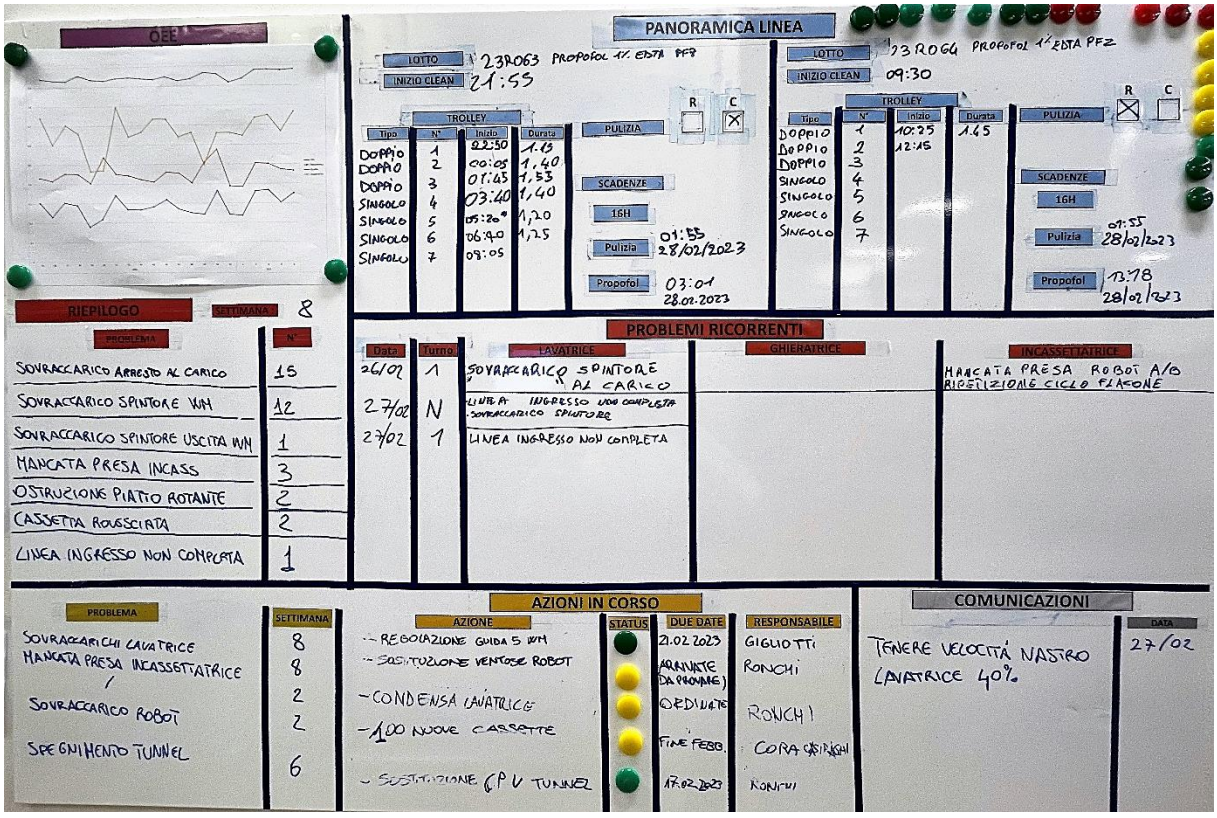
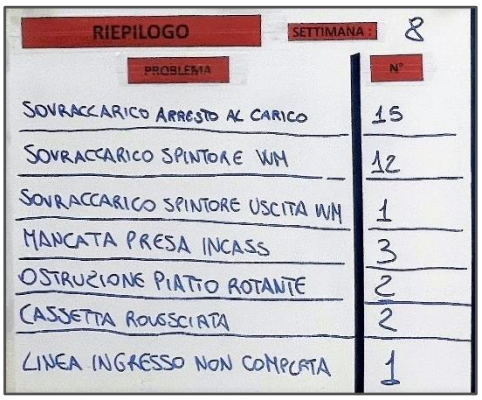


Figure 44 - Visual Board final implementation

The main changes concern the left-most area of the board. In particular, the lack of a defined temporal horizontal for the signalling of micro stops was highlighted. In fact, the limited space did not allow to bring back the micro stops for more than a day, forcing the operator to delete the previous ones to insert the new ones. Consequently, the general "picture" of the problems on the line had a time horizon limited to a single day.



To overcome this problem, it was decided to insert an area called "**Week Summary**" immediately next to the area of micro stops, in which are summarized all the most frequent micro stops occurred during the week, with an indication of the number of shifts in which they were marked on the board. This area will then be filled and deleted every week, while the area of the micro stops on the right will be deleted daily.

Finally, it was decided to eliminate the area dedicated to Quality, which will be printed directly on paper and affixed to the side of the board together with the Security section and the 5S audit, and replace it with an extension of the section "Actions in progress". Indeed, two columns have been added to this area : one column indicating the problem to which the action refers and one indicating the week in which the problem was first reported. This was done to create a direct link between the two sections and improve the logical flow.

In addition, this allows you to further extend the time horizon of the board, since the first two/three most frequent micro stops reported in the week summary will be reported below in the current actions section waiting to be resolved.

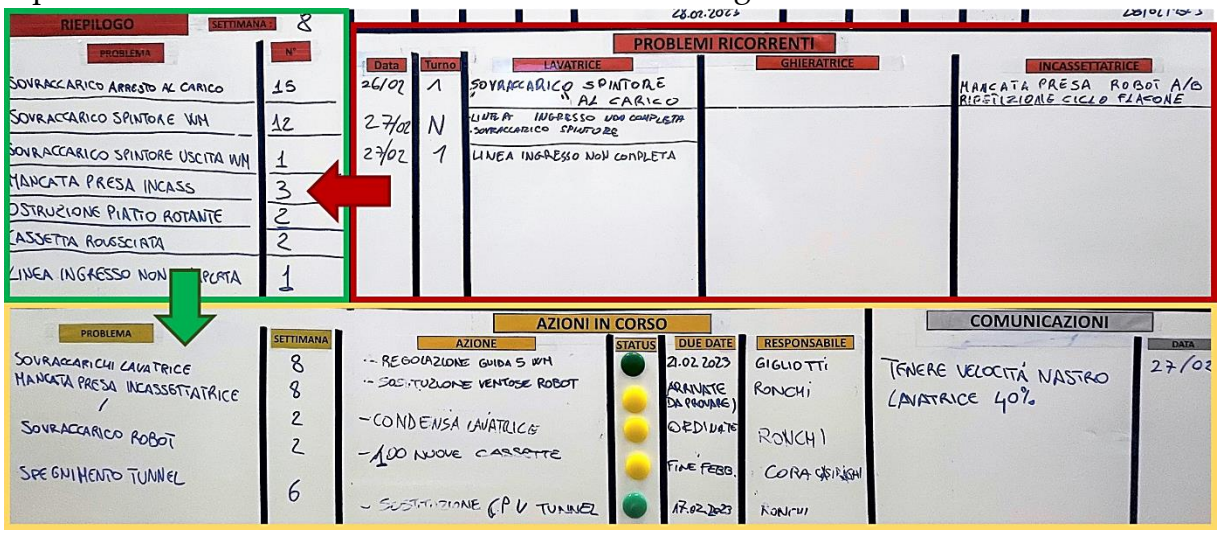


Figure 45 - Micro-stops Flow on the Visual Board

The final visual board was implemented at week 6 of 2023, one week ahead of schedule.

9.5 SMED

The first countermeasure implemented for the Availability was the SMED.

The proposal for the future state was submitted to the validation department and quality department. The feedback from their evaluation was negative: The implementation of the SMED involved too many quality risks. The most critical aspect was the fact that once the components were assembled, they should have gone through areas with lower sterility level. These issues added up to all the eventual activities needed to validate the safety of the process

So the team, decided that the eventual benefit coming from the SMED activity did not justify the effort and the investments needed.

Still, these constraints only concerned the assembling activities. For the disassembling activities instead, the quality constraints did not apply as the components are already dirty with product, and after the disassembly go through cleaning and sterilization phases before they are available for use.

