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# Application of Poka Yokes and proposal of a Fuzzy Logic model to improve maintenance KPIs.

## -Case study for Hikma Pharmaceuticals -

Realized by

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*With the expression of my gratitude, sincere appreciation and warm consideration, I dedicate this modest work to whom I will never be able to express my sincere love. To my dearest parents « IMEDJDOUBEN Abderezak et DAOU Karima » for always loving and supporting me, I could never have done this without your constant faith, support and encouragement.*

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*To all my family and all my*

*friends,I love you*

***IMEDJDOUBEN Noura***

# *Dedication*

*To my dear parents, my mother and father,*

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# List of abbreviations

| | |
|---|---|
| PK | : Poka Yoke |
| KPIs | : Key Performance Indicators |
| MTBF | : Mean Time Between Failures |
| MTTR | : Mean Time To Repair |
| OEE | : Overall Equipment Effectiveness |
| PDCA | : P: plan D: Do C: check A: act |
| FL | : Fuzzy Logic |
| LVs | : Linguistic Variables |
| AI | : Artificial Intelligence |
| FMEA | : Failure Mode Effect Analysis |
| SAP | : Systems, Applications and Products |
| QR | :Quick Response |

# General Introduction

The industry is constantly evolving, and this creates competition within the industrial sector. In this competitive environment, the factor that sets companies apart is the quality of their products and services. The quality action should therefore include its reach throughout the whole product life cycle, starting from customer identification requirements and expectations to the customer's service. In this sense, quality is everyone's responsibility, from the top management to the front-line workers who are directly involved in the production process [1].

Strong quality management procedures are essential considering the complexity of modern production processes and the possibility of human mistake. The Japanese idea of Poka Yoke, commonly referred to as mistake-proofing or error-proofing, develops in this setting as a proactive method of preventing faults and flaws in processes or systems.

Alongside Poka Yoke, Key Performance Indicators (KPIs) are becoming a common technique for companies hoping for continuous development and wise decision-making. KPIs are quantifiable measures that offer insightful data on a number of performance parameters for processes, including quality, productivity, efficiency, and customer satisfaction. Organizations can identify areas for improvement, establish performance goals, and drive strategic efforts to optimize their operations by tracking and evaluating KPI data. However, due to inherent uncertainties and imprecision context, efficient maintenance and optimization of Poka Yoke systems and KPIs can be difficult. In order to improve quality control and maximize performance, this thesis investigates the incorporation of an AI tool which is fuzzy logic as a principal object of our work.

The purpose of our work is to assess the impact of PYs on maintenance KPIs and then propose fuzzy logic model that enables fast and effective decision-making process, by estimating the improvement in KPIs through the combination of proposed solutions.

Our thesis is organized into four (04) chapters, which begin with a general introduction and end with a general conclusion.

The first chapter describes the state of the art of the Poka Yoke and the in general KPIs and those of maintenance in particular.

The second chapter, concerns maintenance management tools and an artificial intelligence tool, fuzzy logic.

The third chapter will focus on our case study, beginning with a presentation of the Hikma company and a description of its process, followed by an analysis of the CAM line.

The fourth chapter will be devoted to the application of fuzzy logic for a fast decision making to choose combination solutions and observe their impact on the KPIs evolution. Finally, we will end this thesis with a conclusion, in which we will evoke the main contributions of this work.

# Chapter 1: State of the art of Poka Yoke and KPI’s

# Introduction:

The industry is constantly evolving, and this creates competition within the industrial sector. In this competitive environment, the factor that sets companies apart is the quality of their products and services. The quality action should therefore include its reach throughout the whole product life cycle, starting from customer identification requirements and expectations to the customer's service. In this sense, quality is everyone's responsibility, from the top management to the front-line workers who are directly involved in the production process [1].

The traditional approach to quality control is based on inspection, where the product is evaluated at the end of the process (specialists call it "judgment inspection") [2]. After having a considerable number of defects, measures will be taken to adjust the process in order to eliminate them. This causes two major problems. First, some defects may escape the inspectors and risk getting into the customer's hands. Second, defective products must be repaired or even scrapped, which incurs additional costs. In the case of services, it is not even always possible to correct the dissatisfaction of the customer and win his trust again.

A new approach to quality control was formalized, in 1961, by the Japanese industrial engineer Dr. Shigeo Shingo (1909–1990), known as the leader in the fields of continuous process improvement and operational excellence. He called it "Poka Yoke", this composite word literally means "avoid (Yokeru) careless mistakes (Poka)" also known as "mistake proofing" or "fool proofing". He later wrote about it in his book "Zero Quality Control: Source Inspection and the Poka-yoke System". This concept appeared within the context of lean management which is also referred to as the Toyota production system (TPS), then it has been adopted by organizations and companies for performance improvement.

Performance measurement is a weighty tool for any organization. It establishes a clear understanding of the organization's performance and provides a base for continuous improvement by identifying performance gaps. It is important for organizations to measure it regularly to ensure that they are on the right track toward achieving their goals and objectives.
To measure this performance, we use Key Performance Indicators, which are a set of important measures used to track and evaluate the performance of activities in an organization.

As maintenance is one of the pillars of manufacturing, manufacturers are called upon to measure its performance, by tracking different metrics such as downtime, MTBF, MTTR, OEE, maintenance costs, preventive maintenance compliance, and work order backlog. These indicators play a crucial role in helping organizations to assess their maintenance efforts, identify areas for improvement, make informed decisions about resource allocation, and reduce overall downtime and costs.

By tracking and analyzing these KPIs, organizations can gain valuable insights into their maintenance performance and make data-driven decisions to improve operations. Maintenance KPIs play a critical role in supporting management in achieving excellence and high asset utilization.

A state of the art is conducted in this chapter to identify current knowledge about Poka Yoke and its importance to help to improve maintenance KPI's and facilitate discussions on its future directions. This provides the basis for a roadmap for further research on it. First, we explain the method of the implementation of Poka Yoke and its different types, then we will discuss the KPIs in general and particularly maintenance KPI's, their illustration forms and objectives. Finally, we will spot some case studies.

## 1.1. Poka Yoke

According to Shigeo Shingo [3], "Defects = 0 is absolutely possible".

### 1.1.1. Definition of Poka Yoke

"Poka-Yoke is a technique for avoiding simple human error at work" [4].

"PY is a system that uses simple devices or work methods for error prevention in manufacturing, service, or other industries. The main purpose of PY is to detect defects, stop the process and define and eliminate the cause. It's a technique developed to reduce physical and cognitive demands of tasks in manufacturing and assembly processes that create a connection between worker and process in the form of feedback, so errors can be prevented in the future. A tool used in achieving the goals of zero defect and Six Sigma" [5].

"The solutions protecting employees from making mistakes are called PY. It's a preventive Lean tool or simple mechanism that focuses on identifying and eliminating causes of variations in the process, which can lead to defects" [6].

In the past, management systems have conducted out control or management in large cycles, as illustrated Figure1.1:

1. An error takes place (cause).
2. As a result, a defect occurs.
3. This information is fed back.
4. Corrective action is taken accordingly.

While in source inspections, control or management is carried out in small cycles:

1. An error takes place (cause).
2. Feedback is carried out at the error stage before the error turns into a defect.
3. Corrective action is taken accordingly [3].

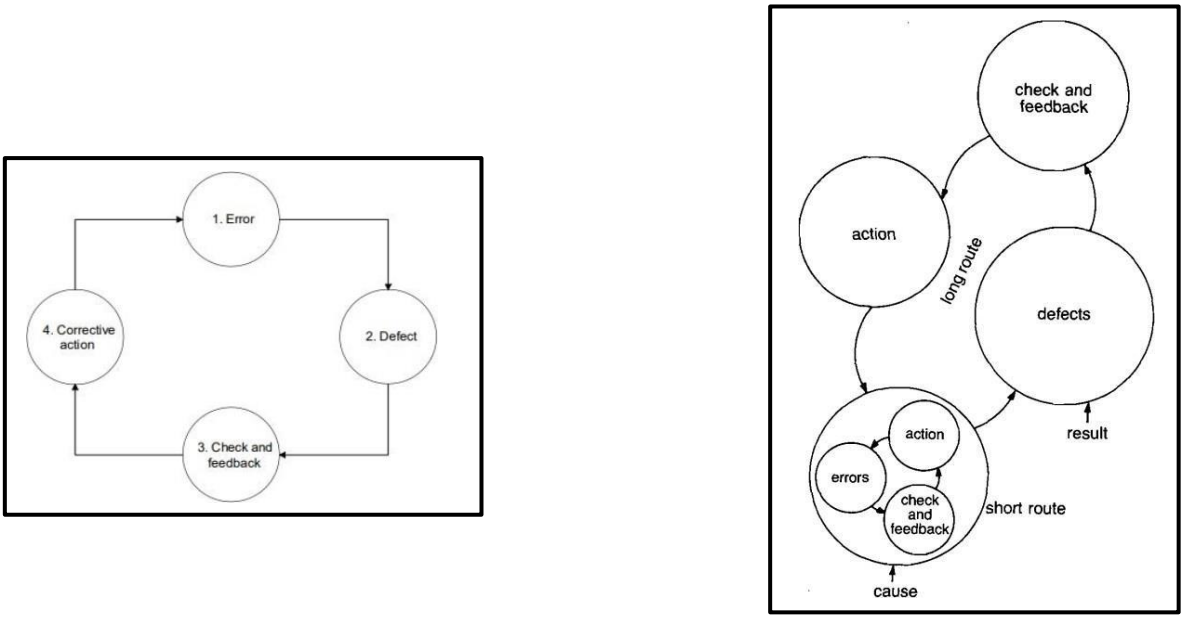



Figure 1.1: Management system vs. Informative Inspection Loop (adapted from Shingo 1986, p).

### 1.1.2. Types of Poka Yoke Systems

The goal of Poka Yoke is to make it impossible for an operator to make a mistake, or to make it immediately obvious when a mistake has been made. In his famous book "Zero Quality Control: Source Inspection by the Poka-Yoke System ", Dr Shigeo Shingo, divided PY systems into two regulatory function categories, depending on their purposes, and three setting function categories, according to the techniques they use [3].

#### 1.1.2.1. Poka Yoke Regulatory Functions

The two main types of Poka Yoke are control methods and warning methods.

- **Control methods** are designed to prevent an operator from making a mistake in the first place. This can be done by using physical barriers, such as guards or fences, to prevent access to certain areas or by using automated systems that will not allow an operator to proceed until the correct steps have been taken.
- **Warning methods** are designed to alert an operator when a mistake has been made. This can be done by using visual or audible alarms, or by using sensors that detect incorrect actions.

Control methods are the most effective way to prevent mistakes, as they are designed to stop an operator from making a mistake in the first place. However, they can be expensive to implement and may require a significant amount of time and effort to set up. Warning methods are less expensive and can be implemented quickly, but they rely on the operator to recognize and correct the mistake.

It is important to consider both control and warning methods when implementing Poka Yoke, as each has its own advantages and disadvantages. By using a combination of both methods, it is possible to create an effective system that will reduce the number of defects and improve the quality of the product or process.

#### 1.1.2.2. Poka yoke Setting Functions

The setting functions of poka-yoke systems can be divided into three categories: contact method, fixed value method, and motion step method.

- **The contact method** is the most basic type of poka-yoke system. It identifies product defects by testing its shape, size, color, or other physical attributes. It uses physical contact between two parts to ensure that the parts are correctly assembled. This method is often used in assembly lines where parts must be connected in a specific order. For example, a contact method may be used to ensure that a screw is inserted into the correct hole before the next step in the assembly process can be achieved.

- **The fixed value method** is a more advanced type of Poka Yoke system. It uses a set value to ensure that the parts are correctly assembled and alerts the operator if a certain number of movements are not performed. This method is frequently used in assembly lines where parts must be connected in a specific order and with a specific amount of force. For example, a fixed-value method may be used to ensure that a screw is inserted with the correct amount of torque before the next step in the assembly process can be achieved.
- **The motion step method** (The sequence) is the most complex type of PY system. It uses a series of steps to ensure that the parts are correctly assembled. It determines whether the prescribed steps of the process have been followed. An example of the sequential PY method might include a car that triggers a warning light or sound when the driver does not put on their seat belt or a manual car that does not allow the engine to start until the driver presses the clutch.

To a large extent, there are three types of setting functions of mistake proofing systems. When companies are looking to reduce the risk of human error and prevent manufacturing defects, it is important to choose the right method for the specific application. Once implemented, these three methods will help eliminate the high costs caused by errors and defects.

### 1.1.3. Implementation of Poka Yokes

Implementation of Poka-Yokes is a process of introducing simple, cost-effective solutions to prevent errors in a production process. Implementing a Poka Yoke pattern is relatively straightforward. Managers need to identify errors in the process and then create a system that will detect and prevent those errors from occurring, following a set of steps shown in the figure1.2 [7].

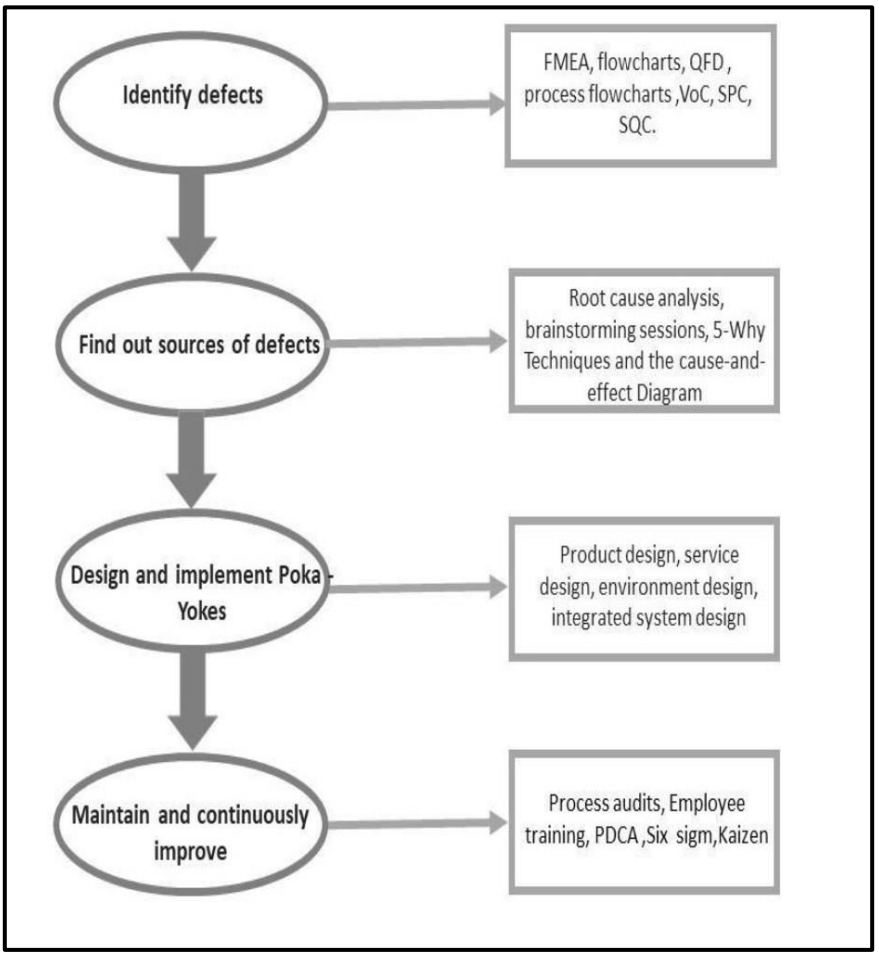



Figure 1.2: Steps of the implementation of Poka Yoke and their associated tools.

### 1.1.3.1. Identify defects

The first step in the PY process is to identify potential errors that could occur in the process. A defect can be any cause of customer dissatisfaction, whether it is a product defect in the manufacturing industry or a lack of attention to customers in the service industry. This can be done by analyzing the process and looking for areas where mistakes could be made. Defects can be identified through a variety of methods, such as failure mode and effect analysis (FMEA), flowcharts, quality function deployment (QFD), process flowcharts, voice of customers (VoC), control charts, or statistical process control (SPC), and statistical quality control (SQC), etc. Additionally, it is important to consider the potential for human error, as well as any environmental factors that could lead to mistakes. Once potential errors have been identified, we move to the next step.

#### 1.1.3.2. Find out sources of defects

The second step is to find out and analyze the sources of the defects. This can be done by conducting root cause analysis, brainstorming sessions, 5-Why techniques, and the cause-and-effect diagram or other methods to determine the underlying causes of the defects. The search for the sources of defects is essential and must be conducted with utmost diligence; otherwise, we may end up merely addressing the symptoms instead of the underlying root causes.

Once the sources of the defects have been identified, the next step is the design and implementation of PY.

#### 1.1.3.3. Design and implement Poka Yokes

This step requires creative thinking and should be done with the involvement of employees who are performing relevant tasks daily.

Design and implementation of Poka Yokes to prevent the occurrence of defects can be realized by product design, service design, environment design, integrated system design, or other means.

To ensure the best possible outcome, team-based brainstorming should be used to come up with the smartest and the most innovative PY ideas.

#### 1.1.3.4. Maintain and continuously improve

Maintaining and continuously improving a Poka Yoke system is very necessary to achieve optimal performance.

The successful implementation of PY systems is a great step in improving the quality of a company's products and services. However, it is important to remember that the pursuit of quality improvement should not end after the successful implementation of a few PY projects. Consequently, regular maintenance and continuous improvement should be part of the company culture in order to ensure that the PY systems remain effective and up to date.

Regular maintenance also helps to ensure that any potential problems are identified and addressed quickly, which can help to prevent costly mistakes and delays. In addition to regular maintenance, it is also important to actively seek out new Poka Yoke opportunities. This could include looking for new ways to improve existing processes, identifying potential problems before they occur, and exploring new technologies that could be used to improve the quality of the company's products and services.

### 1.1.4. The cost of using Poka Yoke

One of the characteristics of a good PY is its low cost, compared with other more cumbersome and expensive methods. Nearly 40% of the 112 poka-yoke implemented by Shingo (1986) cost less than $50 each, with some requiring no investment at all. Nearly 80% cost less than $250. This major feature distinguishes PY mechanisms from other ordinary control methods and techniques. So, considering the low cost of the average PY mechanism, it has become easy to justify its implementation. This brings us to the role of management, which is closely linked to that of cost.

Depending on how the PY is implemented and how it affects the company's operational performance, there may be a relationship between PY costs and KPIs. For example, cost of faults: rework, scrap, and customer complaints can all be decreased by using PY to prevent mistakes and faults. This results in a decrease in the cost per defect which is a crucial financial KPI. Additionally, the PY tries to increase the quality of goods or services by getting rid of mistakes. This can lower non-quality costs like customer loss, returns, repairs, and replacements. These expenses are frequently expressed in terms of money or as a percentage of sales.