So we could proceed with the delegation of the activities to the C5 operator. Although this countermeasure was bind to the implementation of a second countermeasure:

9.6 Third person inside the clean area - proposal

The eventual implementation of the SMED activities, would have overloaded the C5 operator who would require extra support in order to carry out all the activities. To do so we already identified the possible resource that could allow this: one operator of the white area that would go inside the clean area.

Although to make such implementation, we were not able to tell if the operative implementation would have affected the white area activities.

For this reason we proposed to start a measurement campaign in order to map precisely all the activities that are performed in the white area, in order to firstly define if this implementation is possible and eventually what is the maximum time that an operator could spend inside the clean area.

9.7 Dedicated team

This countermeasure was quick to implement. Together with the production line-heads we defined the set of operators, for all the 3 shifts, that would just operate on

the C10 filling line. This countermeasure was implemented in week 5 and has been of huge support also for the implementation of other countermeasures such as the Visual Board: being able to interact with the same operators allowed us to accelerate the implementation and also has helped us to start to spread the lean culture among the plant.

9.8 5S Clean Area

The last countermeasure considered was 5s. We started the implementation in week 9 and we began the activities in the C10 room. The only part of the C10 room was the closet: it was very messy, and it was not clear whether or not the needed material was present inside it.

Sort

In this first phase we removed all the components and examined them: we found some components whose sterilization expired and could not be used. Still those were left there and forgotten. We proceeded to remove these objects and we sent them to the sterilization area.

Shine

For this phase we couldn't improve the current situation as the area is extremely controlled.

Set in order

Here the team proceeded with the standardization of the positions of the components inside the C10 closet. We dedicated one floor to the pump system, one to the reservoir system and one for the other material.

Figure 46 - C10 closet set in order

Then to set the standard we listed all the components that must stay in the closet and associated each to its picture. Then the images have been taped on the closet, each one on its reference floor.

This will help to keep the same positions and avoid mix ups or missing components not reported.

Standardize and sustain - proposal

We couldn't finish the implementation of the countermeasure before the project deadline, although we proposed to finish the 5s activities with the standardization of the positions also on the other lines.

For the sustain part instead, we thought to extend the solution used in the 5s of the white area and apply it to the clean area.

After the 5s inside the filling rooms we also thought to expand the project also to all the areas already identified, with a particular focus on the work flow and the way activities are carried out, and on their standardization.

10 Monitor Results & Process

During our stay in the company for the purposes of the project, we were able to see the implementation of some of the established countermeasures, as well as to implement some ourselves.

In particular, **regarding the performance problem**, we carried out the implementation of the **Visual Board** and **5S** in White Area and it was possible to attend the **maintenance** work carried out **on the Capping Machine** in Clean Area.

On the other hand, the countermeasures that aim at increasing the availability have not been completed at the end of week 10 except for the dedicated team.

In this chapter an assessment of the outcomes resulting from the implementation of the aforementioned countermeasures will be done together with the assessment of the achievement of the established target. The chapter will therefore be divided into two main paragraphs:

1. **Local Impact of the implemented countermeasures :** Assessment of the results achieved through the implementation of countermeasures in terms of troubleshooting for which they were adopted.
2. **Global Impact of the implemented countermeasures on the OEE :** Assessment of the implemented countermeasures in terms of impact on the final goal of OEE improvement

10.1 Local impact of the implemented countermeasures

10.1.15S & Visual Board Results

As shown in the previous paragraph, after the implementation of the **5S** the line was more organized and clean, favouring the increase of the efficiency of the workplace organization and contributing to the improvement of the workplace safety. It can therefore be said that this countermeasure **has managed to solve the problem of poor organization of order and cleaning** and thus eliminate one of the macro causes of inefficiency of the line. On the other hand, the 5s activities in the clean area are yet to be completed but the example set by the white area 5s will ensure an effective completion of the project.

As for the Visual Board, the first few weeks after implementation represented a period of settlement in which it is difficult to assess its benefits. Indeed, it was not possible to perform the training of the operators in a single moment, but it was performed by ourselves together with the production assistant from time to time until all the shifts were "covered" and so the relative operators trained. However,

after completing the training and attending the first meetings held at the 14:00 shift change, it can be said that **the implementation of the visual board has already begun to improve communication between the production and maintenance departments**.

Furthermore, the most interesting thing was the sharp **change of attitude of the operators** towards the visual board, who have gone from being sceptical and reluctant to its use to being almost enthusiastic about it. In fact, they began to recognize its usefulness after the first meetings and even to propose us changes to improve it.

Also the implementation of the **dedicated team** countermeasure helped this process. Being able to interact with the same operators during the development of the visual board allowed us to validate our ideas and modifications receiving daily feedback and at the same time to implement them quickly and effectively.

10.1.2 Capping Machine intervention Results

As already announced, in **Week 2** of 2023 **a maintenance intervention** was carried out for the replacement of all the 4 guides of the vials transport system in the Clean area. This intervention, which cost the stop of the line for 2 days, would have been vital since it would have had to solve most of the micro-stops on the Crimping Machine due to the "High Cap" caused by Capping Machine. The latter, in fact, in addition to causing a large percentage of all the performance losses of the line (21.7%), also cause a large part (about 50%) of the total quality losses, since the vials with high or no cap are automatically discarded from the line.

For this reason, starting from Week 3 of 2023, a new data collection campaign was carried out directly on the line, to monitor the micro-stops after the execution of the maintenance intervention.

The data collection campaign was carried out in the same way as the one before the intervention, therefore involving random measurements carried out in different days and at different times of the day until Week 8.

RACCOLTA DATI MICROFERMATE WEEK 3-8				
Data	**Lotto**	**T rilevazione [min]**	**Somma microfermi [min]**	**% microfermi**
18/1/23	23R010	60	10.0	17%
26/01/23	23R025	65	15.9	24%
08/02/23	23R041	30	11.5	38%
08/02/23	23R041	45	11.2	25%
09/02/23	23R043	68	25.1	37%
10/02/23	23R044	73	13.8	19%

16/02/23	23D016	80	3.1	4%
23/02/23	23R057	80	13.8	17%
TOTALE		**501**	**104.3**	**21%**

Table 13 – Microstops per batch

The results, summarized in Table 14, are graphically shown in the Pareto Diagram in Figure 47.

DURATA TOTALE MICROFERMI PER MACCHINA			
Macchina interessata	**Durata totale microfermi [s]**	**% fermo**	**% cumulata**
Lavatrice	3780	72.07%	72.07%
Incassettatrice	750	14.30%	86.37%
Clean	435	8.29%	94.66%
Ghieratrice	280	5.34%	100.00%
Totale	**5245**	100%	

Table 14 - Microstops per machine

As it can be seen, **the micro-stops of the Crimping Machine have decreased drastically**, reaching a weight of only 5.3% on the total of the micro-stops observed compared to the previous 34.5%.

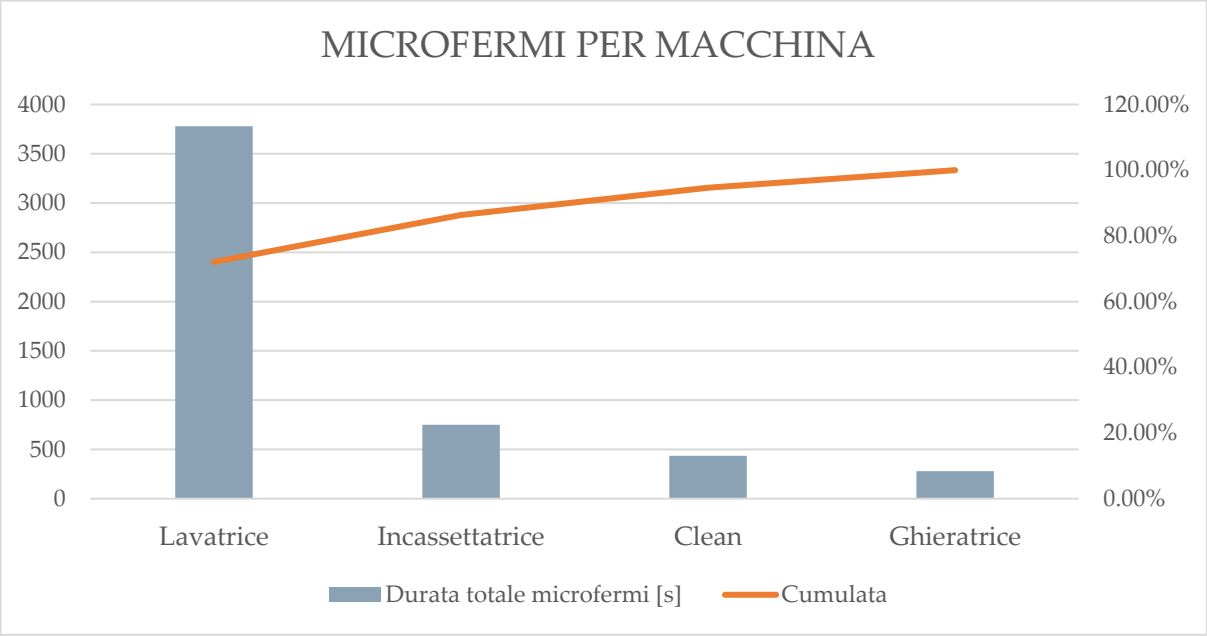


Figure 47 – Microstops per machine

In addition, going in detail of the micro-stops in table 14, it can be seen that the micro stop "High Cap" and all its derivatives have never occurred.

MICROFERMI GHIERATRICE	
Microfermata	**Durata [s]**
Sovraccarico contro guida coclea	250
Ghiere incastrate in lamiera tramoggia	30
Totale complessivo	**280**

Table 15 - Crimping Machine microstops

It can therefore be concluded that **the adopted countermeasure was successful**.

As for the **Encasing Machine**, since the new cases purchased as a countermeasure for the main micro stops of the latter would only arrive at Week 13, it was expected that the Encasing Machine would become the new bottleneck at the time of the data collection campaign.

However, unlike what was expected, **the new bottleneck of the line has become the Washing Machine** and not the Encasing Machine. Indeed, the latter accounts for 72% of the new micro-stops of the line after the intervention. This occurred mainly for two reasons:

1. The problems of the Washing Machine were "masked" by the micro stops of the Crimping Machine upstream, which did not allow the latter to work continuously and consequently to bring out the problems.
2. There were sudden and evident mechanical problems on the machine, which in fact required an emergency maintenance intervention.

The detail of the micro stops of the washing machine is presented in Table 16

MICROFERMI LAVATRICE				
Microfermata	**Durata [s]**	**% su fermi lavatrice**	**% su fermi totali**	**% cumulata su totale**
Sovraccarico arresto al carico	1590	42.06%	30.31%	30.31%
Sovraccarico spintore	1500	39.68%	28.60%	58.91%
Giunto chiusura pinza incastrato	540	14.29%	10.30%	69.21%
Spegnimento nastro tunnel al carico	60	1.59%	1.14%	70.35%
Giunto apertura pinza incastrato	60	1.59%	1.14%	71.50%
Spinta in ingresso non completa	30	0.79%	0.57%	72.07%
Totale fermi Lavatrice	**3780**	**100.00%**	**72.07%**	

Table 16 - Washing Machine microstops

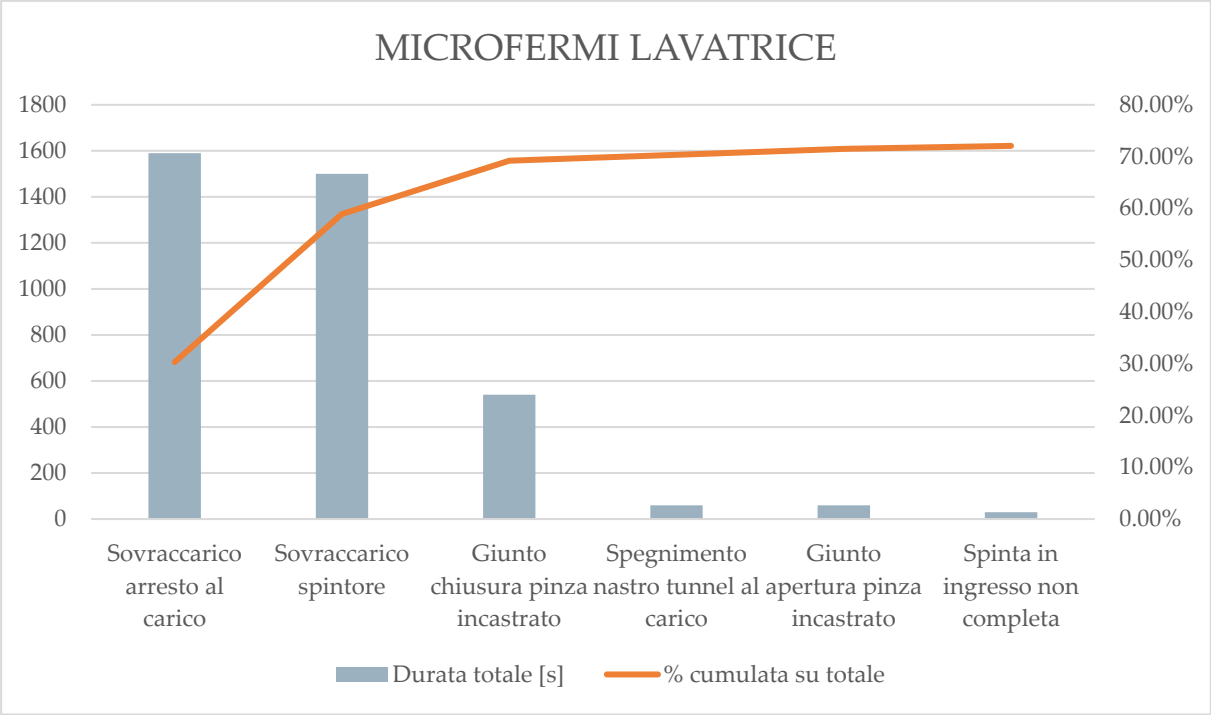


Figure 48 - WashingMachine microstops

The intervention of extraordinary maintenance, which took place at Week 6, was aimed at the resolution of the micro stops "clutch clamp closure stuck" and "joint opening clamp stuck". After the intervention, these micro stops decreased drastically and thus their weight on the total of the micro stops of the machine.

Regarding instead the micro stops "Overload stop to the load" and "Overload pusher", these will be new object of deepening from the company and the new point of departure in the optical of the continuous improvement.

10.2 Global impact of the implemented countermeasures on the final target

As for the impact of the implemented countermeasure on the final target of OEE improvement, **the intervention carried out on the capping machine is the only countermeasure for which an immediate feedback on the target is expected**. Indeed, as regards 5S, the Visual Board and the dedicated team, the impact on the OEE is difficult to be directly traced and quantified to these two improvement actions. However, the positive impact of the latter will certainly be appreciable in the long term.

At the same time as the data collection campaign on micro stops, the results were obviously also monitored offline through the OEE file. Indeed, this represents the ultimate goal of the project and the most important parameter to be monitored.

The OEE data summarized in Table 17 are presented below. These refer to the period from Week 3, first week after the maintenance intervention, to Week 10 coinciding with the closure of our project.

OEE monitoring TO BE - Week 3/10					
Week	**N⁰ batches**	**Availability**	**Quality**	**Performance**	**OEE**
3	11	71.2%	97.9%	52.2%	36.2%
4	11	75.0%	98.1%	50.3%	36.8%
5	10	66.8%	97.7%	47.3%	30.4%
6	9	76.7%	98.1%	46.5%	35.1%
7	9	67.2%	97.3%	47.7%	31.3%
8	14	77.9%	98.2%	56.4%	**43.1%**
9	10	69.3%	97.1%	51.5%	34.7%
10	9	73.1%	97.5%	51.5%	36.9%
Totale	**83**	**72.5%**	**97.8%**	**50.8%**	**36.0%**

Table 17 - OEE monitoring

As clearly visible, since the first week after the intervention there has been a sharp increase of the **OEE**, which reached its **peak in Week 8 with a value of 43.1%**.

In particular, going specifically into the analysis of the three components of the OEE, in the table below a direct comparison is made between the average condition at the beginning of the project and the average condition at the end of it.