## 1.2. Key Performance Indicators

According to Peter Drucker, **"**It is not possible to manage what you cannot control, and you cannot control what you cannot measure!**"**

### 1.2.1. Definition of indicators

The ISO 11620 standard defines an indicator as an expression (which can be numeric, symbolic, or verbal) used to characterize activities (events, objects, persons) both in quantitative and qualitative terms in order to assess the value of the activities characterized, and the associated method.

This expression "includes both raw numbers and ratios". The indicator is a tool for evaluation and decision support. It guides the management of an action.

### 1.2.2. Definition of performance

According to the same standard, performance requires the effectiveness of the provision of services by the library and the efficiency of the allocation and use of resources in providing services before elaborating, it is important to define the notions of effectiveness and efficiency.

According to the ISO 11620 standard, ***Effectiveness*** is the measure of the degree to which given objectives are achieved, while ***Efficiency*** is the measure of the utilization of resources to realize a given objective. These factors are interrelated according to the performance triangle presented in Figure 1.*3* :

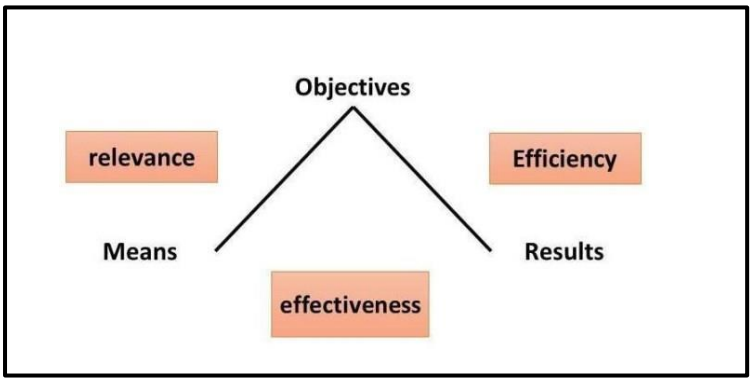



Figure 1.3: Performance triangle (Hubault, 1998)

### 1.2.3. Definition of KPIs

In accordance with ISO 11620 standard, a Key Performance Indicator or KPI is "numerical, symbolic, or verbal expression derived from library statistics and data used to characterize the performance of a library".

KPIs refer to a set of quantifiable measurements used to gauge a company's overall long-term performance. They are a group of quantitative metrics used to assess the overall long-term performance of a company. In particular, they contribute to determining a company's strategic, financial, and operational accomplishments, especially when compared to those of rival companies within the same industry. Thus, a well-designed performance measurement system plays a crucial role in ensuring that a company's actions align with its objectives. This is particularly important in the field of maintenance, where reliable and safe operation is essential for maintaining productivity performance. By measuring maintenance performance through KPIs, it is possible to justify investments in maintenance and detect performance problems easily.

### 1.2.4. Maintenance indicators

When key performance indicators (KPIs) are well-defined, they offer a way for measuring and tracking the development of maintenance performance improvement overtime. Economic indicators, technical indicators, and organizational indicators make up the main three maintenance KPI categories in Europe. Although there are recommended lists of KPIs, only a few of them are commonly used.

The Mean Time Between Failures (MTBF), which measures the typical interval between failures, is one of these regularly used maintenance KPIs. Organizations can assess the reliability and accessibility of their assets using this metric. A higher MTBF number indicates that the assets are more reliable and experience fewer failures.

The Mean Time to Repair (MTTR), which measures the typical time needed to fix a single breakdown, is another crucial KPI. Organizations can evaluate the effectiveness of their maintenance activities by tracking the MTTR. A lower MTTR score shows that issues are dealt with quickly and that assets are back in operation more quickly after a breakdown.

The Overall Equipment Effectiveness (OEE) is a performance indicator that is frequently used in manufacturing and production contexts to gauge the effectiveness and efficiency of machinery or processes. It reveals how effectively a machine or a production line is used and points out areas for improvement. The calculation of this indicator is based on three key factors: availability, performance and quality.

Applying these and other KPIs makes it easier to measure the efficiency and performance of maintenance initiatives. They give companies insightful information about the maintenance approaches used, enabling them to spot areas for improvement and decide which ways to organize their maintenance procedures.

## 1.2.5. Illustrative forms of maintenance indicators

There are several forms of illustrating maintenance indicators, here are some examples:

### 1.2.5.1. Presentation of indicators in numbers

A clear and quantifiable method of monitoring and interpreting maintenance-related data is provided by numerical indicators, here are the different manners to represent them:

- Counts: number with a reference (unit)
- Ratios: count relative to a set (percentage)
- Composite ratios: ratio between two quantities of different units
- Averages
- Ratings: overall assessment according to a defined grid

### 1.2.5.2. Presentation of indicators in graphic presentation

Additionally, graphic indication presentations improve both accessibility as well as engagement in maintenance information. When compared to verbal or numerical data alone, visual representations are frequently more understandable and intuitive.

- Bar graphs: Bar graphs are commonly used to represent maintenance data. They represent the value of each indicator, making it easy to compare performance over different periods.
- Line graphs: Line graphs are particularly useful for representing long-term trends in maintenance. They can be used to track indicators.
- Heat maps: Heat maps are used to represent geographic or spatial data. They can be used to visualize maintenance performance in different geographic areas or to identify problem areas.
- Box plots: Box plots are charts that represent the dispersion and distribution of data.
- Infographics: Infographics are images or diagrams that visually represent data in an easy-to-understand way.
- Dashboards: Dashboards are data visualization tools that allow multiple maintenance indicators to be represented at once. They present key information quickly, making decision-making easier.

Figure1.*4* represents some examples of most used graphic presentations of KPIs.

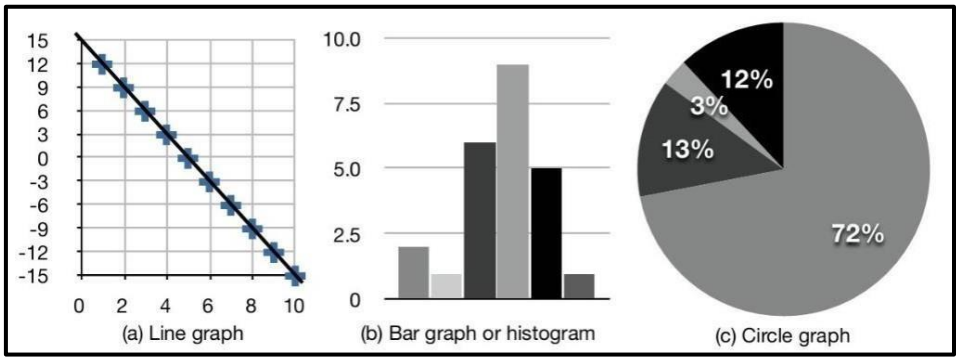



Figure1.4: Example of some graphic presentation of indicators.

### 1.2.6. KPIs objectives:

Performance indicators play an important role in decision-making. They are used to:

- Illustrate information: One of the most common uses of performance indicators is to illustrate information. They provide a quick overview of a trend or situation.
- Adding value to an objective: An indicator can be used to add value to an objective. Profitability (provided it is precisely defined and the framework, context, period and object are defined) can be objective. The same applies to productivity, performance or management ratios.
- Preparing for decisions: a ratio can be a safety tool, a warning, or a kind of flashing light designed to trigger immediate analysis and decisions. A ratio is a provocation for reflection and analysis. Most of the time, these ratios are linked to budgetary control. They are calculated and published at short intervals and are frequent, quick to establish and disseminate. On the other hand, indicators published once a year with a time lag of several months are rarely used for decision-making.
- Making comparisons: Performance indicators enable comparisons to be made either between companies or business sectors or within the company itself: comparisons between products, functions, activities, processes and procedures, networks, management units, etc. In this respect, indicators are useful tools for making decisions. In this respect, indicators are management tools to be used and exploited with a healthy dose of caution and prudence.
- Raising questions and preparing diagnoses: A set of indicators alone does not constitute a diagnosis. The role of indicators is to provoke questions and raise issues or to illustrate and summarize a demonstration or line of reasoning. In this respect, indicators are useful for establishing a diagnosis, whatever the level of that diagnosis (company-wide, sector, management unit, function, etc.).

### *1.2.7.* Methodology for the selection and use of key performance indicators for maintenance, according to "*The European Standard EN 15341"*

The European Standard EN 15341, untitled **"**Maintenance - Maintenance Key Performance Indicators**"** is a set of norms that have been adopted by one of the European Standardization Organizations. This document lists Key Performance Indicators (KPIs) of the Maintenance Function and gives guidelines to define a set of suitable indicators, to appraise and to improve effectiveness, efficiency and sustainability in the maintenance of the existing physical assets either industrial, infrastructures, facilities, civil buildings or transportation systems, etc. in the framework of the external and internal influencing factors.

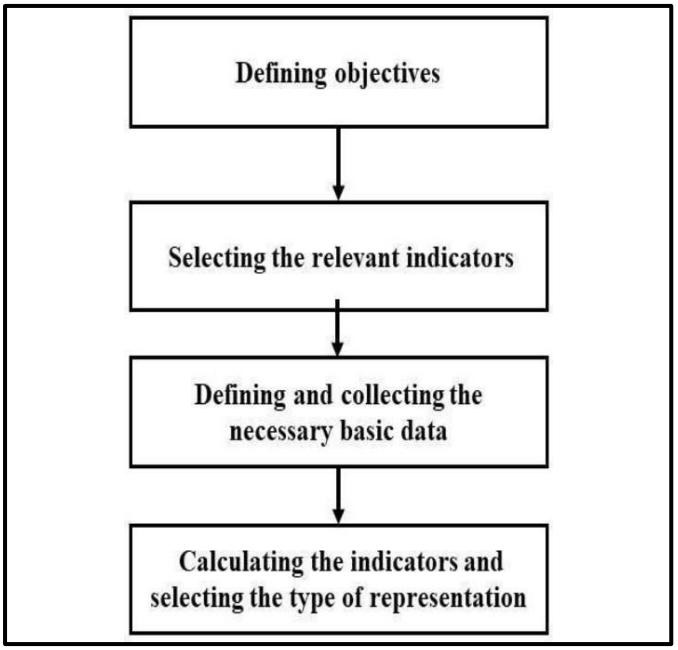



Figure 1.5: Flowchart for the selection of KPI's.

#### 1.2.7.1. Example of a flowchart for the selection and the implementation of KPIS

In order to assist the selection process of KPIs using the suggested Analytic Network Process model, the method depicted in Figure 1.6 is proposed.

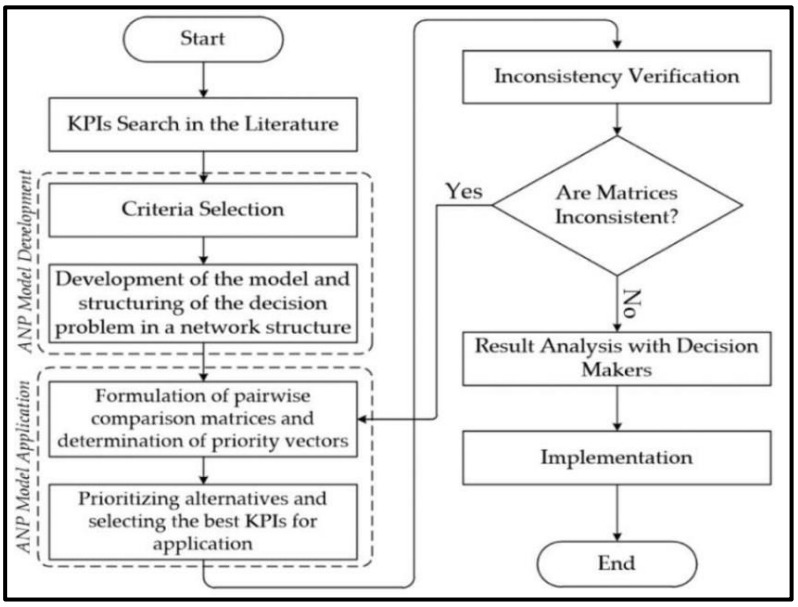



Figure 1.6: Proposed methodology to select and implement KPIs[8].

### 1.2.8. Case studies

Multiple cases were analyzed in this study, in order to outline the importance of KPIs in real life manufacturing operations. They provide a clear picture of how could KPIs be effective in various fields in industry. The most recent cases are presented below and listed in a chronological order, in Table1.1.

Table 1.1: The most recent case studies of KPIs applications.

| **Ref** | **Domain** | **Description** | **KPI's** |
|---|---|---|---|
| [9] | **Tooling and Die Industry** | In order to identify the suitable KPIs for the die casting and Mold-making industry, the use of a multi-criteria decision-making model was proposed, namely the Analytical Network Process (ANP)whereby a reduced number of KPIs areprioritized,9 KPIs were identified, which ensured the correct monitoring of the molding process. | -Number of non-conformities -Revenue vs. costs<br>-%of work done in the company vs. subcontracted<br>-Internal Processes - Hours spent vs. total planned<br>-Occupied capacity of the company. |

| | | | |
|---|---|---|---|
| | | | -Compliance with deadlines for allocated tasks (milestones)<br>-Machine uptime (%)<br>-Employee satisfaction<br>-Customer satisfaction |
| [10] | **Manufacturing planning and control** | In his article, the author tried to find pertinent KPIs for both Manufacturing, Planning & Control (MP&C) and Maintenance Management through a literature review. As a result, he found that throughput time is a crucial KPI in MP&C and Overall Equipment Effectiveness (OEE) is employed in both disciplines. Finally, this essay develops a KPI system that blends MP&C with maintenance management. | -Dock to dock (DTD)<br>-First time through (FTT)<br>-Floor space (savings)<br>-On-time shipment<br>-WIP-to-SWIP<br>-OEE<br>-Sales per person<br>-Average cost per unit<br>-Throughput time |
| [11] | **Rubber industry** | Three factors of economic, social, and environmental dividing into a total of thirteen indicators are proposed as the KPIs for sustainable maintenance evaluation in the rubber industry.<br>Interpretive structural modeling (ISM) methodology is applied to develop a network structure model of the KPIs consisting of three levels. The results show the economic factor is regarded as the basic factor, the social factor as theintermediate factor, while the environmental factor is indicated to be the | - Energy consumption.<br>-Lighting and ventilation<br>-Emission<br>- Working environment -<br>Preventive cost -<br>Failure cost<br>-Maintenance procedure -Breakdown rate -Failure rate -<br>Availability rate<br>-Occupational health |

| | | | |
|---|---|---|---|
| | | leading factor.<br>The results show preventive cost and failure cost are regarded as the most important KPIs. These two costs are the indicators of economic factors that are most<br>related to the maintenance cost. It is followed by occupational health and safety. | & safety<br>-Employee involvement -<br>Training and education |
| [12] | **Clinics facilities** | The present research study employed key performance indicators intended to monitor the performance and maintenance of clinics by implementing some KPIs in a 42-clinicsample. | -Annual maintenance expenditure (AME)<br>-Age coefficient<br>-Density coefficient<br>- Building performance indicator (BPI)<br>- Maintenance efficiency indicator (MEI)<br>-Maintenance sources ratio (MSR)<br>- Managerial span of control (MSC) |
| [13] | **Hospital buildings** | The paper aims to identify the key performance indicator (KPI) of effectiveness of maintenance management for the public hospital building. A total of 32 sets of questionnaires were distributed to the maintenance manager for each hospital in the northern region of peninsular Malaysia by using self- administration strategy. The survey answer | - Monitoring and supervision<br>-Task planning and schedule<br>-Information system a<br>-Maintenance approach.<br>-Spare part management - |

| | | | |
|---|---|---|---|
| | | was analyzed by performing descriptive analysis in SPSS. Overall, the result of descriptive analysis shows that all the ten factors of effectiveness of maintenance management are accepted as KPI since the mean value is at least 3.93 which is classified as important and significant. The most significant factor of effectiveness of maintenance management is task planning and scheduling with the mean score of 4.35. | Outsourcing strategy - Policy deployment and organization<br>- Human resources management<br>- Financial aspect<br>-Continuous improvement |
| [14] | **Aircraft Maintenance Industry** | Through improved analytics of procurement KPIs, an aircraft engineering company seeks to increase procurement efficiency. They aim to improve decision-making, forecast trends, avoid making poor purchases, and deal with Aircraft on Ground (AOG) issues by utilizing Business Intelligence (BI). The objective is to enhance the current KPI system and effectively answer enquiries from headquarters. | -Cost(Part Price Variance ,Contract Utilization ).<br>-Quality( ContractCoverage, Procurement Coverage).<br>-Timeliness (Response Rate, EmergencyProcurement).<br>-Learning (Emergency Procurement ). |
| [15] | **Regulating Maintenance Contracts** | On the idea of modular maintenanceoffers, a KPI structure for maintenance contracts is suggested. Modularmaintenance offerings are an approach to categorize maintenance service optionswith a focus on usage for the consumer and the business ecosystem and improving | - Total cost during the contract period<br>- Costs in relation to system availability<br>- Penalty for lost performance.<br>-Agreed system |

| | | | |
|---|---|---|---|
| | | the integration of the offering. The KPI framework covers six categories of indicators: economic, technical, organizational, quality, safety and health, and the relationship between actors. It proposes indicators for controlling contracts on three levels (resource, performance, and utility level).<br>The framework includes both hard and soft measures for the regulation of contracts. | performance (functionality, reliability).<br>- Maintenance organizational capacity.<br>- Mean waiting time (MWT)<br>- Mean time to repair (MTTR) |
| [16] | **KPIs to improve industrial performance** | In a combined heat and power plant that burns municipal solid waste as fuel, the objective of this case study was to increase boiler efficiency. Here, we've established the boiler efficiency KPI as the main stream flow rate (kg/s) / fuel power (MW).A plot of the KPI and the best forecast are shown in Figure 1 (left). Take note of the broad range in this boiler's efficiency, which ranges from 0.31 to 0.35. | -Maintenance costs / Produced output over a time period.<br>- Maintenance time / Produced output over a time period. - Number of alarms over a time period. |

#### 1.2.8.1. Findings:

The analysis of previous studies related to Maintenance Key Indicators Performance has revealed that they are used in a wide variety of different industries, each of which has used different indicators.

Those studies affirm that there is no standard of the use of KPIs, every company chooses its own ones so that they fit its specific requirements and objectives.

## Conclusion

In order to achieve zero defects, Poka Yoke solutions are used as a very effective tool for quality control, and they have been used in many industries, especially when it is used as a continuous improvement tool associated with other lean manufacturing methods and new technologies such as artificial intelligence and big data.

Continuous improvement activities are essential for cost reduction in the manufacturing industry. These activities involve identifying and eliminating defects, reducing variances, and improving the overall quality of the product [17]. By reducing defects and variances, the cost of production is reduced, resulting in lower prices for the customer. Additionally, by improving the quality of the product, customer satisfaction is increased, leading to increased sales and profits.

By preventing mistakes, cutting down on defects, and improving process efficiency, Poka Yoke boosts performance which is quantified by KPIs. Costs are reduced, staff engagement is increased, and it promotes ongoing development. It results in higher quality, more productivity, and satisfied customers.

Maintenance KPIs are very important for all types of industrial companies, despite their sector of activity. There are so many strategies to choose them, but it is always better to follow a normalized methodology. The number of these indicators is huge, this is why they are always regrouped according to the factors.

KPIs are essential in maintenance to evaluate the effectiveness and efficiency of its activities. KPIs enable organizations to track maintenance performance against set objectives and targets, identify areas that require improvement, and make informed decisions based on reliable data.

Effective use of KPIs in maintenance requires careful selection of relevant metrics, setting targets, regular monitoring and reporting of KPIs, and continuous improvement efforts based on KPI results. It is also important to ensure that KPIs are aligned with organizational goals and objectives, and that they provide meaningful insights into maintenance performance.

# Chapter 2: Tools and technologies

# Introduction

In today's world, engineering tools and techniques play a fundamental role in many areas of activity. They are designed to facilitate tasks, automate processes and improve the overall efficiency of companies and organizations. Maintenance management tools play a crucial role in identifying problems, prioritizing corrective actions, and proactively managing risks. They help improve equipment efficiency, reliability and availability, thereby reducing maintenance costs and unplanned downtime. By using these tools, organizations can optimize their maintenance operations and maintain high levels of performance, these are traditional tools. Modern ones are characterized in Artificial Intelligence tools, they consist of implementing several techniques designed to enable machines to imitate a form of real intelligence.

In the first part of this chapter, we will present the maintenance management tools used in our case study, such as risk assessment, Ishikawa diagram, and Pareto diagram, we will explain them. In the second part, we will talk about an AI tool which is fuzzy logic where we will highlight its basic concepts and how to use them, as well as its advantages and disadvantages.

## 2.1. Analysis tools

In this part we present the maintenance management tools that will be used in the next chapter for the diagnostic of our system.

### 2.1.1. Risk assessment

Risk assessment according to ICH Q9 Quality Risk Management Guideline consists of the identification of hazards and the analysis and evaluation of risk associated with exposure to those hazards [18].

The risk assessment is based on the Failure Mode Effect Analysis Method **(FMEA)**. This method is based on the identification of potential risk sources – defined as failure modes. Each failure mode is evaluated and classified because of the probability of occurrence [P], severity of the potential effects [S] and detectability (D).

Criticality is assessed by a Risk Priority Number (**RPN**): **RPN = [P] × [S] × [D].**

Quality risk management is a systematic process for the assessment, control, communication, and review of risks to the quality of the drug (medicinal) product across the product life cycle [1].

#### 2.1.1.1. Likelihood/probability (P)

The likelihood of an adverse event occurring is measured on a relative scale, such as across a period or number of operations (probable to rare)**.**

Table 2.1: Likelihood table used for risk assessment.

| Rating | Likelihood | Description |
|---|---|---|
| 5 | Almost certain probable | It has likelihood regularly or many times during the life of the product under specification operating conditions (the frequency of an event is perceived to be once per hundred transactions). |
| 4 | Frequent | It has likelihood several times during the life of the product under specified operating conditions (the frequency of the event is perceived to be once per five hundred transactions). |
| 3 | Occasional | It has likelihood infrequently during the life of product under specified operating conditions (the frequency of the event is perceived to be once per thousand transactions). |
| 2 | Remote | It has likelihood of every unlikely during the life of the product under specified conditions (the frequency of the event perceived to be once per five thousand transactions) |
| 1 | Rare | Failure impact is not expected to occur under specified operating conditions (the frequency of the event is perceived to be once per ten thousand transactions) |

#### 2.1.1.2. Severity of potential failure effect

This approach requires the team to consider the impact of this event on product quality or data integrity. The impact of the consequence is expressed on a scale deemed appropriate (high to low) according to the following table:

Table 2.2: Guidelines for Severity Assessment used for risk assessment.

| Ranking | Severity | Description |
|---|---|---|
| 5 | Catastrophic | 1. Medical: the effect of failure mode can result in death or life-threatening injury.<br>2. Significant regulatory impact<br>3. Product functionality is affected.<br>4. Failure to comply with patient safety and efficacy specifications.<br>5. Compliance issue causing plant shutdown |
| 4 | Major | 1. Lot that could not be reworked/ "Reworked".<br>2. Product quality is affected, and the effect of failure mode may result in non-compliance with quality attribute specifications.<br>3. Product recall |
| 3 | Moderate | 1. Defects detected during the inspection.<br>2. Batch reprocessing with human-hour impact; and Resulting Investigation.<br>3. Possible regulatory impact; regulatory inspection observations with no significant impact on the plant. |
| 2 | Minor | 1. The quality of the product is affected, but the effect of the failure mode leads to attributes of aesthetic defects.<br>2. Cosmetic defects found during the inspection: the risk is considered acceptable.<br>3. Possible impact on yield, manufacturing efficiency<br>4. Deviation; can be closed without any investigation. |
| 1 | Negligible | 1. The risk is considered acceptable. The functionality and quality of the product are intact.<br>2. Medical: the functionality of the product is intact, no impact on the health /safety of the patient. |

- **Classification of risk – risk matrix (C)**

Having assigned the likelihood of the risk and the level of severity that such an event may have, the risk can be classified.

The risk is obtained by the multiplication of likelihood or probability (P) and severity (S).

The risk classification ((P*S) =C) gives an indication of the impact on product quality, patient safety, or data integrity according to Figure 2.1

| Likelihood / Severity | Rare (1) | Remote (2) | Occasional (3) | Frequent (4) | Almost Certain (5) |
|---|---|---|---|---|---|
| Catastrophic (5) | 5 | 10 | 15 | 20 | 25 |
| Major (4) | 4 | 8 | 12 | 16 | 20 |
| Moderate (3) | 3 | 6 | 9 | 12 | 15 |
| Minor (2) | 2 | 4 | 6 | 8 | 10 |
| Negligible (1) | 1 | 2 | 3 | 4 | 5 |

Figure 2.1: Risk classification matrix.

- Level 1: (C= 15 to 25)

Means that the likelihood that this failure appears high and that the impact on the product quality, patient safety or data integrity is high.

Additional risk controls must be implemented such that the risk is no longer in the red zone (“high risk”) before work commences.

- Level 2: (C= 4 to 12)

Means a moderate impact on product quality, patient safety, or data integrity.

Risk controls for risk in the yellow zone (“medium risk”).

Additional risk controls shall be implemented such that the risk is no longer in the yellow zone where possible.

- Level 3: (C= 1 to 3)

Means that we have practically no impact on production quality. Patient safety or data integrity.

The risk is in the green zone (“low risk”).

#### 2.1.1.3. Detectability (D)

The likelihood that a negative condition will be detected and recognized before the negative impact occurs, the probability of a risk being detected is rated 1,2,3,4,5 according to its detection possibilities. Determine the detection that will mitigate the risk based on the description provided below in Table 2.3:

Table 2.3: Detectability table used for risk assessment.

| Rating | Detection | Description |
|---|---|---|
| 1 | High | 100% confidence, control will almost certainly prevent a failure cause or detect a failure mode, there is reliable detection device continuously used on the system for direct parameter measurement and leads to alarm activation or automatic (secured) |
| 2 | Moderate | Control may detect a failure cause or failure mode, there is a reliable detection procedure systematically used while operating the system or there is a direct measuring device in line but with no alarm and not automatic system (sufficiently secured) |
| 3 | Low | Control may detect a failure or a failure mode, there is a reliable detection procedure systematically used while operating the system but that gives delayed information/results or there is an indirect measuring device but with no alarm and no automatic system. (Insufficiently secured). |
| 4 | Very low | Controls probability will not prevent a failure cause or detect a failure mode no reliable detection device nor procedure, there are no reliable detection devices nor detection procedure as part of the system operation or monitoring (very low secured). |
| 5 | No controls | The failure is not detectable or is not routinely checked, there is no reliable detection device nor detection procedure as part of the system operation or monitoring (not secured) |

- **Risk evaluation**

Risk evaluations consider the strength of evidence for all three of the fundamental questions.

The Figure 2.2 display the risk classification method used in the assessment process.

RPN: a risk level threshold is established based on the severity rating multiplied by the likelihood rating multiplied by detectability number based on the description provided in the Figure 2.2:

| | | | Detectability (D) | | | | |
|---|---|---|---|---|---|---|---|
| | | | 5 | 4 | 3 | 2 | 1 |
| Risk Classification (C) | Level 3 | 25 | 125 | 100 | 75 | 50 | 25 |
| | | 20 | 100 | 80 | 60 | 40 | 20 |
| | | 16 | 80 | 64 | 48 | 32 | 16 |
| | | 15 | 75 | 60 | 45 | 30 | 15 |
| | Level 2 | 12 | 60 | 48 | 36 | 24 | 12 |
| | | 10 | 50 | 40 | 30 | 20 | 10 |
| | | 9 | 45 | 36 | 27 | 18 | 9 |
| | | 8 | 40 | 32 | 24 | 16 | 8 |
| | | 6 | 30 | 24 | 18 | 12 | 6 |
| | | 5 | 25 | 20 | 15 | 10 | 5 |
| | | 4 | 20 | 16 | 12 | 8 | 4 |
| | Level 1 | 3 | 15 | 12 | 9 | 6 | 3 |
| | | 2 | 10 | 8 | 6 | 4 | 2 |
| | | 1 | 5 | 4 | 3 | 2 | 1 |

Figure 2.2: Risk evaluation matrix.

It is the compression of the estimated risk to given risk criteria using a quantitative and qualitative scale to determine the significance of the risk.

Table 2.4: RPN evaluation

| RPN# | Risk Level | S*L*D Evaluation |
|---|---|---|
| 50-125 | High | • Assess current controls effectively, this function or component is critical<br>• Evaluate the need for further action, such as new design (to lower severity) or new prevention control (to lower occurrence) |
| 30-48 | Medium | • This function or component is potentially critical and validation measures are to be taken |
| <30 | Low | • This function or component is not critical, Risk is considered acceptable and no need to consider or measure any actions<br>• Frequent review and monitoring of hazards are required to ensure that the risk level assigned is accurate and does not increase over time. |

### 2.1.2. Pareto diagram

Application of the 20/80 or ABC law, highlighted by Italian economist Valfredo Pareto, who observed that 80% of a country's wealth is held by 20% of its inhabitants. In business, it is often observed that 80% of problems are due to 20% of malfunctions.

The Pareto diagram is a continuous improvement technique that aims to prioritize the problems, or the causes i.e., to distinguish clearly between what is more important from what is less important [19].

This diagram is composed of a bar chart that orders the frequencies of occurrences in descending order and allows vital problems to be located.

### 2.1.3. Ishikawa diagram

This quality tool is designed to identify the potential causes of a malfunction. It is universal and applicable to practically every aspect of human activity [20]. Applied to maintenance, it enables an investigation to be carried out on five families of failure causes: methods, manpower, operating resources, environment, and materials. It lends itself well to a collective search, carriedout by building a tree structure from downstream (the fault) to upstream (potential causes), as shown in Figure 2.3.

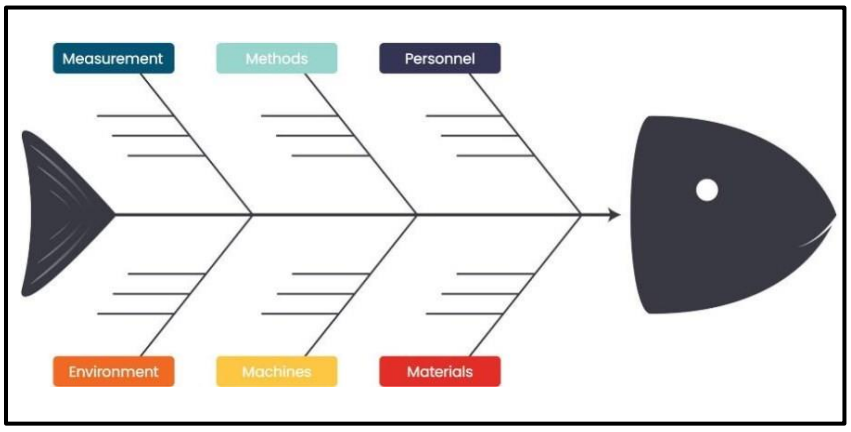



Figure 2.3: Ishikawa cause and effect diagram.

### 2.1.4. FMEA

FMEA is a qualitative, inductive method designed to identify the risks of potential failures in a preliminary product or system project, whatever the technology, in order to eliminate or control them. It is standardized by AFNOR: standard X 60-510 of December 1986.

### 2.1.5. Brainstorming

Brainstorming is the process of using the brain to generate and storm original and creative solutions for a given problem. It is a technique for coming up with ideas and finding solutions to issues. A brainstorming session is a group activity in which every member of the group contributes ideas, which are subsequently discussed. This allows to create connections between ideas by analyzing, synthesizing, and evaluating.

## 2.2. Fuzzy logic

In the context of research for the development of new technologies based on artificial intelligence, fuzzy logic has received immense interest from researchers and industrialists since the beginning of the second half of the last century. Prior to this turn in the definition of logic, all algorithms and processes were based on classical logic which admits no states between true and false, or values between 0 and 1, unlike fuzzy logic, which has the advantage of handling even values between 0 and 1, based on human reasoning.

### 2.2.1. Definitions of fuzzy logic

Two definitions can be given for the term "FUZZY LOGIC":

- The first is that fuzzy logic is used to handle insufficient and imprecise knowledge. It enables knowledge to be represented and processed, so that complex systems can be handled.
- The second is an extension of classical logic, with the aim of reasoning about imperfect knowledge [23].

### 2.2.2. Fuzzy logic principle

The principle of fuzzy logic control approaches the human approach in the sense that the variables processed are not logical variables (in the sense of binary logic, for example) but linguistic variables, close to everyday human language. What's more, these linguistic variables are processed using rules that refer to a certain knowledge of the system's behavior [24].

## 2.2.3. The basic elements of fuzzy logic

### a. Universe of discourse

This is the set of real values (the numerical interval) that the fuzzy variable can take on. In general, the universe of discourse is denoted by uppercase letters "U, W, ...". The linguistic values will then be projected into the universe of discourse to define the subset associated with each linguistic value [25].

### b. Variables and linguistic values

A linguistic variable represents a state in the system to be controlled, or a control variable in a fuzzy controller. Each value constitutes a fuzzy set of the universe of discourse. A linguistic variable is generally characterized by [26]:

- A name for the linguistic variable.
- A set of linguistic values that the linguistic variable can take.
- The universe of discourse

### c. Fuzzy sets

A fuzzy set is a class of objects in which the transition from membership to non-membership is gradual rather than abrupt.

### d. The membership functions

The aim is to establish a relationship between the degree of truth of the fuzzy variable and the corresponding input variable. Fuzzy subsets are those characterized by a membership function $\mu_A(u)$ defined on [0,1] [27].

The choice of membership function form is arbitrary. Comparative studies have shown that with the different forms of membership functions, the results are practically similar in the closed loop. The most frequently used form in fuzzy control is the triangular function. Membership functions can be symmetrical, non-symmetrical and equidistant or non-equidistant. There are various forms of membership functions, such as triangular, trapezoidal, Gaussian and singleton.

## 2.2.4. Fuzzy logic operators

Let fuzzy sets A and B be defined over universes of discourse V and W, with membership function $\mu_A$ and $\mu_B$ respectively [28]:

**a. Fuzzy set union (Fuzzy Union)**

The union membership function $\mu_A$ and $\mu_B$is defined by:

$$\mu_{A\cup B} = max(\mu_A, \mu_B)$$

**b. Fuzzy intersection**

The membership function of the intersection $\mu_A$ and $\mu_B$ is given by:

$$\mu_{A\cap B} = min(\mu_A, \mu_B)$$

**c. The fuzzy complement**

The complement Ā of A in the fuzzy set is included in V with the membership function defined by:

$$\mu_{\bar{A}} = 1 - \mu_A$$

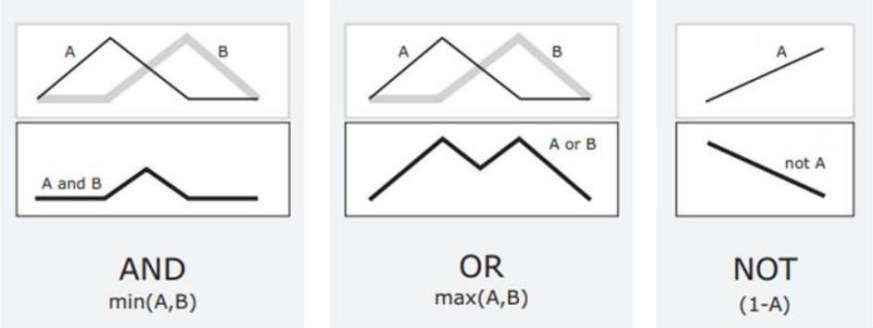



Figure 2.4: Graphical representation of FL operators [28]

**d. Linguistic rules**

The main idea behind systems based on fuzzy logic is to express human knowledge in the form of linguistic if-then rules. Each rule has two parts [10]:

1. Antecedent part (premise or condition), expressed as "If…" describes the state of the system.

2. The consequent part (conclusion), expressed as "then..." expresses the action to be performed by the operator controlling the system.

Each fuzzy rule is based on fuzzy implication. Zedah was the first to introduce the notion of fuzzy rule in the form:

***Rule: If x is A, then y is B.***

## 2.2.5. Structure of a fuzzy controller

Now we turn to the structure of a fuzzy controller. Its conventional structure is shown in Figure 2.5, and is made up of four distinct blocks, the definitions of which are given below in Figure2.5:

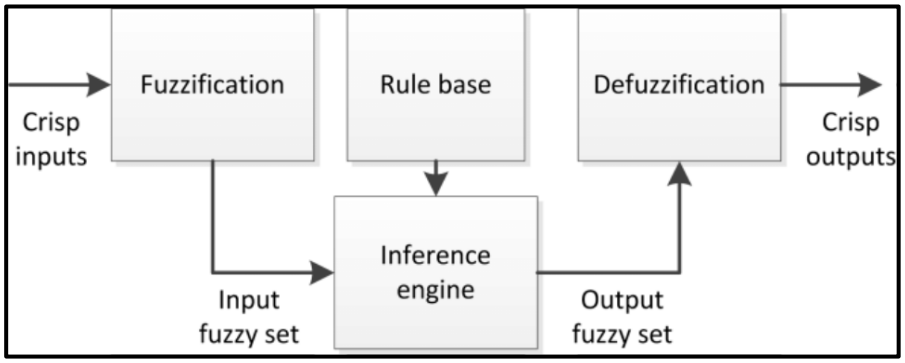



Figure 2.4: Fuzzy logic Controller block diagram [29]

### 2.2.5.1. Fuzzification

Its aim is to transform deterministic input variables into linguistic variables, by defining membership functions for different input variables [30]. A degree of compatibility is obtained by superimposing numerical input variables and linguistic variables.