	PROJECT START Week 25-43, 2022	PROJECT END Week 3-10, 2023	DELTA
Avg Performance	45.5%	50.8%	**+ 11.7%**
Avg Quality	95.2%	97.8%	**+ 2.7%**
Avg Availability	66.2%	72.5%	**+ 9.5%**
Avg OEE	**28.6%**	**36.0%**	**+ 25.9%**

Table 18 - OEE comparison

As expected, the component that has undergone the greatest increase is the **Performance**, which has increased by 11.7% from the previous 45.5% to the current 50.8%. In the definition of the nice to have target it was estimated to reach a performance of about 56%, however this was not possible because of the new problems occurred to the washing machine.

As for the **Quality** factor, this is increased by 2.7%, reaching the current value of 97.8%. This result coincides almost perfectly with what was estimated in the

definition of the target, i.e. the achievement of a Quality factor equal to 97.6%. From this it can be concluded that the elimination of the micro stop "High Cap" and all its derivatives has involved the elimination of more than 50% of all the scraps of the line.

On the other hand, regarding the **Availability** factor, this has increased surprisingly by 9.5%, from the initial 66.2% to the current 72.5%. Analysing the reasons behind this increment, it turned out to be a consequence of the improvement of the other two factors. In fact, the improvement of the Performance and Quality factors has led to a decrease in the actual filling time of batches. As a result, it was possible to **increase the percentage of reduced cleaning compared to complete cleaning**, since the deadlines described in the previous paragraphs could be met.

To do an example, if the complete cleaning must necessarily be carried out every 24h, managing to fill a lot in 10h means having the possibility to perform a reduced cleaning to move to the other lot and conclude the two batches before the expiry of 24h. On the contrary, this is not possible if the filling time of a lot is equal to 13h.

The increase of the number of reduced cleaning was significant:

	2022 (weeks 25-52)	2023 (weeks 3-10)
n° of batches filled	168	85
n° of reduced changeovers	19	28
% of reduced changeovers	11%	33%
increase (%)	-	191%

Table 19 - Changeover improvement

This phenomenon has perfectly compensated the least increase of Performance, allowing the **achievement of an average OEE equal to 36.0% compared to 28.6% of the initial condition**. From these results we can therefore say that **both the must to have target and the nice to have target of the project have been fully achieved**.

10.2.1 Two sample-t Test

In order to establish statistically that the difference between the average OEE at the initial condition and the one at the final condition is not due to a sampling error, but there is actually a systematic factor (in our case the implemented countermeasure) that differentiates the averages in the two reference populations, it was decided to make a **hypothesis test on the difference between the two mean.**

The OEE values presented in Table 18 of the previous paragraph refer to the averages calculated on a weekly basis, but for this type of analysis a higher level of detail is required. For this reason, the OEE values of the individual batches produced

between **weeks 25-43 for the initial condition** and between **weeks 3-10 for the final condition** has been extrapolated. Indeed, working with values of individual batches instead of the weekly averages, the sample size increases and so the accuracy of the test.

The OEE values of the individual batches produced in the reference weeks are shown below.

OEE Initial Condition Weeks 25-43							
Batch	**OEE**	**Batch**	**OEE**	**Batch**	**OEE**	**Batch**	**OEE**
22D090	32,22%	033A22	20,67%	22R108	32,45%	R001B22	18,44%
22D091	25,78%	22D099	9,65%	22R109	23,83%	V22R125	14,75%
22D092	30,75%	22D102	23,21%	22R110	33,65%	034A22	13,27%
22R070	29,19%	22D105	27,46%	22R111	40,90%	035A22	17,84%
22R071	25,15%	22R084	24,96%	22R112	28,86%	036A22	21,22%
22R072	20,16%	22R090	33,03%	22R113	20,46%	037A22	18,60%
22R073	25,89%	22R091	31,03%	22R114	24,26%	038A22	29,40%
R22008	31,16%	22R092	34,75%	22R115	21,00%	039A22	27,15%
22D093	31,07%	22R093	29,45%	22R116	27,03%	041A22	17,94%
22D094	31,14%	22R094	37,41%	22R118	20,25%	22R138	10,79%
22D095	24,84%	22R095	33,25%	22R119	23,47%	22R139	23,30%
22R074	28,53%	22R096	44,65%	22R120	23,48%	22R140	29,48%
22R075	39,39%	22R097	34,15%	22R121	23,81%	22R141	27,20%
22R076	39,20%	22R098	45,09%	22R122	23,82%	22R142	26,66%
22R077	28,14%	22R099	30,18%	22R123	22,05%	22R143	38,67%
22R078	27,44%	22R100	32,61%	22R124	27,55%	22R144	38,93%
22R079	33,00%	22R101	32,28%	22R126	31,60%	22R145	32,16%
22R080	24,36%	22R102	46,41%	22R127	43,94%	22R146	41,61%
026A22	20,93%	22R103	27,18%	22R128	16,83%	22R147	27,59%
027A22	28,27%	22R104	31,26%	22R129	33,39%	22R148	40,67%
028A22	21,55%	22R105	26,89%	22R130	27,86%	22R149	38,01%
22R081	28,40%	22R106	26,17%	22R131	46,20%	22R150	31,86%
22R082	33,32%	22R107	29,70%	22R132	21,30%	22R151	22,49%
V22R083	15,56%	22R085	30,80%	22R133	33,85%	22R152	25,36%
029A22	17,04%	22R086	25,95%	22R134	36,53%	22R153	31,93%
030A22	23,23%	22R087	33,01%	22R135	27,73%	22R155	24,62%
031A22	28,44%	22R088	44,16%	22R136	39,04%	22R156	33,66%
032A22	25,72%	22R089	29,74%	22R137	39,90%	22R157	17,64%
						22R158	26,40%

Table 20 - OEE values of the individual batches

OEE Final Condition Weeks 3-10					
Batch	**OEE**	**Batch**	**OEE**	**Batch**	**OEE**
23R006	34,74%	23R038	34,72%	23R058	37,85%
23R007	34,37%	23R039	25,25%	23R059	46,03%
23R009	33,95%	W23D001	25,44%	23R060	38,27%
23R010	32,27%	23D012	27,50%	23R061	42,69%

23R011	42,25%	23R040	30,49%	23R062	36,42%
23R012	29,37%	23R041	27,96%	23R063	37,92%
23R013	27,69%	23R042	37,02%	23D023	42,68%
23R014	38,27%	23R043	42,01%	23D024	28,50%
23R015	39,61%	23R044	37,39%	23D025	20,68%
23R016	34,80%	23R045	34,73%	23D026	30,39%
23R017	51,22%	23R046	36,96%	23R064	38,34%
23R018	37,82%	23R047	41,72%	23R065	34,61%
23R019	39,93%	23D013	32,64%	23R066	35,08%
23R020	33,40%	23D014	24,97%	23R067	30,61%
23R022	42,62%	23D015	27,94%	23R068	46,19%
23R023	47,56%	23D016	20,75%	23R069	40,06%
23R025	35,57%	23D017	32,11%	23R070	34,54%
23R026	31,70%	23D018	25,54%	23R071	56,26%
23R027	42,48%	23D019	33,80%	23R072	29,61%
23R028	29,57%	23R048	40,54%	23R073	36,17%
23R029	35,17%	23R049	42,97%	23R074	39,52%
23R030	29,15%	22R052	45,78%	23R075	31,23%
23R031	29,26%	22R053	56,93%	23R076	35,18%
23R032	38,63%	22R054	41,86%	23R077	34,99%
23R033	39,04%	22R055	51,08%	R23001	34,42%
23R034	26,28%	23R050	41,58%	23R078	40,57%
23R035	32,56%	23R051	41,20%	23R079	31,70%
23R036	25,82%	23R056	39,79%	23R080	26,03%
23R037	26,90%	23R057	46,53%	23R081	37,39%

Table 21 - OEE values of the individual batches

Assumptions

1. **"**OEE final condition**"** is a random sample from population 1 with mean μ1.

2. **"**OEE initial condition**"** is a random sample from population 2 with mean μ2.

3. The two populations are independent.

4**.** Both populations are normal, or if they are not normal, the conditions of the central limit theorem apply

Using the Minitab software, it was then carried out the hypothesis test on the difference between two averages called "**Two Sample T-Test**", since the test statistics has a Student's t-distribution. The results are shown below.

Method

μ_1: population mean of OEE final condition
μ_2: population mean of OEE initial condition
Difference: $\mu_1 - \mu_2$

Equal variances are assumed for this analysis.

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
OEE final condition	83	0,3599	0,0731	0,0080
OEE initial condition	113	0,2856	0,0763	0,0072

Estimation for Difference

Difference	Pooled StDev	95% Upper Bound for Difference
0,0743	0,0750	0,0922

Figure 49 - Two sample T-Test results

Equal variances were assumed for the test. The population standard deviation, being unknown, is estimated through the Pooled standard deviation calculated from the correct variances of the two samples.

Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$
Alternative hypothesis $H_1: \mu_1 - \mu_2 > 0$

T-Value	DF	P-Value
6,85	194	0,000

Figure 50 - P-Value

The **null hypothesis H0**, the one we're testing, is that the difference between the averages of the two reference populations is equal to 0. In that case both samples would come from the same reference population and consequently the difference between the sample averages would be due to the mere fact of sampling error.

The **alternative hypothesis H1** is that the difference between the two averages is actually greater than 0 (one-tail test). In this case, the sample "OEE final condition" would come from a population with a higher average than the population from which the sample "OEE initial condition" comes and therefore would prove that the countermeasure adopted significantly increased the average OEE of the line.

By adopting a significance level $\alpha = 0.05$, we will accept the null hypothesis H0 if and only if the P-Value resulting from the test is greater than α. As highlighted in red in Figure x, the P-value resulting from the analysis is equal to 0.000, less than $\alpha = 0.05$. Consequently, H0 cannot be accepted, concluding that **there is statistical evidence to state that the countermeasure adopted significantly increased the average OEE of the line.**

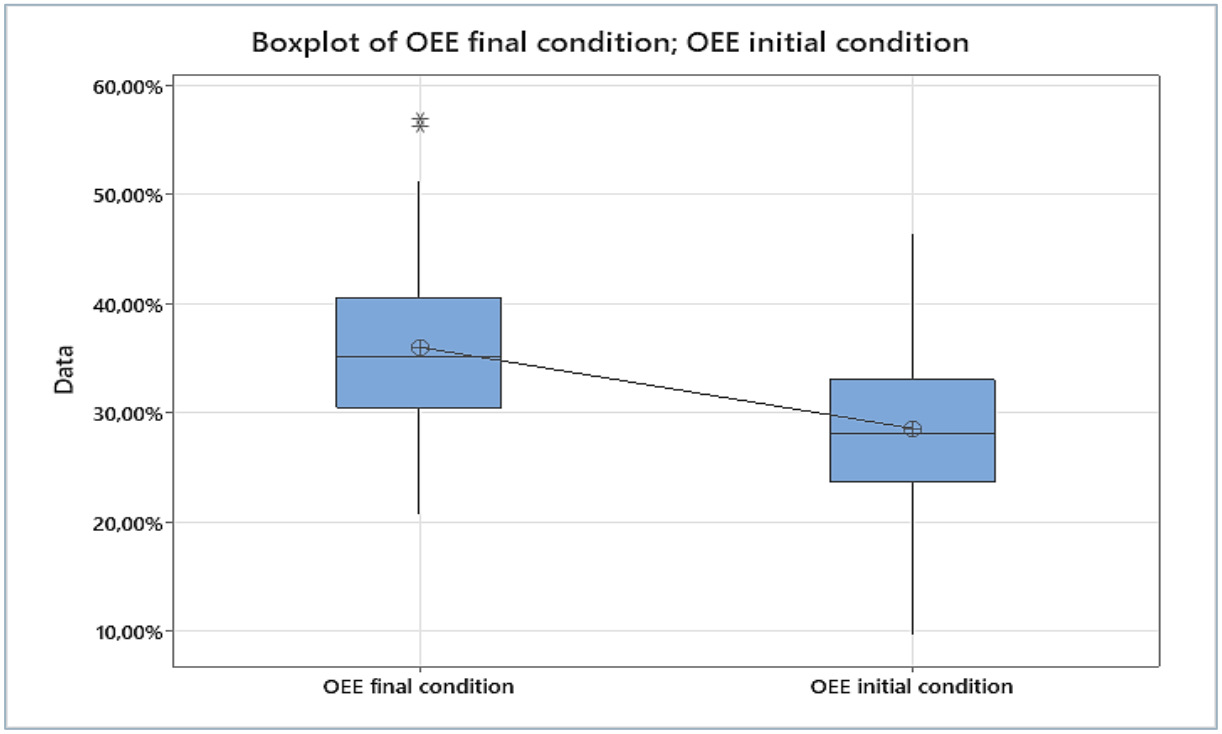


Figure 51 - OEE Boxplot

11 Standardize and Share success

Having quantified the results obtained after the implementation of the first countermeasures, we enter the **last phase of the A3 Thinking methodology :** standardize and share success.

In this paragraph we develop a continuous monitoring system that the company can use to make sure that the achieved results become the new standard for the process.

11.1 Control Chart for Scraps

As we have seen, the elimination of micro-stops caused by the Capping Machine has led to a significant increase in OEE, for this reason it is necessary to develop a continuous monitoring system that is able to quickly detect any deviations from the current condition and act accordingly to avoid returning to the initial situation.

To monitor the condition of the Capping Machine it was decided to take the **scraps** recorded in both clean and white area as a reference parameter to. Indeed, more than 50% of the scraps are formed by vials with high or no cap caused by the Capping Machine.

The scraps of the Clean and White area are automatically recorded thanks to sensors placed on the machines, then they are manually inserted by the operators on the FLP and transcribed again manually on the OEE file by an operator.

From this data, it was possible to create a **control chart** on the production scraps of the line.

11.1.1 Design Phase

The first step in the process of creating a control chart is called the "design phase". At this stage, a sample of data is identified on the basis of which the control chart will be constructed and its limits will be defined. The data sample needs to be extrapolated when the process is "in control", that is when it is believed that the process is in the "target" conditions that you want to maintain. Indeed, the purpose of the control chart is to be able to detect promptly deviations of the process from the state of control.

For this reason, it was decided to use as a reference sample the one relating to production scraps recorded between Week 3 and Week 10 of 2023, as it coincides with the period following the intervention on the Capping Machine and the consequent improvement of the OEE parameters.

The data extracted from the OEE file and "cleaned" from some detected outliers are reported in Table 52.

Batch	Week	Scraps	Batch	Week	Scraps	Batch	Week	Scraps
23R007	3	1032	22R054	8	403	23R057	8	484
23R009	3	1000	23R035	5	1105	23R058	8	606
23R010	3	632	23R036	5	1058	23R059	8	116
23R011	3	390	23R037	5	578	23R060	8	580
23R012	3	985	23R038	5	594	23R061	8	795
23R013	3	534	23R039	5	680	23R062	8	676
23R014	3	479	23R040	6	790	23R063	8	718
23R015	3	555	23R041	6	995	23R064	9	548
23R016	3	677	23R042	6	567	23R065	9	582
23R017	3	603	23R043	6	518	23R066	9	497
23R018	4	522	23R044	6	728	23R067	9	791
23R019	4	405	23R045	6	888	23R068	9	550
23R020	4	519	23R046	6	610	23R069	9	455
23R022	4	408	23R047	6	650	23D023	9	1115
23R023	4	550	23D012	6	522	23D026	9	1028
23R025	4	854	23D013	7	461	23R070	10	538
23R026	4	944	23D014	7	986	23R071	10	820
23R027	4	608	23D016	7	1035	23R072	10	583
23R028	4	717	23D017	7	941	23R073	10	1262
23R029	4	758	23D018	7	962	23R074	10	722
23R030	4	484	23D019	7	1157	23R075	10	1196
23R031	5	676	23R048	7	1157	23R076	10	770
23R032	5	260	23R049	7	760	R23001	10	997
23R033	5	962	23R050	8	720	23R077	10	977
23R034	5	1200	23R051	8	749			

Figure 52 - production scraps between Week 3 and Week 10

Check on the Assumptions

Many standard statistical process control (SPC) methods rest on an assumption that a stable process is one that generates **observations** which are **random** and **normally distributed**. So, the first thing to do is to assess those assumptions in order to understand if standard SPC methods can be used for the creation of our control charts.