### 2.2.5.2. Inference engine

Fuzzy inference consists in creating rules whose syntax is very strict, although the terms used appear natural. The creation of the set of linguistic control rules is usually carried out by experts or qualified operators working on the process itself.

Tuning therefore derives a priori from knowledge of how the system works. The linguistic representation of the rules is as follows [30]:

"If antecedent 1 AND antecedent 2 THEN consequence 1".

The number of rules depends on the number of inputs and the number of zones in each input.

### 2.2.5.3. Rule base

This block is a knowledge base corresponding to the operator's expertise or know-how about the system's behavior. It is composed of all the information and knowledge concerning the application domain and the expected control result.

It is used to determine the fuzzy controller's output signal and expresses the relationship between input variables transformed into linguistic variables and output variables also converted into linguistic variables [25].

#### 2.2.5.4. Defuzzification

The inference system provides a fuzzy output by evaluating the rules following one or more real inputs. The problem then arises of giving it an approximate fuzzy representation or a precise value. This is known as defuzzification [30].

Defuzzification is generally one of the most time-consuming tasks in fuzzy processing. There are many defuzzification methods, but only four are practiced. The most commonly used methods are:

- The surface method.
- The height method.
- The center of gravity method.
- The maximum method

## 2.2.6. Types of fuzzy controllers

It exists several types of fuzzy logic controllers. These are some common types of fuzzy logic controllers:

**Type 1: Mamdani-type:** Linguistic fuzzy models, where the antecedent and the consequence are fuzzy propositions.

**Type 2: Takagi-Sugeno (TS) type:** where the consequence is an ordinary function of the input variables (antecedent). Here, there is no defuzzification. In fact, the conclusion of each rule is equal to a constant or a more general polynomial form. The final output is equalto the weighted average of the output of each fuzzy rule.

**Type 3: Tsukamoto-type:** In this case, the outputs are monotonic functions of the input variables. The total output is a weighted average of the degrees of confidence of each fuzzy rule and the values of the functions of the output variables.

## 2.2.7. Areas of application

Fuzzy logic has applications in many fields, including:

- Control and automation.
- Decision support systems.
- Pattern recognition (computer vision, speech recognition and signal processing).
- Expert inference systems (medicine, engineering, finance, and planning).
- Robotics.
- Finance and economics.

- Recommendation systems.
- Computer science.
- Man-machine communication.

### 2.2.8. Benefits and limits of a fuzzy system

The main advantages of the fuzzy logic are:

- Fuzzy systems make it easy to include qualitative data into controller design.
- Fuzzy systems don't need an analytical model of the process to be controlled, and setting up the control loop just requires a little amount of data.
- Fuzzy systems are nonlinear systems that are better suited to control non-linear processes.

On the other hand, the disadvantages are:

- Lack of precise guidelines for the design of a setting (choice of quantities to be measured, determination of fuzzification, inferences and defuzzification).
- Hand-crafted, non-systematic approach (often difficult to implement operator knowledge).

## Conclusion

Fuzzy logic, established by Zadeh in 1965, enables the representation and processing of imprecise or approximate knowledge. The number of applications based on fuzzy logic theory has grown considerably in recent years. As fuzzy logic is usually expressed by linguistic rules of the form If-Then form. It is used to solve decision problems in control or to describe the dynamicbehavior of an unknown system.

In this chapter, we have presented the methods that will be used to better understand, analyze, and simulate our case study. Firstly, we defined the necessary management tools such as Ishikawa and Pareto, where we gave their definitions. Then we introduced fuzzy logic, where we saw the different basic concepts for application as well as the structure of a fuzzy controller and finally application fields of fuzzy logic and its advantages and disadvantages.

In the following chapters, we will present our case study where these methods have been used and developed.

# Chapter 3: Analysis of “CAM 1” undesirables’ effects

# Introduction

Medicines have the power to save countless lives and enhance the quality of life for millions of people, whether it be for minor ailments or life-threatening disorders. The pharmaceutical sector is vital to our contemporary civilization as it provides a lifeline for people all around the world.

Hikma Pharmaceuticals has a strong focus on quality assurance and continuous improvement, which is a great environment for our project. By undertaking a Poka Yoke project there, we could contribute to the company's commitment to enhancing operational efficiency, minimizing errors, and ensuring product quality. Furthermore, it fits our scope to study the impact of this technology on the maintenance KPIs of the organization.

This chapter will start by introducing the host organization, Hikma Pharmaceuticals Algeria, then, we continue with the study of the existing situation to present the details of the process and recognize the production system. Later, a dysfunctional study is carried out to identify the anomalies and malfunctions of the system using maintenance management tools to analyze current defects and problems.

## 3.1. Company presentation

Hikma pharmaceuticals is a Jordanian company specializing in generics, with headquarters in London. Hikma pharmaceuticals was founded in 1978 in Amman, Jordan, by Samih DARWAZAH. In the early years, the company focused on developing a branded pharmaceuticals business throughout the Middle East and North Africa (MENA) region. Then, in the early 1990s, Hikma expanded outside the MENA region by acquiring other generic pharmaceutical companies in the USA and establishing injectable pharmaceutical operations in Portugal. Since then, the company has grown significantly, both organically and through acquisitions, with worldwide operations in Italy, Germany, Tunisia, Egypt, Jordan, and Saudi Arabia.

Today, Hikma is a pharmaceutical manufacturer with a broad portfolio of generics, marked by patented products. With sales of $2.5 billion (2021), and a presence in the Middle East, North Africa (MENA) region, and the USA, it supplies nearly 700 products to patients worldwide to improve their lives and satisfy their needs.

With 7 research and development centers and 30 production plants, these products are sold in over 50 countries and span a wide range of products. The diversity of its business model and product markets, combined with its long-term commitment to quality investment, are integral to its success.

### 3.1.1. Hikma in Algeria

Hikma pharma has been active in Algeria since 1994, importing medicines to serve public health institutions and learned societies, then investing in local production by opening its first plant in Staouali (Algiers). The company operates to international pharmaceutical industry standards, obtaining several licenses from the U.S. Food and Drug Administration (FDA).

A wide variety of goods are available from Hikma Pharma Algeria, including medications for the management of infections and common ailments like diabetes, hypertension, and cardiovascular conditions. The company also offers a variety of medications for chronic diseases and unusual illnesses, including those that treat hormone imbalances and hemophilia.

Today, the Hikma pharma group has four manufacturing units, equipped with several extrusion lines, the latest technology, and large, functional warehouses and storage areas, witha workforce of over 700 employees.

In conclusion, Hikma Pharma Algeria is a well-known pharmaceutical firm dedicated to offering patients in Algeria high-quality medications at reasonable costs. The business takes great pride in helping the nation's social programs and helping to raise the standard of living for Algerians.




Figure 3.1: Global view of Hikma in Algeria

## 3.2. Brief description of the process

Figure 3.2 describes the process of all Hikma's medicines fabrication. For our case, we are interested only in the one specific to tablets.

In general terms, the production of drugs starts with the reception of the raw material, the next step is its granulation, then the mixing and blending of the raw material with other substances. After that, the mix is compressed in the compressing machine and coated in the next step.

When the pills are made, they pass to the second level which is blistering. The third level is the packaging, where the blisters and the leaflets are put on the boxes. Finally, the final product is ready to be delivered to the customer.

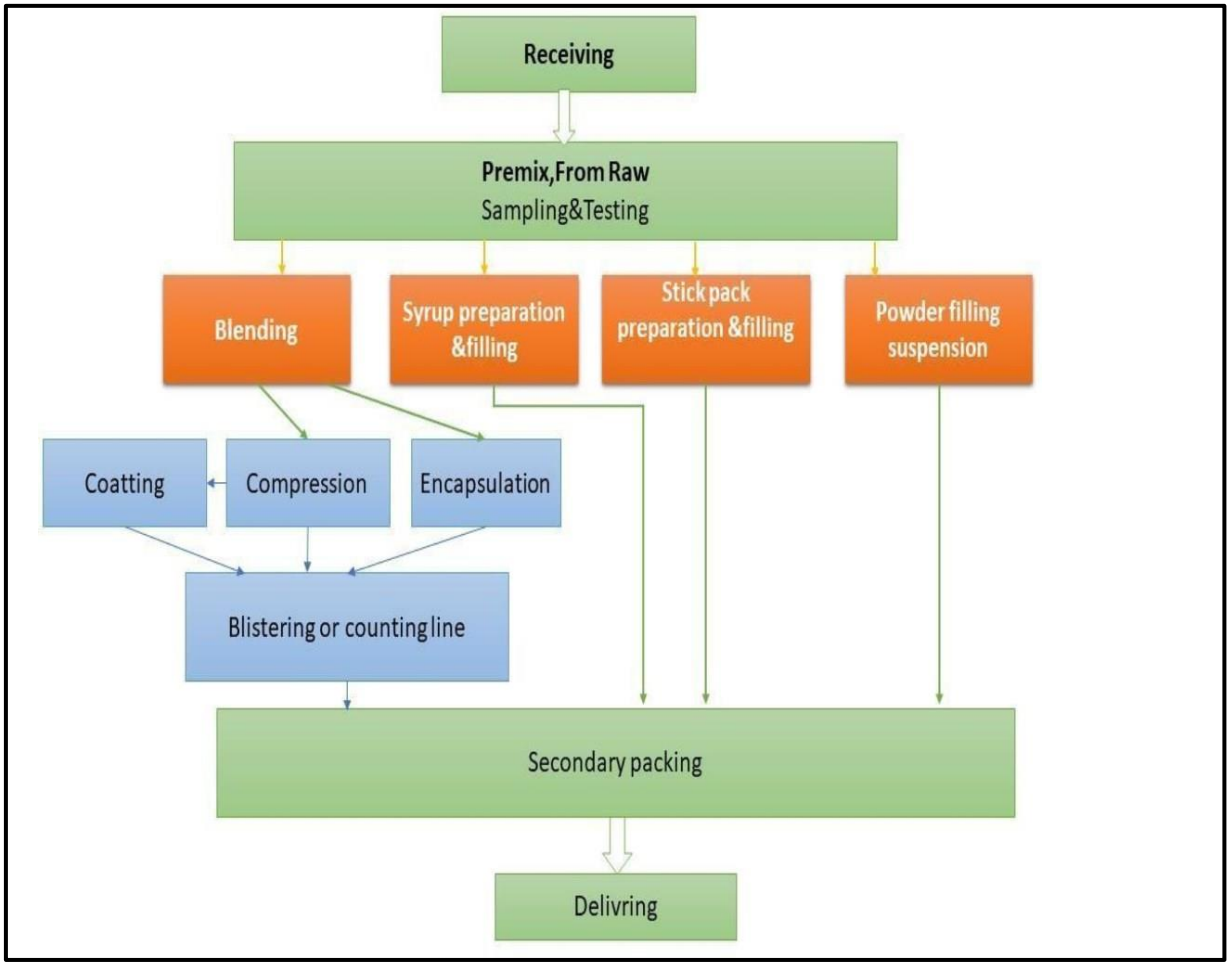



Figure 3.2: Description of Hikma's production process

## 3.3. The production system

The tablets production line was put into operation for the first time in 2018, with the aim of producing different types of medicine in oral solid dosage form.

This line mainly consists of 3 levels of machines, 2 of them are supplied by Italian industry leader CAM.As shown in the Figure 3.3

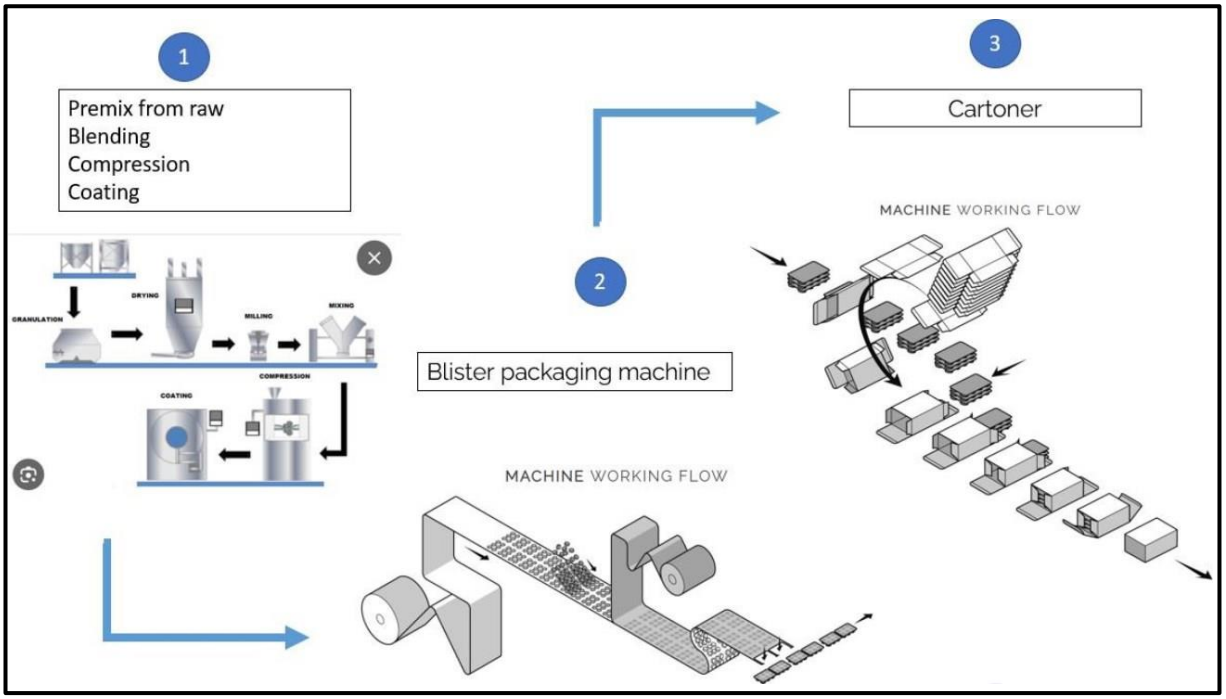



Figure 3.3: Hikma's pills production line

In this phase we'll take a specifical look at our line system, by identifying the machine's units. Such as the blistering machine is described in Figure 3.4, while the packaging one is in Figure 3.5.

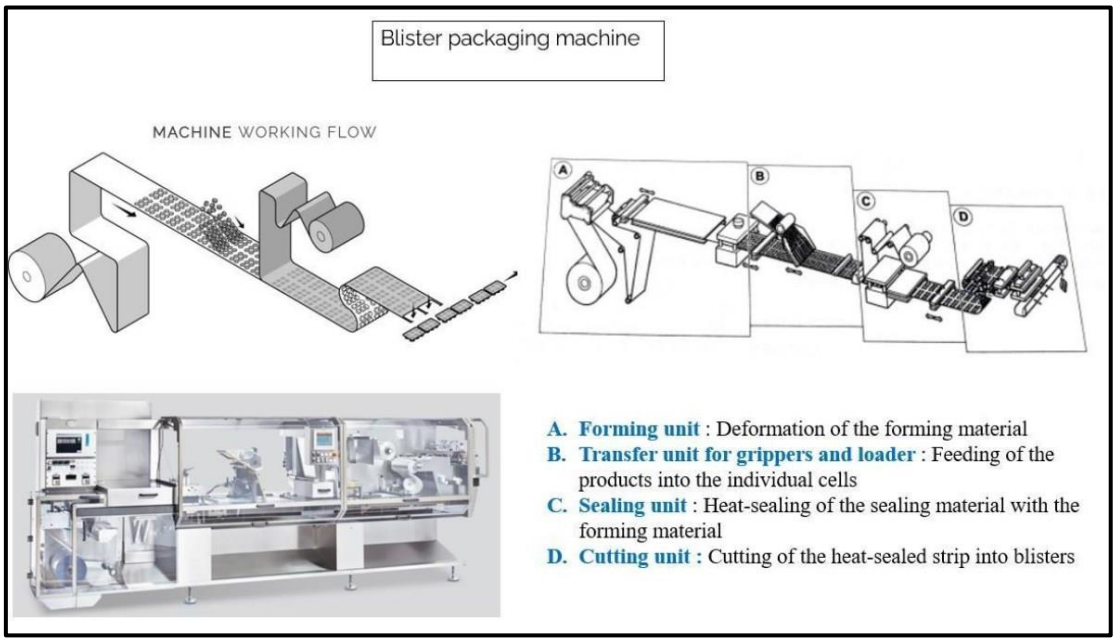



Figure 3.4: Blistering machine information.

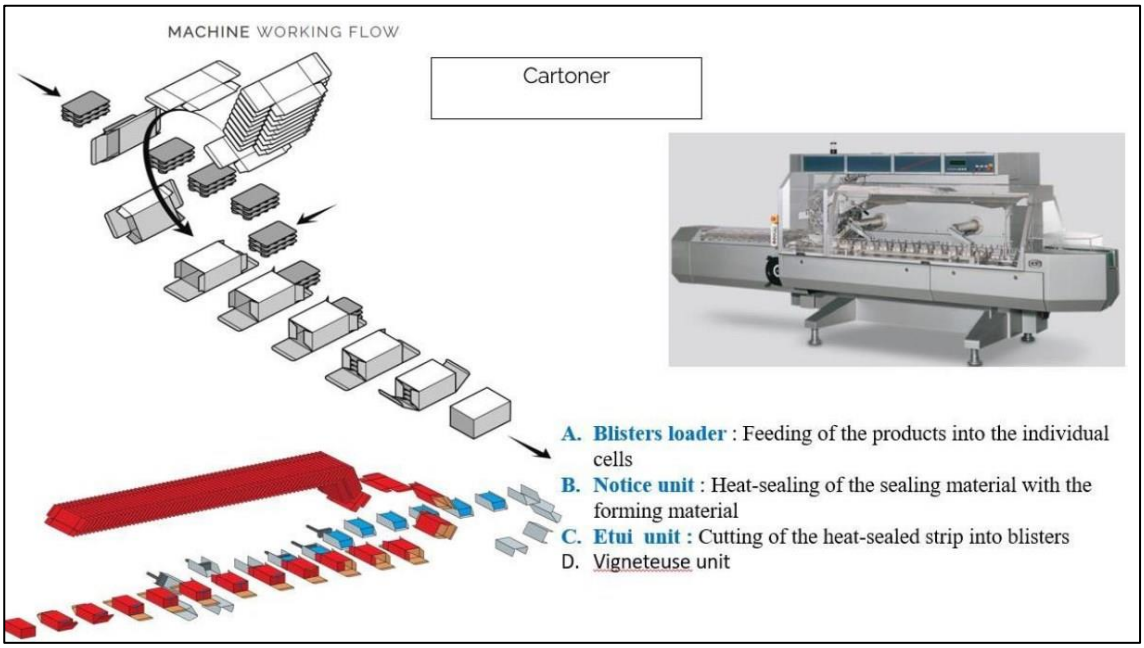



Figure 3.5: Cartooning machine information.

## 3.4. Selection of undesirable effects

Hikma produces various types of medicines on several production lines. This obliges the production department to ensure effective and efficient flexibility of production activities while respecting product quality and delivery times to satisfy its customers, and on the other side, to create added value for the company.

The company's ongoing efforts to improve the performance of its production lines are driven by this flexibility, which has a positive effect on the rate of return. In fact, because of the many maintenance operations that have to be carried out every day, and due to the strong number of orders, line CAM 1 is considered to be the most important line in the plant, which makes it the subject of our study.

To identify and localize the problems of this line, we will carry on an analysis study using different tools.

### 3.4.1. Pareto diagrams

In this step, we classified the problems of CAM1, according to frequency of each one of them, over a 4-month period, from 1st January 2023 to 30th April 2023 in the table 3.1, then, we calculated the increasing cumulative to draw the Pareto diagram.

Table 3.1: Breakdowns frequency report of CAM1

| **Problem** | **Frequency** | **Cumulative** | **% of Cumulative** |
|---|---|---|---|
| Leaflet | 13 | 13 | 22% |
| Charger | 10 | 23 | 40% |
| Pusher | 8 | 31 | 53% |
| Camera | 8 | 39 | 67% |
| Batch number | 5 | 44 | 76% |
| Sealing | 4 | 48 | 83% |
| Programming | 4 | 52 | 90% |
| Box | 3 | 55 | 95% |
| Cooler | 2 | 57 | 98% |
| Sticker | 1 | 58 | 100% |
| **Total** | 67 | | |

Based on the data in Table 3.1, the Pareto diagram of the frequency of different problems on the Cam line is plotted and illustrated in Figure3.6

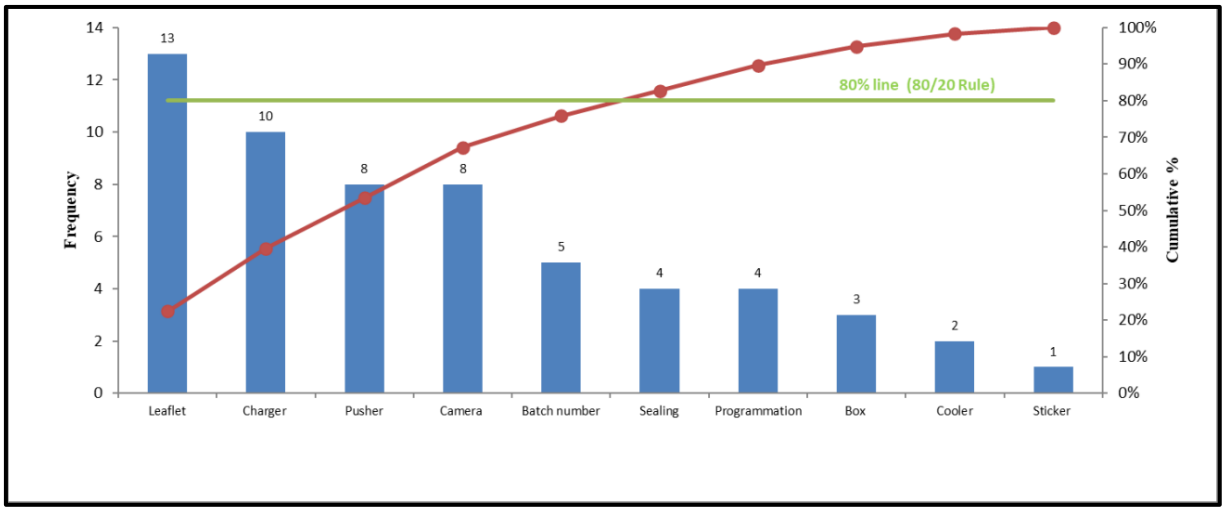



Figure 3.6: Classification of effects breakdowns frequency

- **Interpretation**

We notice from this diagram that the most repetitive problem relates to the leaflet with 13 appearances in the 4 months, which represents 22% of the total shutdown frequency.

It is also clear from the diagram that it belongs to zone A (it exceeds the 80% line).

But this gives us insufficient information about the line, for that we are going to plot another diagram depending on the time of breakdowns.

Table 3.2, represents the breakdown times of different problems with their associated percentage increasing cumulative.

Table 3.2: Breakdowns time report of CAM1

| **Problem** | **Breakdown time (h)** | **Cumulative** | **% of Cumulative** |
|---|---|---|---|
| Charger | 14,97 | 23:16:48 | 24% |
| Camera | 13,80 | 18:28:48 | 46% |
| Batch number | 12,76 | 12:43:12 | 66% |
| Leaflet | 10,30 | 19:55:12 | 82% |
| Pusher | 4,75 | 13:55:12 | 90% |
| Box | 2,33 | 21:50:24 | 93% |
| Sealing | 2,58 | 11:45:36 | 97% |
| Cooler | 0,87 | 08:38:24 | 99% |
| Programming | 0,52 | 21:07:12 | 100% |
| Sticker | 0,20 | 01:55:12 | 100% |
| **Total** | 63,08 | | |

Based on the data in Table3.2, the Pareto diagram of breakdowns of different problems on the Cam line is plotted and illustrated in Figure 3.7.

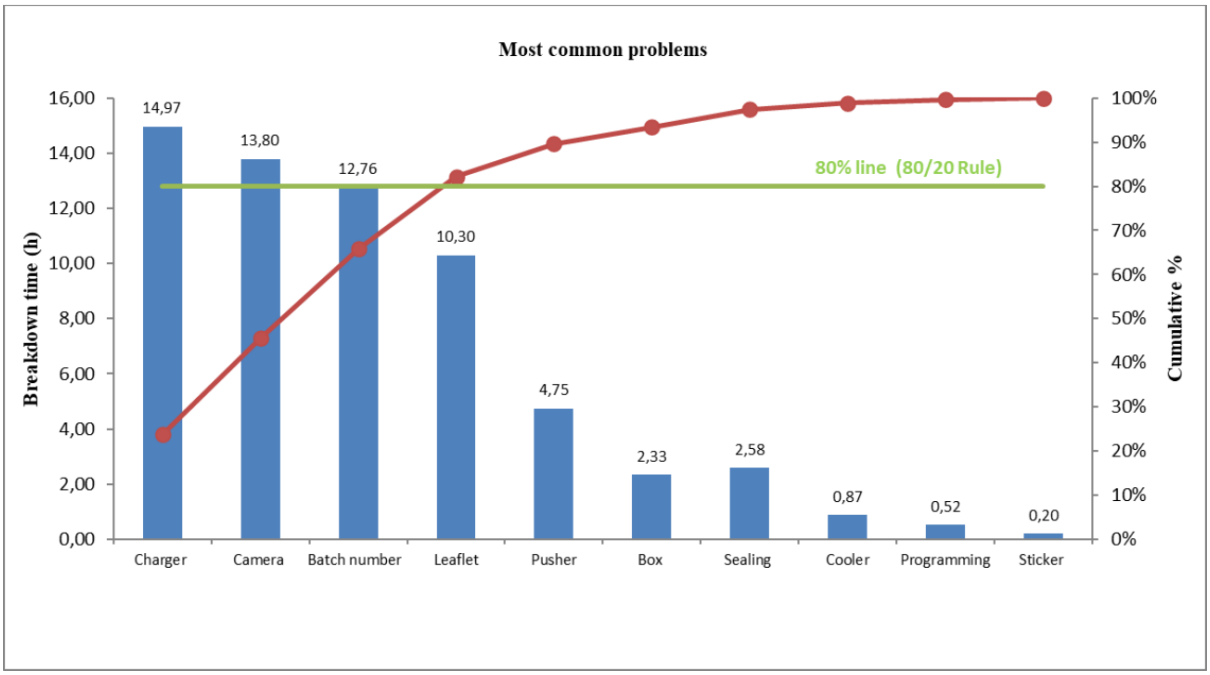



Figure 3.7: Classification of effects breakdowns time

### Interpretation

From the Pareto diagram shown in Figure 3.7, we can see that 80% of stops account for 20% of problems.

The charger problem has the highest value, which means it's the problem with the most breakdowns. It caused 14h 58 min of breakdowns, making it the most significant cause.

The second most important problem causing the largest downtimes is the camera problem with 13h 48 min of breakdowns, followed by the batch number and leaflet problems with 12h 45 min and 10h18 min of breakdowns respectively.

Charger and camera problems belong to zone A of the pareto diagram, which exceeds 80%. In our study, we focus on this zone, also on the effects with the most breakdowns in zone B, since it contains the problems with the highest number of breakdowns.

To clarify the situation, a risk assessment is carried out to select the most critical problems. To do this, we choose problems preselected thanks to Pareto diagrams, which represent the highest number and periods of breakdowns (Charger, camera, batch number and leaflet problems).

## 3.4.2. Risk assessment

The objective of this part is to calculate the risk priority number (RPN) of each preselected problem, so that we can classify them from the most critical one to the least, starting with the charger problem.

### 3.4.2.1. Charger problem

In this analysis, we'll be looking at the specific causes linked to the blister loader since it occupies an essential role in the line. As shown in Table 1, a risk assessment is elaborated for the charger problem.

Table3.3: Risk assessment of the charger.

| No. | Systems Description | Failure Mode | Impact of the Failure | Causes of the Failure | Current process controls | Severity (S) | Probability (P) | Detectability (D) | Risk Priority Number (RPN) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Blistering machine | Charger problem | Impact on patient safety, product quality, regulatory compliance, production costs and customer confidence. | -Tablet twins<br>-Dosage errors (missing or excess tablets in blister packs)<br>-Mechanical malfunctions | -Visual inspection by the operator<br>-Verification every start of run<br>-Camera detection<br>-Tablet quality control<br>-Cleaning and disinfection<br>- Preventive maintenance | 4 | 3 | 3 | 36 |

- **Interpretation**

After making this risk assessment, we can see that this failure mode has RPN= 36, which is a significant result that belongs to the orange zone.

### 3.4.2.2. Camera problem

The camera is one of the most important monitoring systems. It allows to detect different anomalies in the tablets, Table 3.4 represents a risk assessment for the camera problem.

Table 3.4: Risk assessment for the camera problem

| No. | System Description | Failure Mode | Impact of the Failure | Causes of the Failure | Current process controls | Severity (S) | Probability (P) | Detectability (D) | Risk Priority Number (RPN) |
|---|---|---|---|---|---|---|---|---|---|
| 2 | Blistering machine | Camera problem | Camera defects can lead to filling errors, customer complaints, product recalls, regulatory non-compliance, reduced efficiency and additional costs for the company. | -Camera failure<br>-Detection errors<br>-Synchronization problems<br>-Variability-related problems<br>-Sensitivity<br>-Learning | - Visual inspection<br>-Staff training<br>-Preventive maintenance<br>-Camera calibration | 4 | 2 | 2 | 16 |

#### Interpretation

As RPN is equal to 16, which belongs to the green zone, consequently, the camera problem isn't critical for the line.

### 3.4.2.3. Batch problem

To ensure product traceability and conformity in the pharmaceutical industry, batch number management is of utmost importance and can have significant consequences on the traceability and conformity of products. As shown in table 3.4 a risk assessment is elaborated for the batch number problem.

Table 3.5: Risk assessment for the batch number problem.

| No. | Systems Description | Failure Mode | Impact of the Failure | Causes of the Failure | Current process controls | Severity (S) | Probability (P) | Detectability (D) | Risk Priority Number (RPN) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Cartoner machine of blisters | Batch number and date | Impact on product quality and patient: When a product exceeds its expiration date, there is a risk that its potency or effectiveness may decrease over time, expired products may pose safety risks to patients. | -Illegible batch number.<br>-Misplaced characters on the reel.<br>- Characters detachment.<br>-Wear and tear.<br>-Poor printing quality.<br>- Packaging or label damage.<br>- Wrong entry of the batch number.<br>- Operator fault. | - Visual inspection every 4h by shift<br>-Verification every start of run | 5 | 3 | 4 | 60 |

- **Interpretation**

This risk assessment confirms that the problem of batch number and date is a critical problem as the RPN is equal to 60, which belongs to the red zone.

#### 3.4.2.4. Leaflet problem

Among the key stages in the packaging process, the production of leaflets in a cartoner machine plays a key role. In this analysis, we will explore the specific causes associated with the production of leaflets, by highlighting the risks of this problem. Table3.5 presents the risk assessment for leaflet problem.

Table 3.6: Risk assessment for leaflet problem.

| No. | Description | Failure Mode | Impact of the Failure | Causes of the Failure | Current process controls | Severity (S) | Probability (P) | Detectability (D) | Risk Priority Number (RPN) |
|---|---|---|---|---|---|---|---|---|---|
| 4 | Cartoner machine | Leaflet problem | Impact on patients' health, legal claims, damage to the company's reputation and significant costs. | -Regulatory compliance issues<br>-Missing or incorrectly inserted notices<br>-Content errors<br>-Poor paper quality<br>-Non-compliance with size or format requirements<br>-Lack of staff training<br>-Incorrect clamping | - Visual inspection<br>-Preventive maintenance<br>-Position sensors | 4 | 3 | 3 | 36 |

- **Interpretation**

The leaflet problem presents a medium risk as its risk assessment shows that its RPN is equal to 36 which belong to the orange zone.

After analyzing our problems criticality, we can see that the batch number is the most critical one, followed by the charger and the leaflet problems. To understand more about these problems, we have to carry on a Root Cause Analysis which will be established by a Fishbone diagram (Ishikawa), which aims to classify problems by 4 M.

### 3.4.3. Ishikawa diagrams

In this part, we will try to classify causes of effects into 4 categories (Material, Machine, Method, Manpower), to find the root causes of the effect. We start with the charger problem presented as follows in Figure 3.8, followed by the one of batch number in Figure 3.9 and finally the fishbone of the leaflet in Figure3.10.