Through the use of the Minitab software was carried out the Runs Test for the verification of data independence and the Anderson-Darling test for the verification of the normality of the latter.

Descriptive Statistics

	Number of Observations		
N	K	≤ K	> K
74	726,676	42	32

K = sample mean

Test

Null hypothesis H_0: The order of the data is random

Alternative hypothesis H_1: The order of the data is not random

Number of Runs		
Observed	Expected	P-Value
29	37,32	0,047

Figure 53 - Runs Test on Scraps sequence

The results of the Runs Test, shown in Figure 53, show that the data cannot be considered random because the p-value is lower than the level of significance $\alpha = 0.05$ chosen as a rule of thumb.

Regarding the **hypothesis of normality** of the data, also this cannot be accepted as the results of the Anderson-Darling test shown in figure x indicate a p-value = 0.008 much lower than the chosen level of significance $\alpha = 0.05$.

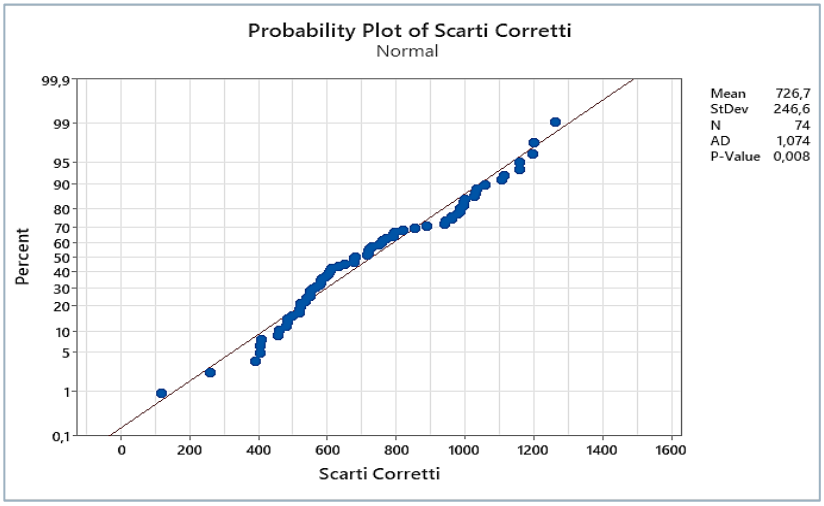


Figure 54 - Anderson-Darling Test on Scraps sequence

For this reason, it can be concluded that the **data under analysis do not comply with the assumptions** and therefore standards SPC methods cannot be used.

Data snooping to search for a model

Processes encountered in practice often produce non-random and/or non-normal observations, but they can still be predictable. In these cases, we need to consider statistical methods to describe or "model" the nature of the process behavior**.** So, we now have to **find a model that "fits" our data.**

To find a model that fits the data, Minitab software was used. The first step was the so-called data snooping. Looking at the Time Series plot, ACF and PACF of the Scraps sequence shown in figure 55.

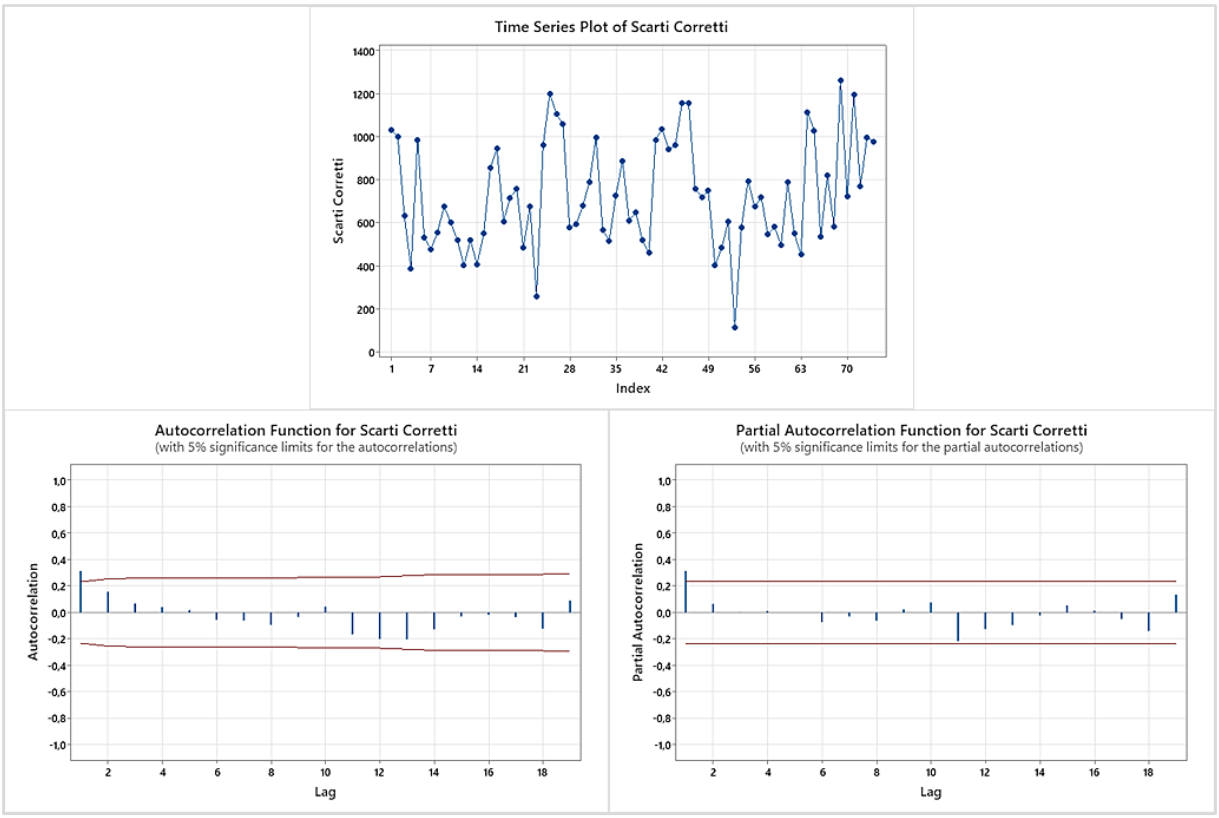


Figure 55 - ACF and PACF

The ACF and PACF confirm the non-random pattern exhibits by the Runs Test, showing a strong correlation to Lag1. A random process is also defined as an independent process since the observations made in different time points are independent or unrelated with one another. Referring to our case, it is plausible that the number of production scraps is not a completely random variable and that the observations may be related to each other. In fact, the number of production scraps recorded today can be somewhat dependent on the number of scraps recorded yesterday, perhaps because of a problem on the machine that could not be solved by the end of the previous batch.

For this reason, after snooping the data and making the necessary considerations, the proposed data model is an **ARIMA(1,0,0).** To search for the coefficients of the model, a regression analysis was performed on Minitab using the initial variable lagged twice as a regressor. The results are shown in Figure x.

The estimated coefficients are significant, since the p-value resulting from the ANOVA is very close to zero and still less than 0.05