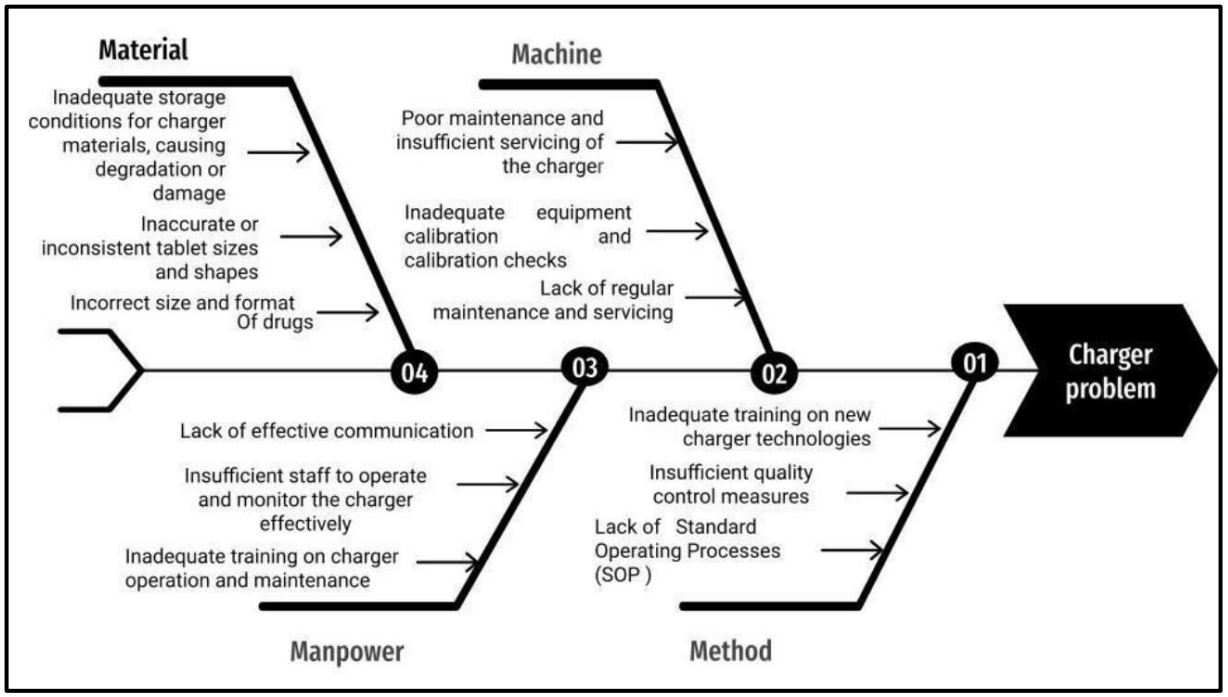



Figure 3.8: Fishbone diagram of the charger

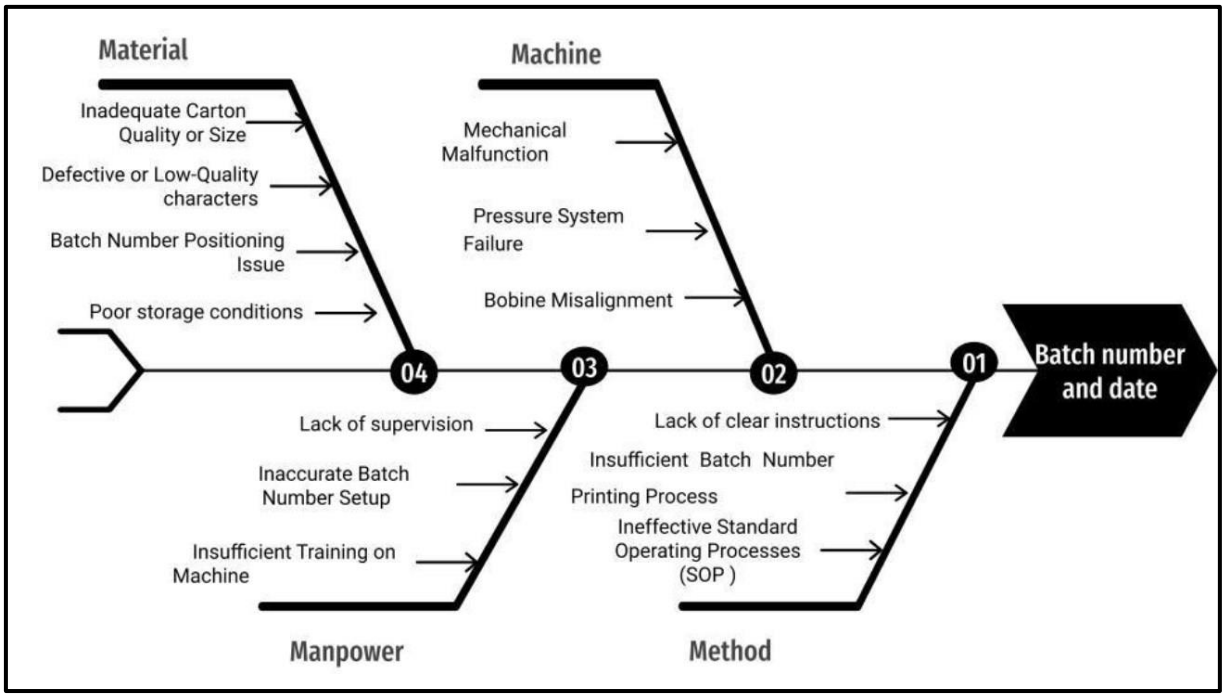



Figure 3.9: Fishbone diagram of the batch number and date

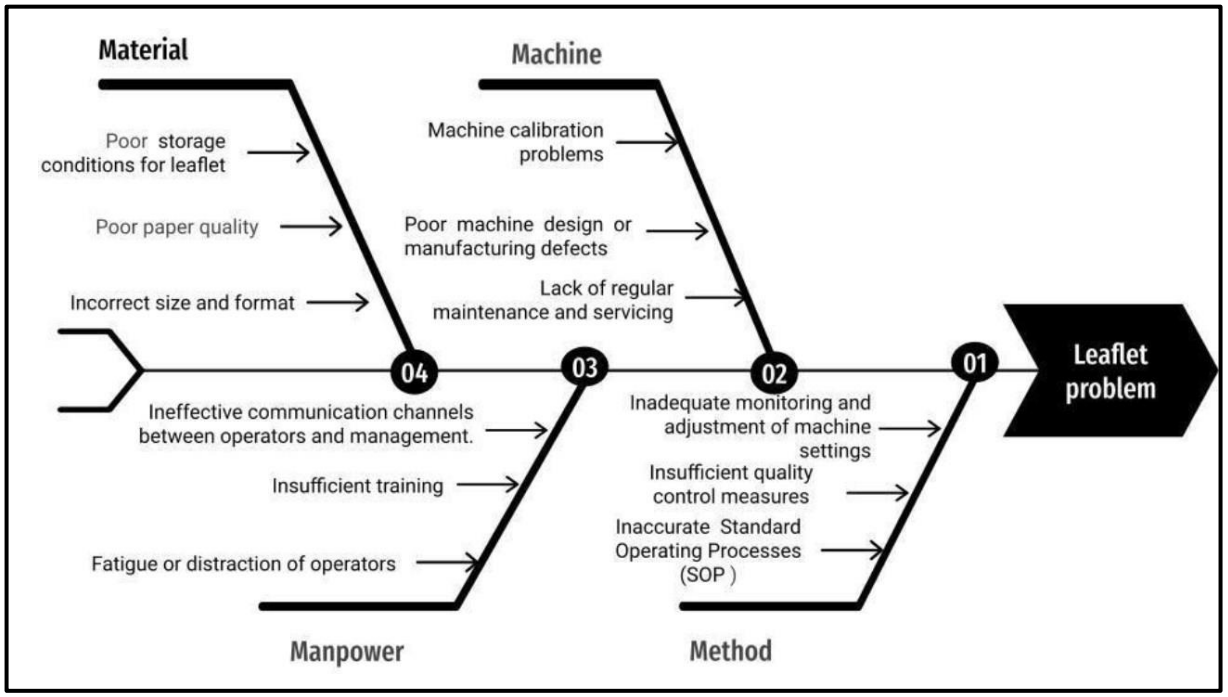



Figure 3.10: Fishbone diagram of the Leaflet

Thanks to the conducted analysis in these Ishikawa diagrams, we arrived to identify the root causes of each one of the different effects, which will help us to propose the appropriate solutions.

## 3.5. Proposed Solutions

Now that we have identified the root causes of each problem, we can rely on the professional team at Hikma Pharmaceutical Algeria who is familiar with the production line, and we can get benefits from their experience and feedback.

After brainstorming sessions, we extracted and proposed as many solutions as possible for each critical undesirable effect that can cause the stop of our production line CAM1. Then, we have listed them in the Table 3.6.

Table 3.7: Proposed solutions for the critical effects

| Failure mode (Effect) | Proposed solutions |
|---|---|
| Charger problem | -Enhance tablet coating<br>-Quality control checks<br>-Adjustment |
| Leaflet problem | -Adjust clamping procedures<br>-Follow procedures and quality checks |
| Batch number problem | -Replace old characters |

## 3.6. Recommendations:

Based on our experience at Hikma, we have identified a number of shortcomings and recommend the following solutions, which are effective in the long term and can be used in a variety of situations.

- Standard Operating Procedures (SOPs).
- Staff Training.
- Optimize packaging process parameters.
- Enhance spare parts management.
- Select high-quality materials.
- Apply 5s to organize workspace.
- Improve data integrity.

# Conclusion

To identify and address the core reasons that could compromise the production system and to determine where to implement process changes, a company must employ analysis tools and methodologies.

This chapter is divided into two sections. In the first section, we present the company Hikma and its production system. The second section, devoted to analysis, where we used various analysis tools for a better understanding of CAM line effects and found their root causes, then propose solutions, which is going to help us to respond to Poka Yoke philosophy which is to anticipate errors before they occur by targeting the root causes.

In the next chapter, we are going calculate chosen KPIs and compare. In the second part, we simulate the proposed solutions combinations with a fuzzy logic controller to have a vision of the evolution of maintenance KPIs.

# Chapter 4: Poka Yokes and Fuzzy Logic model proposal for evaluating maintenance KPIs

# Introduction

In a previous chapter, we have explained that Fuzzy Logic enables degrees of membership to be represented and manipulated, unlike classical logic, which assumes binary values for truth and falsity. This is what allowed us to consider it the most suitable AI tool for our case study. Besides, since our system is very complex, it is well suited for dealing with it by considering it as a black box. In addition, it provides the opportunity to express approximate knowledge and to update it in light of fresh data.

The analysis of our system and its anomalies has given us lightful information about the most critical effects and their root causes, afterward, we have proposed as many solutions as possible. Now in this chapter, we aspire to compare the evolution of Maintenance KPIs before and after Poka Yokes.

In order to meet this need, we suggest using a fuzzy logic model to assess KPIs evolutions since Poka Yokes were implemented. A flexible and adaptive framework for evaluating the effects of process modifications is provided by fuzzy logic, a potent tool for dealing with ambiguity and imprecise information.

## 4.1. KPIs analysis

Based on the history of breakdowns, this part will be dedicated to the analysis of KPIs, by calculating them before and after PYs.

### 4.1.1. KPIs' selection

During our training at Hikma Pharmaceuticals Algeria, we noticed that the engineering department does not offer the KPIs the attention they deserve, they have no maintenance indicators follow-ups. So, we had to select them and calculate them ourselves, in order to evaluate them later.

Due to their capacity to offer crucial details regarding the production system's dependability, availability, and overall performance. MTBF and MTTR were chosen as evaluation indicators. These indicators make it possible to locate weak points, make wise maintenance choices, and optimize operations to raise system productivity and profitability.

We would like to consider the OEE a one of the chosen KPIs for our study since it is very important for both quality and maintenance. But unfortunately, because of a lack of data, we were enable to calculate it properly.

We could work out the tables listed below, according to the CAM 1 breakdowns history, provided by the maintenance service thanks to the data saved in SAP, which is spread over a period of 4 months from January 1st, 2023. Table 4.1 represents the MTBF and MTTF values for the four-month period.

Table 4.1: The MTBF and MTTF values for the four-month period.

| | Values (hours) |
|---|---|
| Total Production Time | 2240 |
| Total Amount of Downtime | 63,08 |
| Number of Failures | 58 |
| Mean Time Between Failures (MTBF) | 38,62 |
| Mean Time to Repair (MTTR) | 1,08 |

## 4.2. Proposition of Poka Yokes

In this part and taking into account analysis done in the previous chapter, and also experience feedback and our training at Hikma Pharmaceuticals, we could propose these Poka Yokes as a definitive solution for the critical effects already discussed.

### 4.2.1. Charger Problem

To address charger problems, which is one of the most important failures and which has a significant impact on production, we suggest some Poka Yokes, such as:

- Adjusting tablet formulation can be seen as a PY, to prevent or minimize the occurrence of tablet twin errors. The goal is to modify the surface texture of the tablets. Smoother surfaces or the inclusion of anti-sticking agents can help prevent tablets from adhering to one another. We can also consider altering the mechanical properties of the tablets, such as hardness or friability, which eliminates the existence of both tablet twinning and small pieces caused by tablet breakages which

engender feeder blocks.

- Modifying the shape or design of tablets refers to making changes to their physical appearance to ensure that the tablets have a consistent and suitable shape that reduces the chances of them getting entangled with each other. This modification can be done by altering the dimensions, contours, or surface features of the tablet. (For example, the oval or round shape is best suited to avoid bonding than the rectangular one).
- Place a unit loader to fill the empty cells, which have not been previously loaded. These voids will be detected by a position sensor, which will indicate whether the cell is empty or full.

### 4.2.2. Leaflet problem

Hikma Pharmaceuticals Algeria owns a machine called Track & Trace which is a system based on the use of technologies such as barcodes, QR codes and RFID (Radio Frequency Identification) tags. It is a part of the cartoner machine in CAM line, but which is not operational, despite its importance in product authentication, supply chain visibility, product recall management, traceability, and consumer safety and transparency.

- By implementing it, the company will eliminate the leaflet problem, as they can introduce the information written in the leaflet in a QR code on the box and give up on the traditional leaflet papers. With a simple scan, consumers can have all information about the medicine on their phones.

### 4.2.3. Batch number problem

To remedy the problem of the illegible batch number on the medicines boxes, we, first, suggest replacing the old manual system with an automated one, we propose:

- Thermal transfer printer: It transmits the ink to the boxes using a thermal transfer ribbon. They are renowned for creating sharp, durable prints that are appropriate for printing batch numbers on a variety of materials. Zebra, Sato, and Honeywell are a few of the well-known names in this area.
- Laser printer: It provides quick and precise printing. However, they can have restrictions regarding the materials they can print on or the sizes of the labels they can accommodate.

- Inkjet printer: It prints using liquid ink and provides high resolution capabilities for clear printing. Industrial-grade inkjet printers are available from manufacturers including Epson, HP, and Brother.

Second, we suggest implementing a Vision System Verification:

- This device can be a camera, placed at the end of the production line, that captures an image for each box. The system performs an optical character recognition (OCR) algorithm to read and interpret the batch number from the captured images and compare it with the expected content. The system can raise an alarm, stop the production line, and alert the operator to take corrective action if the batch number is missing or illegible.

And finally, we insist on implementing the Track & Trace system, for its importance shown above, as it can be a solution for two problems at once.

- Encoding batch numbers into QR codes can help eliminate the problem of illegibility since it can contain a significant amount of information in a compact form.

The proposed solutions eliminate human errors, too, in selecting characters of the number and placing it manually in the reel.

## 4.3. Estimated costs related to proposed Poka Yokes

As we lack real data and exact information, we estimated the cost of each PY as follows:

- The costs associated with formulation adjustment and design modification can encompass research and development expenses, testing and validation costs, manufacturing changes, regulatory compliance expenses, and intellectual property considerations. The expenses involved can range from ten or so of dinars for minor modifications to millions of dinars for extensive changes.
- The cost of a very simple and basic unit loader with limited features can be found in the 1000 DZD to 2000 DZD price range as it might not have sophisticated features.
- We may consider the cost of the Track & Trace system nil, because the company already has the machine, but we consider the cost of subcontracting and exploitation, so it’s about 100000 DZD.

- The prices of different types of printers varies according to the type, the brand and many other features between 100 000 DZD and 1 000 000 DZD.
- On average, for a relatively simple batch numbering system with one camera and one sensor, the cost can be approximately 3 000 000 DZD.

It's important to note that all these costs listed in Table 4.2 are only rough estimates, gathered from various online sales sites. The real costs can only be determined by specialized consultants.

Table 4.2: Estimated costs for proposed Poka Yokes

| Effect | Proposed PY | Estimated cost |
|---|---|---|
| Charger problem | Unit loader | [1000 - 2000] DZD |
| | Adjust tablet formulation | [100 000 -1 000 000] DZD |
| | Modify the design of tablets | |
| Leaflet problem | QR or bar/ code | 100000DZD |
| Batch number problem | QR code | 100000 DZD |
| | Thermal transfer printer | 100 000 DZD |
| | Laser printer | 800 000 DZD |
| | Inkjet printer | 600 000 DZD |
| | Vision System Verification | 3 000 000 DZD |

Even though the initial cost of various Poka Yokes may seem high, the implementation's return on investment (ROI) should be considered. Smart Poka Yokes have evolved, but larger businesses frequently have higher expenditures to support them. It's crucial to take into account the possible financial savings, boosted output, and enhanced product quality that

Poka Yokes can offer. PYs should ultimately be used based on a cost-benefit analysis and the specific requirements of the firm.

## 4.4. KPI's evaluation

As Poka Yoke eradicates errors, we applied our proposed PYs by eliminating existing critical failure modes (charger, leaflet and batch number problems), to see their influences on maintenance KPIs, by re-calculating MTBF and MTTR to see their evolution. Table 4.3 represents the MTBF and MTTF values for the four-month period with the elimination of charger problems after applying the proposed PY, and the percentage of their evolution.

$$MTBF = \frac{Total\ Production\ Time}{Number\ of\ failures} \qquad MTTR = \frac{Total\ Amount\ of\ Downtime}{Number\ of\ failures}$$

Table 4.3: KPIs evolution after eliminating the charger effect.

| | Values (hours) | Evolution (%) |
|---|---|---|
| Total Production Time | 2240 | |
| Total Amount of Downtime | 48,11 | |
| Number of Failures | 48 | |
| Mean Time Between Failures (MTBF) | 46,67 | 20,84 |
| Mean Time to Repair (MTTR) | 1,002 | - 7,82 |

Table 4.4 represents the MTBF and MTTF values for the same period with the elimination of leaflet problems after applying the proposed PY, and the percentage of their evolution.

Table 4.4: KPIs evolution after eliminating the leaflet effect.

| | Values (hours) | Evolution (%) |
|---|---|---|
| Total Production Time | 2240 | |
| Total Amount of Downtime | 52,78 | |
| Number of Failures | 45 | |
| Mean Time Between Failures (MTBF) | 49,78 | 28,89 |
| Mean Time to Repair (MTTR) | 1,17 | 7,82 |

**Note:**

We can notice that there is an increase in MTTR since the weight of TTRs of the leaflet- related is low compared to other effects.

Table 4.5 represents the MTBF and MTTF values for the four-month period with the elimination of batch number problems after applying proposed PY, and the percentage of their evolution.

Table 4.5: KPIs evolution after eliminating batch number effect

| | Values (hours) | Evolution (%) |
|---|---|---|
| Total Production Time | 2240 | |
| Total Amount of Downtime | 50,32 | |
| Number of Failures | 53 | |
| Mean Time Between Failures (MTBF) | 42,26 | 9,44 |
| Mean Time to Repair (MTTR) | 0,94 | - 12,7 |

Table 4.6 represents the MTBF and MTTF values for the four-month period, with the elimination of all critical effects after applying the proposed PY, and the percentage of their evolution.

Table 4.6: KPIs evolution after eliminating all critical effects.

| | Values (hours) | Evolution (%) |
|---|---|---|
| Total Production Time | 2240 | |
| Total Amount of Downtime | 25,05 | |
| Number of Failures | 30 | |
| Mean Time Between Failures (MTBF) | 74,67 | 93,04 |
| Mean Time to Repair (MTTR) | 0,84 | - 23,18 |

### 4.4.1. Interpretation

By analyzing the data, we can observe that the elimination of the three critical effects leads to significant improvements in both MTBF and MTTR. Specifically, the MTBF increases by an impressive 93%, while the MTTR decreases by a notable 23%.

The increase in MTBF signifies that the system or equipment under consideration can operate for a longer duration without experiencing failures. With a 93% increase in MTBF, the system's overall reliability is substantially improved, leading to increased productivity and efficiency.

On the other hand, the decrease in MTTR is also significant. MTTR refers to the average time required to repair a system or equipment after a failure occurs. By reducing the MTTR by 23%, the time taken to restore the system to its operational state after a failure is significantly minimized. A shorter MTTR is particularly beneficial in such a critical system where time is of utmost importance.

The combined effect of the increased MTBF and decreased MTTR is a substantial improvement in the system's overall availability.

### 4.4.2. Limitation

It is true that proposed PY can eliminate defects definitely, but we must take into account some limitations, such as costs and delays. Before implementing them, the company needs to draw up a feasibility and financial study, in order to make the appropriate decision of solution choice, which requires specific resources, like cost, human resources and especially time. Besides the resources and delay in implementation.

Meanwhile, we propose a fuzzy logic model, to try to solve these critical problems by applying existing and classical solutions; then, we observe their impact on maintenance KPIs' evolution.

## 4.5. Fuzzy logic model

At Hikma Pharmaceuticals, we noticed a remarkable delay in reaction time to act, after the occurrence of a failure. Corrective actions take place surroundings a hundred quality loss. To get closer to the PY philosophy, we propose a fast and effective fuzzy model to remedy this problem, which triggers as soon as there is a single loss per quality appears. To create it, we follow these steps:

### 4.5.1. Elaboration of linguistic variables

In this step, we have to elaborate the input variables, in our case we have three ones that represent our three critical effects. The LVs of these inputs are extracted from the number of solutions for each one. We need to find linguistic terms for each input variable.

### 4.5.2. Choice of membership function

By default, we have opted for a triangular function since it is the simplest and the most used one.

### 4.5.3. Fuzzy rules

Fuzzy rules represent the database of the fuzzy system where the inputs are processed, and give the appropriate output to the model. The number of inference rules depends on the number of inputs and the number of fields in each one. The average number of linguistic variables is three in each universe of discourse. In our model, we have three inputs so with two fields each, the maximum number of rules is $2^3$ =8, which means that we have 8 fuzzy rules.

We have 3 effects, which means that we'll have 3 inputs, each one has 2 LVs, Table 4.7 represents inputs with their associated intervals, which represent the number of applied solutions .

Table 4.7: LVs intervals for each input.

| Input | Linguistic Variables | Intervals |
|---|---|---|
| Charger solutions | Low | [0 ; 1] |
| | High | [2 ; 3] |
| Leaflet solutions | Low | [0 ; 1] |
| | High | [1 ; 2] |
| Batch number solutions | Low | [0 ; 0] |
| | High | [0 ; 1] |

### 4.5.4. Fuzzy inference rules

We have three inputs, and two linguistic variables. We obtained eight inference rules ($2^3 = 8$). Table 4.8 represents outputs with their associated intervals.