The final regression equation is : **Scraps = 491,8 + 0,319 Scraps_Lag1.**

Regression Equation

Scarti Corretti = 491,8 + 0,319 Scarti Corretti_Lag1

Coefficients

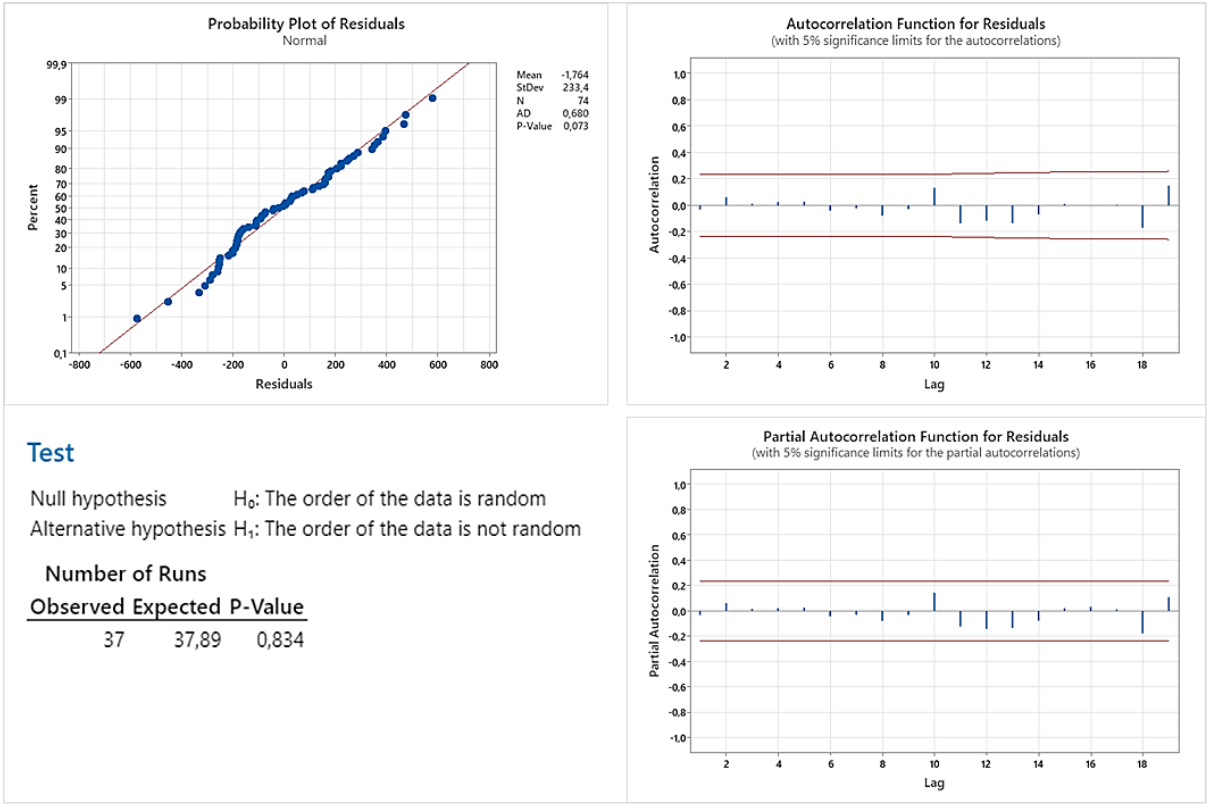
Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	491,8	85,5	5,75	0,000	
Scarti Corretti_Lag1	0,319	0,112	2,85	0,006	1,00

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	445202	445202	8,10	0,006
Scarti Corretti_Lag1	1	445202	445202	8,10	0,006
Error	71	3900726	54940		
Lack-of-Fit	65	3632496	55885	1,25	0,426
Pure Error	6	268230	44705		
Total	72	4345928			

Figure 56 - Regression

At this point, to validate the model there is the most important check on the **residuals**. So, Runs Test is repeated and ACF and PACF are displayed to verify the independence of the data, while the Anderson-Darling Test is performed to verify its normality.



Test

Null hypothesis H_0: The order of the data is random

Alternative hypothesis H_1: The order of the data is not random

Number of Runs

Observed	Expected	P-Value
37	37,89	0,834

Figure 57 - Runs Test

As shown in Figure 57, the residues result to be random and normal, therefore **the model used to represent our data is correct**.

At this point, an I-MR control card will be created on the residuals:

As shown in Figure 58 below only one point appears beyond the control limits of the Moving Range CC. However, no special causes have been found to justify the outlier,

which is only slightly out of the UCL. For this reason, the Design phase of the Control Chart can be considered concluded and consequently both the model

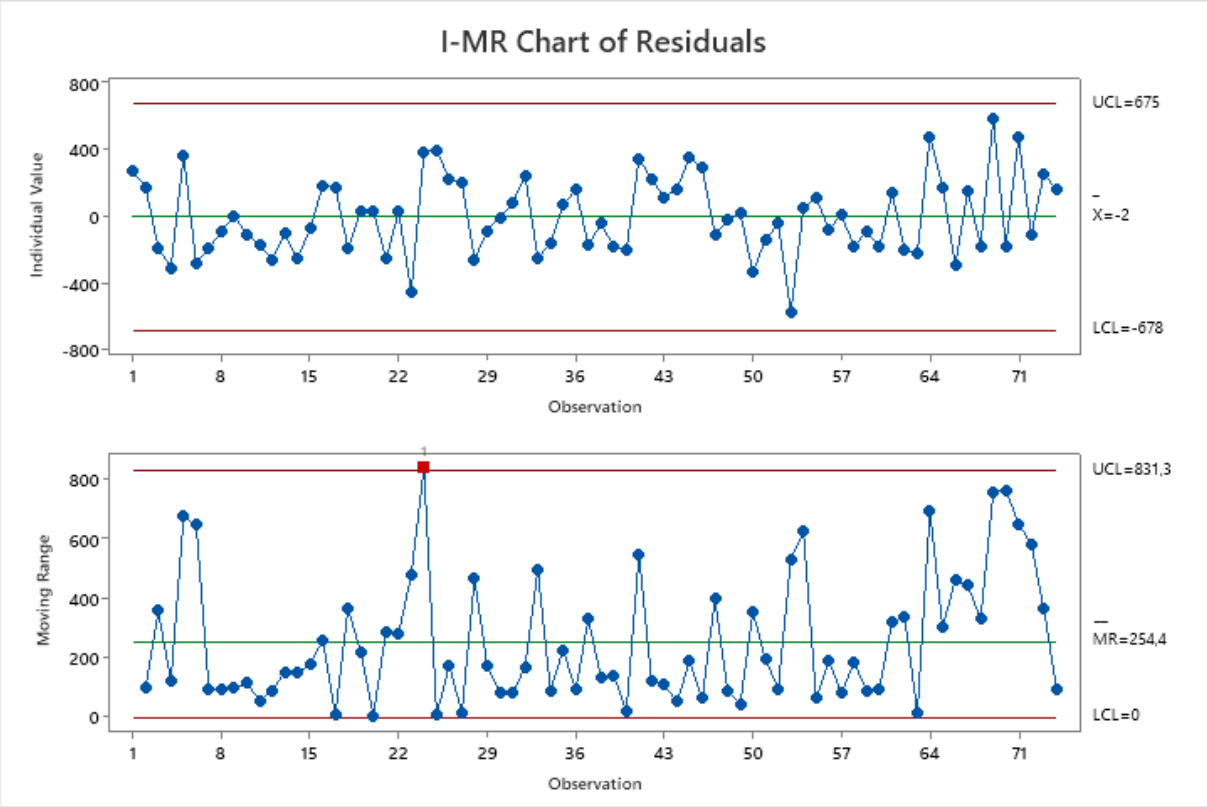


Figure 58 - I-MR Chart of residuals

parameters and the CC limits will be kept fixed for the "Usage" phase.

11.1.2 Usage Phase

For the Usage phase of the Control Chart, an Excel file has been created in which every time a new observation is inserted, that is the number of Scraps of the lot, the "residual" will be automatically calculated as the difference between real data inserted and the so-called "fit" calculated with the formula that contains the model parameters: **Scraps = 491,8 + 0,319 Scraps_Lag1.**

The calculated residual will then be added to the control card "I", while for the control card MR the new point will be calculated as the absolute difference between two subsequent observations: MRi = |Residual(i) – Residual(i-1)|.

The I-MR can indicate a situation of out of control both when one or more points fall beyond the control limits and when the course described by the points, even if inside the limits, is not random. For this reason, some sensitivity rules have been inserted for the CC, so an alarm will be reported if :

1. One or more points fall outside the 3 sigma control limits

2. 9 consecutive points are above or below the mean

3. 6 observations in a row grow or decrease

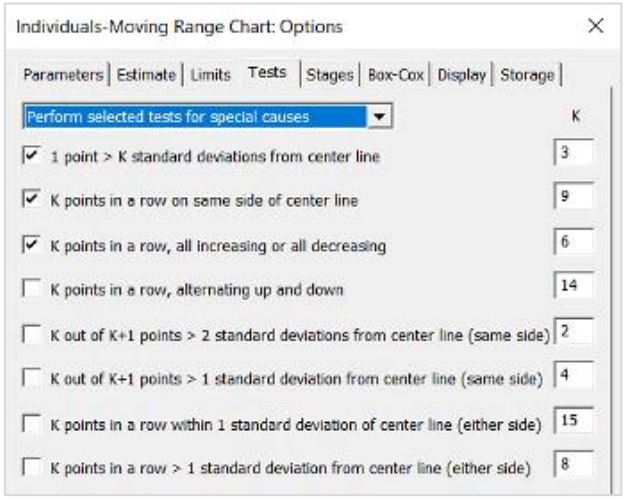


Figure 59 - Individuals-Moving range chart

The control chart will be printed and affixed alongside the Visual Board on the line. Daily, it will be automatically updated to the Excel file and then the individual dots on the printed sheet will be added. Afterwards, any alarms will be discussed at the meeting set up for the Visual Board at 14:00.