Table 4.8: LVs intervals for each output

| Intervals | LVs | |
|---|---|---|
| [1 2] | Low MTBF | Low MTTF |
| [3 4] | Medium MTBF | Medium MTTR |
| [5 6] | High MTBF | High MTTR |

We regroup all the rules in Table 4.9:

Table 4.9: Appropriate model rules.

| AND conjunction | | | Score | Results |
|---|---|---|---|---|
| Charger solutions | Leaflet solutions | Batch number solutions | | |
| Low | Low | Low | 2 | -Low MTBF<br>-Low MTTR |
| Low | Low | High | 3 | -Medium MTBF<br>-Medium MTTR |
| Low | High | Low | 3 | -Medium MTBF<br>-Medium MTTR |
| Low | High | High | 4 | -Medium MTBF<br>-Medium MTTR |
| High | Low | Low | 4 | -Medium MTBF<br>-Medium MTTR |
| High | Low | High | 5 | -High MTBF<br>-High MTTR |
| High | High | Low | 5 | -High MTBF<br>-High MTTR |
| High | High | High | 6 | -High MTBF<br>-High MTTR |

### 4.5.5. Development of the fuzzy model using MATLAB

To create the fuzzy model in MATLAB, we'll follow the three previous steps: we'll create the three variables (inputs) and by using the Table 4.7, we'll add the intervals for each VL. In the next step, we add the intervals for the output e and finally implement the rules defined in Table4.9. The construction of a fuzzy model is based on three essential steps, which we have followed to build our model.

#### 4.5.5.1. Fuzzification

In the first part, "fuzzification", we enter our three categories as input variables, and the MTBF and MTTR as outputs. The notion of fuzzy sets is used to define inputs and outputs. A membership function needs to be defined for each input. The s success of an application is largely dependent on the appropriate selection of these functions.

**a. Input definition**

As we said earlier, the three variables, charger solutions, leaflet solutions and batch number solutions are input variables, so we start by defining them, as shown in Figure 4.1.

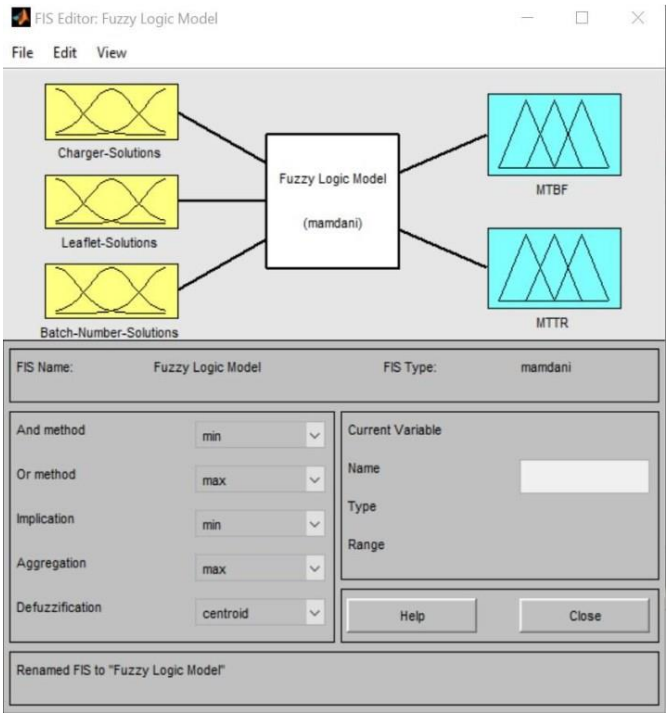



Figure 4.1: Model inputs

## b. Linguistic variables

In Table 4.7, we define all the intervals for our LVs, so in this step we'll define the intervals "the range", then choose the triangular function and finally define the intervals for each Low and High variable in this way. Figures 4.2 and 4.3 show the LVs for the three inputs.

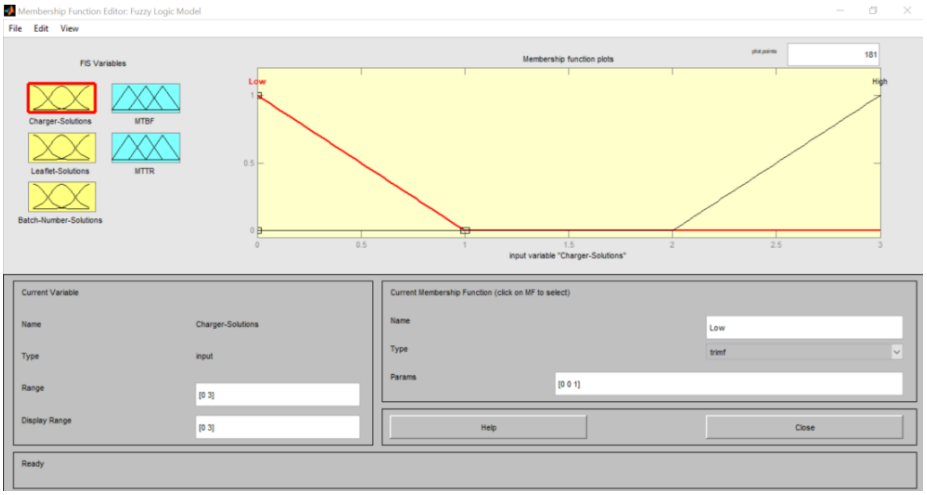



Figure 4.2: Charger solutions LVs.

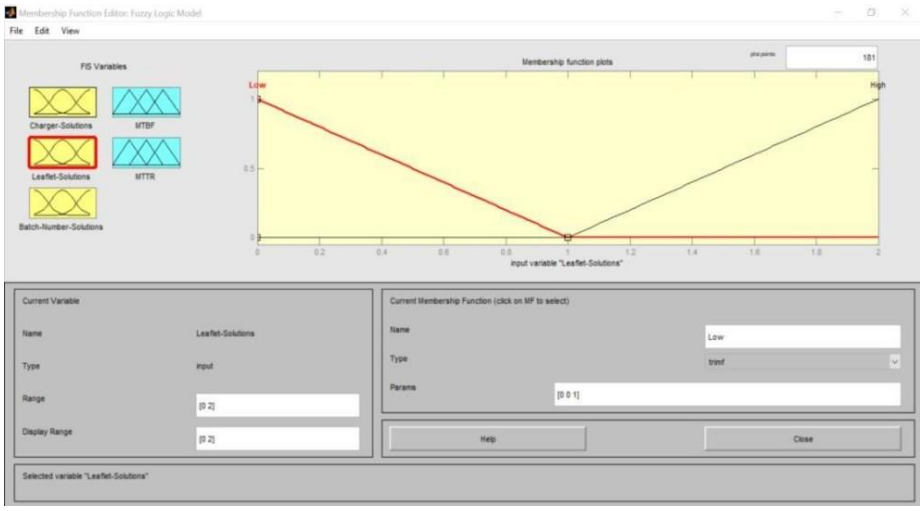



Figure 4.3: Leaflet solutions LVs.




Figure 4.4: Batch number solutions LVs.

### c. The outputs

Our model has two outputs, MTBF and MTTR, and in this section we'll look at the three possible outputs: Low, Medium and High. The outputs of the fuzzy model are configured in Figure 4.5 and Figure 4.6.

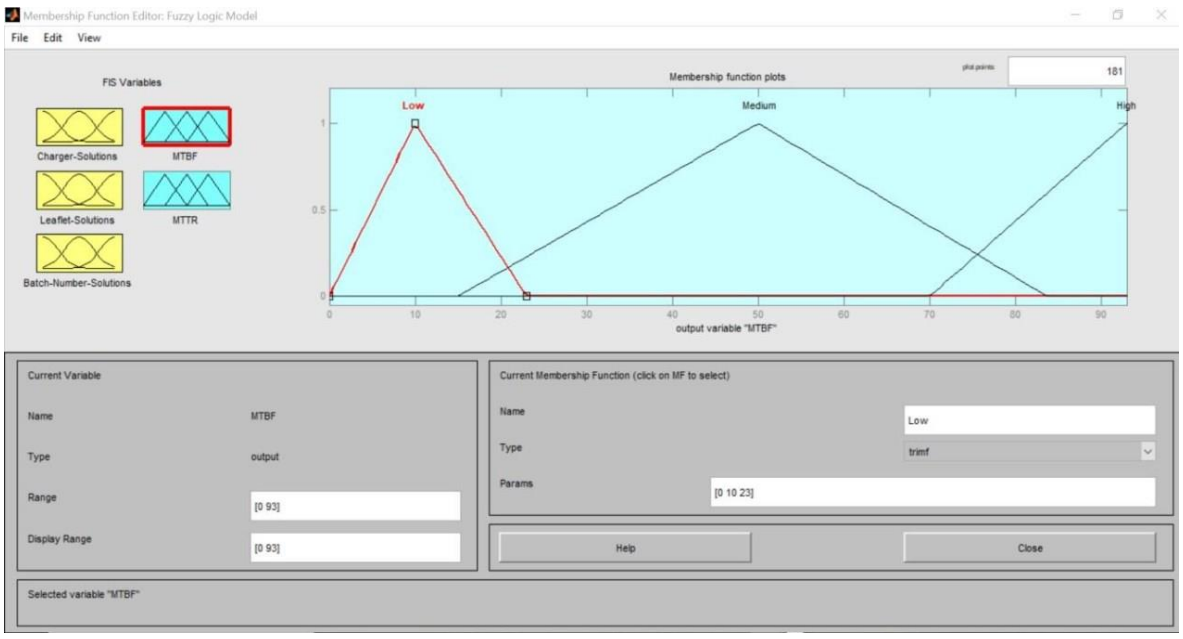



Figure 4.5: Model output (MTBF)

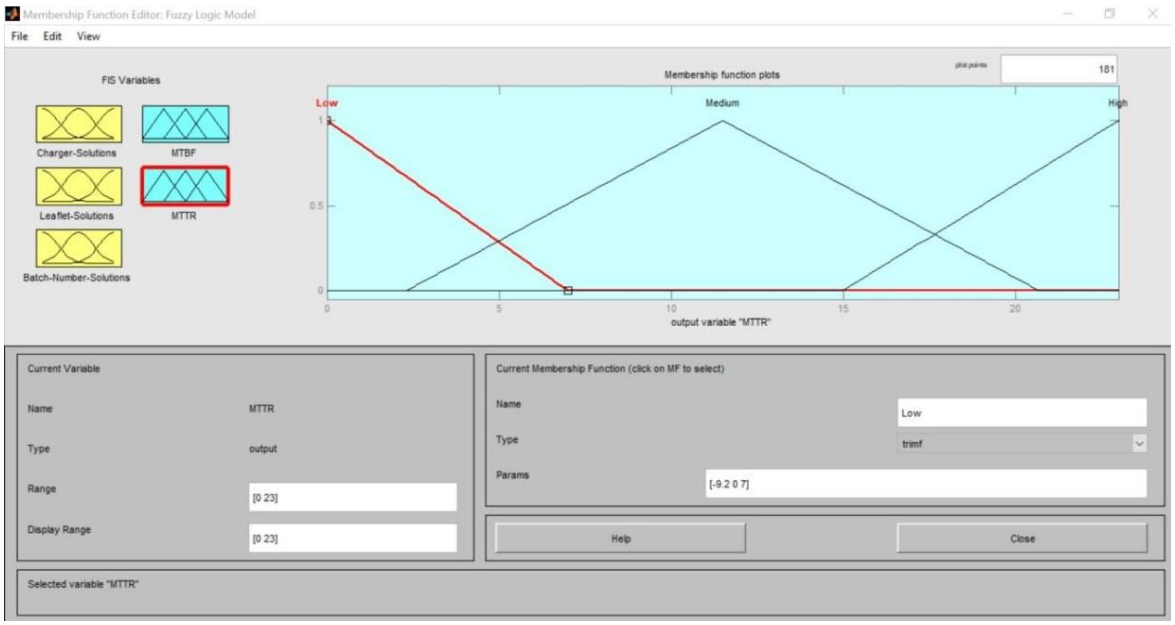



Figure 4.6: Model output (MTTR).

### 4.5.5.2. Fuzzy inference rules

Let's move on to the fuzzy inference rules. In this step, we'll insert the rules represented in Table 4.8. Figure 4.7 shows the rules of our fuzzy model. To insert them in MATLAB, click on edit, then on rules and add the eight rules ($2^3 = 8$).

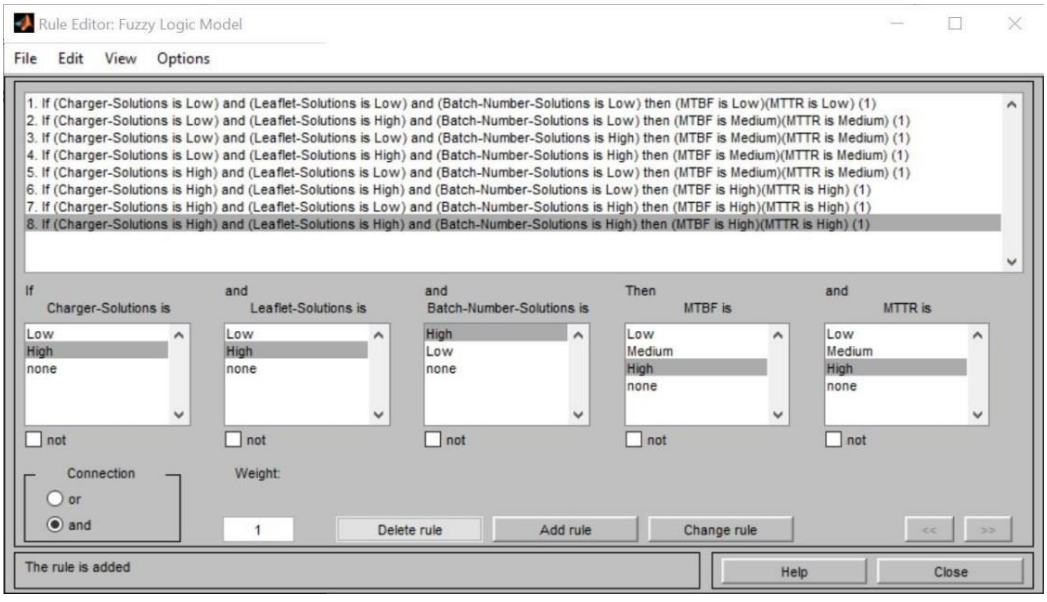



Figure 4.7: FL rules.

The results of our fuzzy model are displayed and illustrated in Figure 4.8 using the view Rules command in editor FIS.

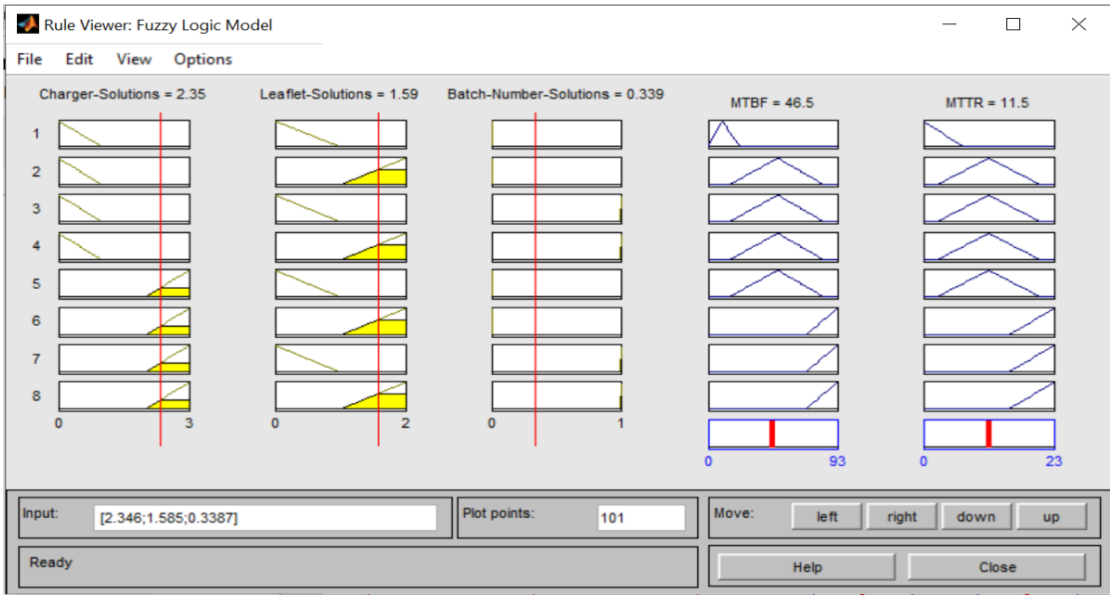



Figure 4.8: Rule viewer of the model

### 4.5.5.3. Defuzzification

Defuzzification curves and surfaces can be displayed for each category. Some of them are represented in Figure 4.9 et Figure 4.10 respectively.

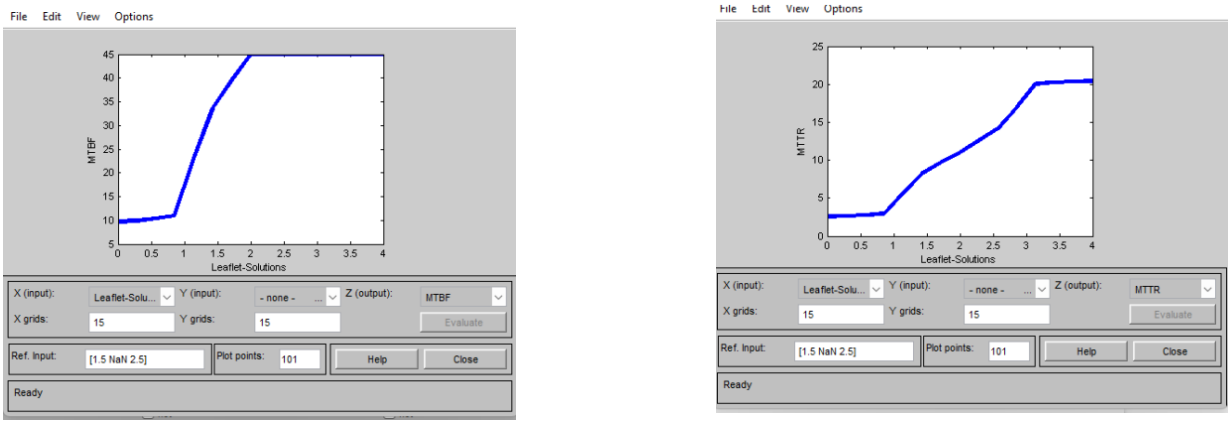



Figure 4.9: Some examples of defuzzification curves of the model

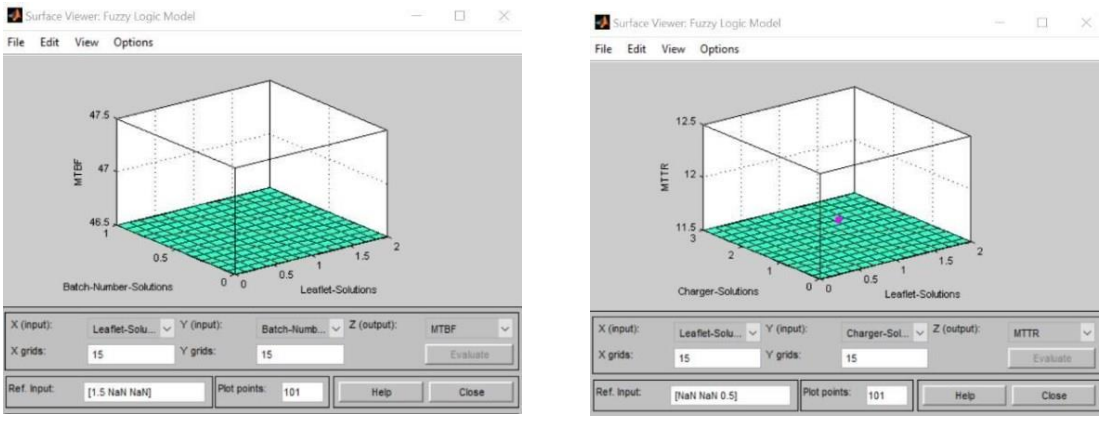



Figure 4.10: Some examples of defuzzification surfaces of the model.