12 Conclusions

During the last 5 months we were able to learn a lot on what it means to work in a company and understand its processes. On top of that we also learned the value and the complexity of carrying out a project with people with different background and culture. On the other hand this heterogeneity allowed us to see the all the processes on different points of view.

Applying the A3 structure allowed us to methodologically narrow down our focus and be able to naturally identify the root causes thanks to the measurements performed.

We also believe that this case study is a great example of the power of the OEE measurement. It supported the funneling process and allowed us to monitor the effects of the countermeasures. As well it will act as metric for future implementation of the countermeasures developed during the project.

Improving an automated filling line in a pharmaceutical context has revealed to be very complicate. Moreover, being a company that produces intravenous injectables the number of constrains increases even more and, as we have seen for the SMED can impede the implementation of certain solutions.

The other main obstacle we faced was to introduce a lean culture among the company: at the beginning of our project, the company had already started to promote the lean culture with improvement projects, although we noticed that the operators were still skeptical about the project. We learned how to approach them and to transmit the values of the lean culture, also once the results started to come the operators started to be much more cooperative and even began to propose improvement actions themselves.

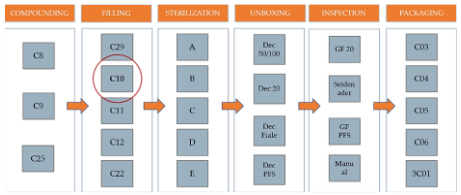
To conclude we can state that both the nice to have and the must have targets of the project have been reached. Indeed, the average OEE registered at the end of the project is to 36.0%. However, the target for the end of 2023 of reaching an OEE equal to 45% is still to be reached. Still, we are confident that the actions implemented and the established lean culture will favor continuous improvement and, with the correct effort, also the final target of the company will be reached by the end of 2023

Figure 60 - Final A3 Thinking

A3 No. and Name	Team members (name & role)	Stakeholders (role & department)	Company objective	Organisation objective
Corden Pharma OEE improvement project	1. Maria Giulia Perrone	1. Matteo Rossini, methodological tutor	Increase OEE of a strategic filling line	Improve production productivity
Team Leader (name & 'phone ext)	2. Massimiliano Maiocchi	2. Maria Rosaria Giancippoli, company tutor		
	3.	3.	**Start date & planned duration**	**Start date & planned duration**
	4.	4.	October 2022 , 5 months	11/10/22 - 11/03/23

1. Problem Background

Despite its strategic importance, the **C10 filling line** is the one with the lowest average **OEE value, equal to 28.6%** at the beginning of the project in October.

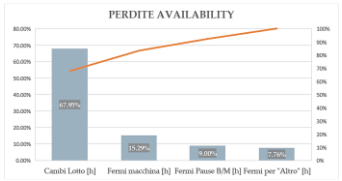


For this reason, our contribution was requested to support a dedicated team created for the **productivity improvement of the C10 filling line.**

2. Problem Breakdown

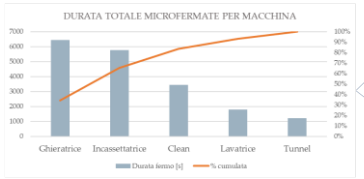
Breaking down the indicator into its components, the current **average Availability** resulted to be equal to **66.2%**, the current **average Quality 95.2%** and the current **average Performance 45.5%**

Availability Problem



Most of the availability losses (68%) are attributable to time spent for **Changeovers.** In particular, 89% of these are **complete cleaning.**

Performance Problem



Crimping Machine : the three main categories of micro stoppages are "High Cap", "Spilled Vial" and "Stucked Cap".

Encasing Machine : the most frequent categories of micro stops are "Robot Overload" and "Cases Change".

3. Goal

MUST TO HAVE TARGET : defined on the basis of a goal set at a managerial level

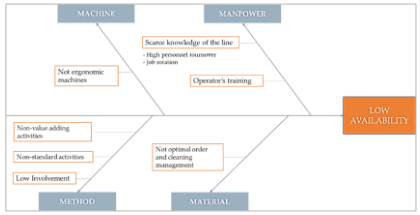
"Increase OEE measurement from 28.6% to 34.5% by Week 10 of 2023"

NICE TO HAVE TARGET: defined following a data-based approach

"Increase OEE measurement from 28.6% to 36.0% by Week 10 of 2023"

4. Analyse the Root Cause

Availability Problem - ROOT CAUSE ANALYSIS

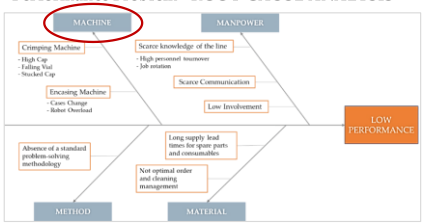


The major root causes concern the **method** and **material** category :

- Non value adding activities performed during the changeover

- Material and order management

Performance Problem - ROOT CAUSE ANALYSIS

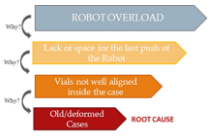


As for the category "Machine", being the most impactful category, a **5 Whys analysis** was carried out on each of the most relevant micro stops of the Crimping and Encasing Machine. :

Crimping Machine

Transport system guides worn-out + misalignment and damaging of the transport cells of the Capping Machine

Encasing Machine



Old Cases which are too deformed and have too thick side rails that do not allow the correct alignment of the vials inside

5. Countermeasures

PROBLEM	ROOT CAUSE	COUNTERMEASURE	DUE DATE	RESPONSIBLE
LOW PERFORMANCE	Transport cells misalignement	Transport cells replacement	Week 12, 2023	Maintenance Manager
	Guides Worn-out	Guides replacement and cells realignement	Week 2, 2023	Maintenance Manager
	Old cases	Purchase and use of new dedicated cases	Week 12, 2023	Maintenance Manager
	Low involvement	Visual Board	Week 7, 2023	Visual Board dedicated team
	Scarce communication			
	Scarce Knowledge of the line	Dedicated Team	Week 5, 2023	Production Manager
	Not optimal order and cleaning management	5S	Week 51, 2022	5S dedicated team

PROBLEM	ROOT CAUSE	COUNTERMEASURE	DUE DATE	RESPONSIBLE
LOW AVAILABILITY	Non standard activities	Standard work	proposal	TBD
	Operators' organization	Third person inside the clean area	proposal	TBD
	Non value adding activities	SMED	Week 5	Project team
	High turnover, too quick training	Standard work	proposal	TBD
	Scarce knowledge of the line	Dedicated team	Week 5	Production manager
	Material management, disorder	5s	Week 15	Project team

6. Implement

The countermeasures actually implemented are:

- Guides replacement and cells realignment of the transport cells of the Capping Machine

- Visual Board

- 5S

- DedicatedTeam

6. Final Results & Monitoring

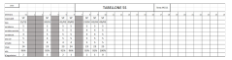
	PROJECT START Week 25-43, 2022	PROJECT END Week 3-10, 2023	DELTA
Avg Performance	45.5%	50.8%	+ 11.7%
Avg Quality	95.2%	97.8%	+ 2.7%
Avg Availability	66.2%	72.5%	+ 9.5%
Avg OEE	**28.6%**	**36.0%**	**+ 25.9%**

From these results we can therefore say that **both the must to have target and the nice to have target of the project have been fully achieved**.

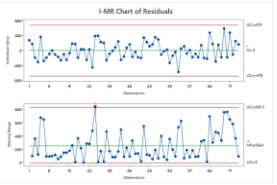
7. Standardise and share success

To make sure that the achieved results become the new standard for the process we developed a continuous monitoring system :

5S : regular audits



Capping Machine : Control Chart on Scraps



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