This defuzzification process translates the fuzzy output of a fuzzy logic model into a precise, non-fuzzy value. It enables us to move from a fuzzy representation, usually expressed as a membership function, to a real value or concrete decision.

### 4.5.6. Simulation

We will use our model to simulate every combination of solutions possible, to observe KPIs evolutions.

Possible combinations: {A; B; C; AB; AC; BC; ABC}; knowing that:

- A: represents the charger solutions.
- B: represents the leaflet solutions.
- C: represents the batch number solutions.

**First case "Low combination":** we simulate here the three cases: {A; B; C}, results are shown in Figure 4.11 Figure 4.12 Figure 4.13 respectively:




Figure 4.11: Results of simulating the case A




Figure 4.12**:** Results of simulating the case B

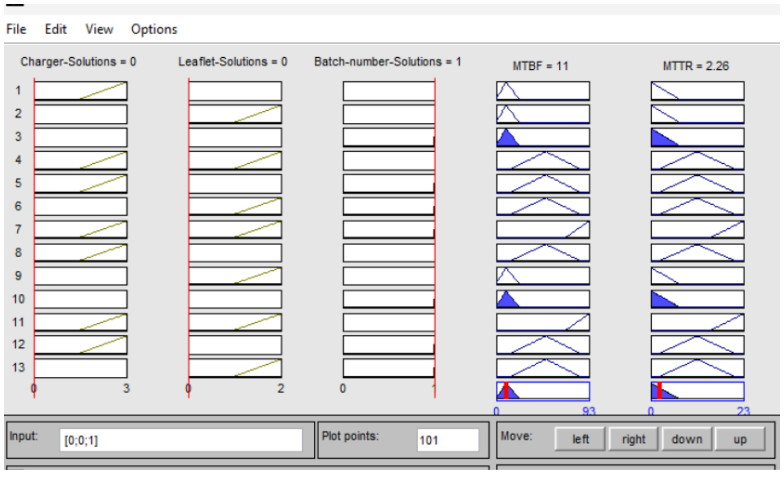



Figure 4.13**:** Results of simulating the case C

- **Interpretations:**

When we give the instruction to eliminate one of the three effects,

- we improve the MTBF by 49,6% and reduce the MTTR by 11,5% for Charger solutions.
- we improve the MTBF by 46,5% and reduce the MTTR by 11,5% for Leaflet solutions.
- we improve the MTBF by 11% and reduce the MTTR by 2.26% for Batch Number solutions.

This means that if we eliminate just one effect, the risk of the other two occurring remains.

But in the case where we apply a PY (QR code for example), we eliminate both effects (leaflet and batch number), which means that applying the 3 solutions on the charger problem couldbe an optimal solution, and by doing this, we optimize resources.

**Second case "Medium combination":** we simulate here the three cases: {AB; AC; BC}, results are shown in Figure 4.14 Figure 4.15 Figure 4.16 respectively:

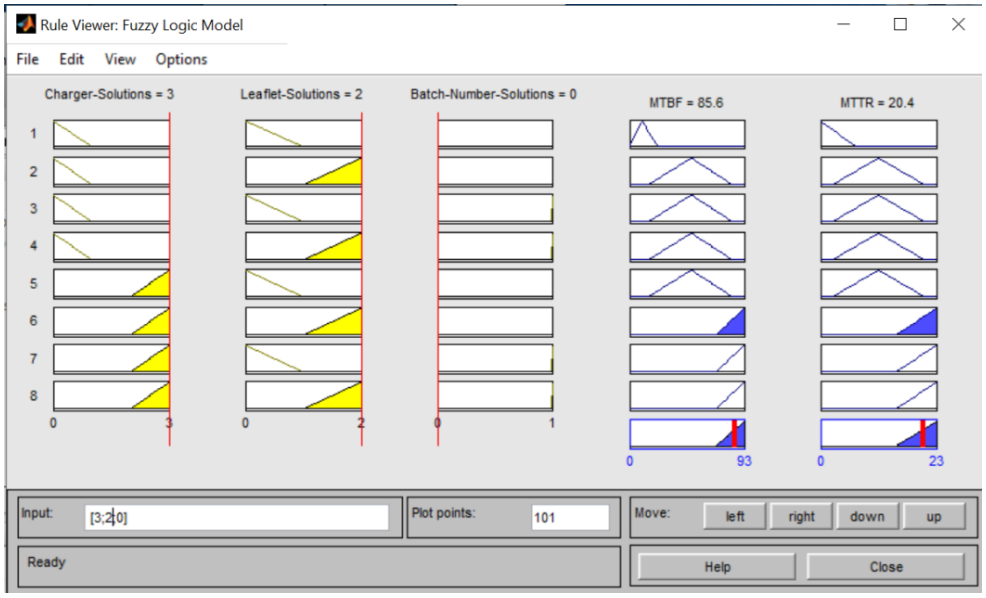



Figure 4.14**:** Results of simulating the case AB.

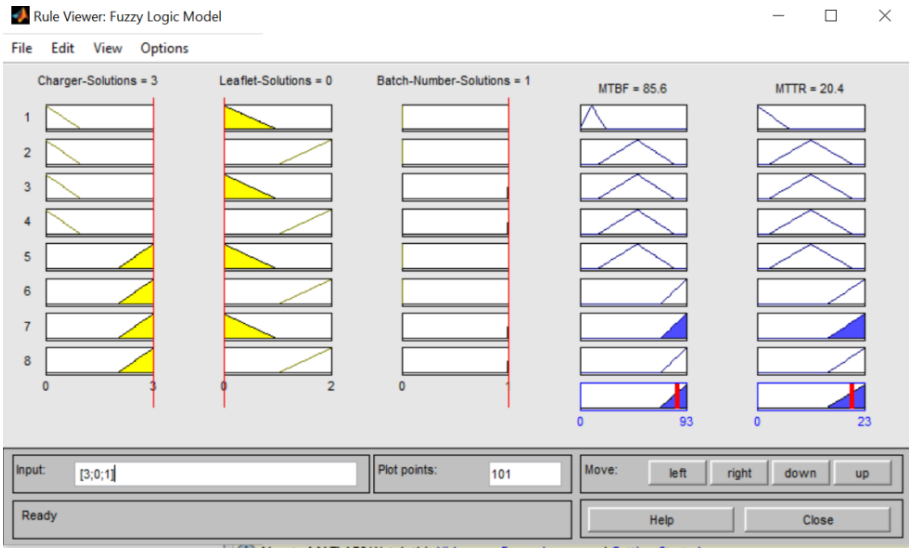



Figure 4.15**:** Results of simulating the case AC.

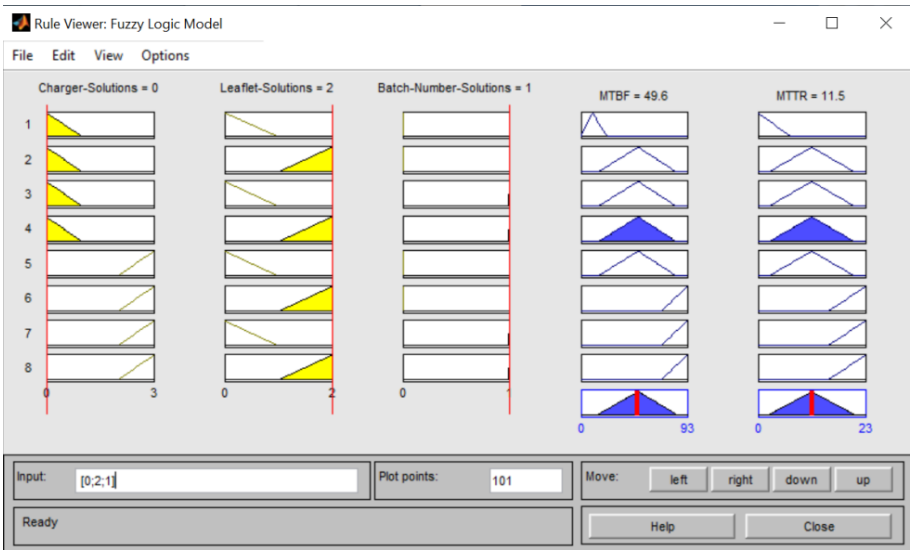



Figure 4.16**:** Results of simulating the case BC.

- **Interpretations:**

- By eliminating the charger problem and the leaflet problem, we increase MTBF by 85,6% and reduce MTTR by 20,4%.
- By eliminating the charger problem and the batch number problem, we increase MTBF by 85,6%and reduce MTTR by 20,4%.
- By eliminating the leaflet problem and the batch number problem, we increase MTBF by49,6% and reduce MTTR by 11,5%.

We can see clearly that the elimination of the charger problem with one other problem considerably increases MTBF and decreases MTTR.

**Third case "High combination":** we simulate here the last case: {ABC}, results are shown in Figure 4.17.

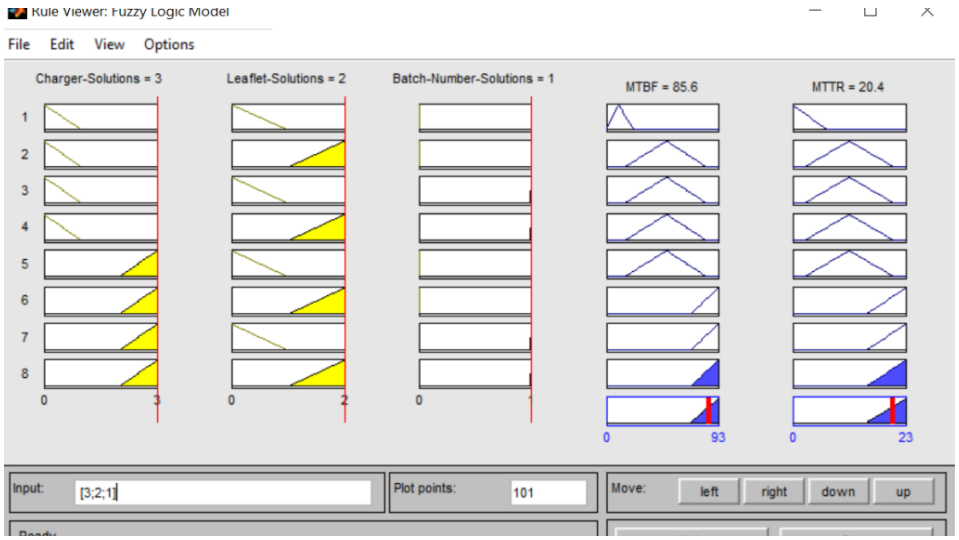



Figure 4.17**:** Results of simulating the case ABC.

- **Interpretations:**

- By eliminating the three problems at once, we increase MTBF by 85,6% and reduce MTTR by 20,4%.

This combination does not provide any better evolution on KPIs compared with the medium solutions {AB; AC}.

## 4.5.7 Results

After analyzing and interpreting all the previous simulated cases, we conclude that we could keep the three following potential combinations:

-Elimination of charger and leaflet effects.

- Elimination of charger and batch number effects.

- Elimination of all critical effects.

Since the three combinations provide the same percentage of evolution for both MTBF and MTTR. The main criterion of selection is the mobilized resources required to realize and implement each one of them.

# Conclusion:

In this chapter, we have presented the simulation results of our fuzzy logic model which get closer to PY philosophy by getting triggered as soon as there is one loss per quality, this model aims to eliminate delays in reaction time to failures. First, we calculated the KPIs before and after the Poka Yokes that we have suggested, explained, and affected estimated costs. Then, we used solutions proposed in the previous chapter for the most critical effect as inputs for our fuzzy model, and the two chosen maintenance KPIs MTBF and MTTR as outputs in order to evaluate their evolution by simulating various cases.

# General conclusion and perspectives

Defects in companies can have significant impacts on various aspects of their operations, reputation, and overall performance, which implies a decrease in maintenance KPIs. To solve these problems, Shigeo Shingo developed a system called Poka Yoke which eliminates defects from their sources.

Our work aimed to evaluate Poka Yokes' impact on maintenance KPIs, MTBF and MTTR in our study. Also, propose optimal solution combinations using a fast and effective FL model for decision making to reduce reaction delays, which improves existing KPIs.

This dissertation is divided into two parts, the first two chapters are state of the art, bibliographical research, and a reminder of the definitions and basics of PY, KPIs, and maintenance management tools necessary in our work. The second part is the application of this knowledge, in which we analyze undesirable effects using presented tools and propose PYs, solutions and recommendations. Those solutions were implemented in the FL model where we simulated and evaluated the possible combinations, every combination has given an estimation of KPIs evolution.

The results have shown that the charger problem has a potential ponderation which justifies the highest result obtained in these combinations:

-Elimination of charger and leaflet effects.

- Elimination of charger and batch number effects.

- Elimination of all critical effects.

Where the MTBF increased by 85,6% while the MTTR decreased by 20,4%. By proposing these solutions, managers can already get an idea about the appropriate solutions depending on their resources (cost, time, and training level)

# General conclusion and perspectives

During our internship, we would have liked to implement all the Poka Yokes on offer, but the limited time available did not allow us to do so. The same goes for the KPIs, since we encountered difficulties, so we would have liked to have the data to be able to calculate them ourselves.

As a perspective, we would like to test this model for larger case studies and improve it using classificatory for a better decision making.

We would also like to implement our fuzzy model in their APIs, with the aim of tripping as soon as there is a quality loss and mobilizing the appropriate solutions, to improve production performance and company management.

Finally, to ensure the proactive features and long-term effectiveness of a PY, it's essential to improve it continuously to guarantee its long-term effectiveness.

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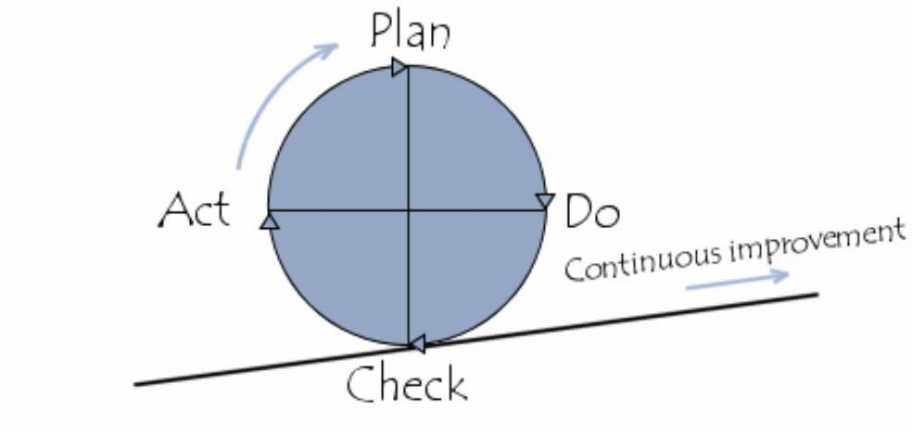
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# Appendix A: PDCA cycle

The PDCA cycle is a representation of a continuous improvement process, developed by Deming, as a four-stage repetitive problem-solving:

- Plan: Analyze, study the problem, define objectives, strategy, means, indicators, schedule.
- Do: Learn, act, achieve.
- Check: Measure results and compare them with objectives.
- Act: Complete action if deviation persists.

This PDCA cycle is renewed to ensure continuous improvement.




*PDCA cycle.*

# Appendix B: Methodology of selection maintenance KPIs

Extracted from the European Standard EN 15341:2007

## 7 Methodology for the selection and use of key performance indicators for maintenance

### 7.1 Defining the objectives which characterise the maintenance management process

To select relevant indicators, the first step is to define the objectives to be reached at each level of the enterprise.

At the company level, the requirement is to identify how maintenance can be managed in order to improve global performance (profits, market shares, competitiveness etc). In this case, the most efficient means of maintenance improvement shall be determined.

At the systems level and production lines, the maintenance objectives can address some particular performance factors, which have been identified through previous analysis, such as:

— improvement of availability;

— improvement on cost-effective maintenance;

— retaining health, safety and environment preservation;

— improvement in cost-effective management of the value of the maintenance inventory;

— control of contracted services;

— etc.

At the equipment level, machines or types of machines, better control of the following may be desirable:

— reliability;

— costs;

— maintainability and maintenance supportability;

— etc.

The objectives may also consist of giving advice for decisions concerning:

— investments;

— duration of utilisation;

— choice of a strategy such as the recourse to contractors;

— etc.

### 7.2 Selecting the relevant indicators

When the objectives have been defined, and the performance parameters to be measured have been identified, the next step is to find the indicators that allow measuring these parameters. When selecting the indicators for maintenance management, the system could for example include:

— capacity of maintaining the equipment which includes:

  — maintainability of the equipment;

  — logistic support (spare parts, tools, documentation, etc.);

— work organisation;

— reliability of the equipment;

— efficiency of the maintenance activities;

— health, safety and the environment;

— etc.

An indicator is relevant when its value or its evaluation is correlated with the evaluation of the performance parameter to be measured. A relevant indicator shall be one element of decision making. This means that the data that constitute this indicator shall have a relation to the defined objective. This link can be proved by analysis or through interviewing experts. Statistical techniques can also be utilised to ascertain correlations between indicators.

In the search for relevant indicators, two approaches are possible:

— first: consists of choosing from amongst lists of existing indicators, which after analysis, fulfil the requirements;

— second: starts from the following methods which begin with the evaluation of the various processes of maintenance which can be obtained through functional analysis.

In practice, both approaches can be used.

### 7.3 Defining and collecting the necessary basic data

It is necessary to precisely define:

— data to be collected to determine the values required for the indicator;

— measurement method (operating mode);

— tools required for the measurement (documents, counters, sensors, analysers, computerized maintenance management system, etc.).

To make the possible evaluation and comparisons easier, it is necessary that the collected data are in conformity with the standardised definitions when they exist (see EN 13306 and IEC 60050-191). If the definition does not exist, it will be necessary to derive such a definition.

### 7.4 Calculating the indicators and selecting the type of representation

#### 7.4.1 Frequency of calculating the indicators

Independently from collecting data, the frequency of the calculation could be predetermined (for instance, it is possible to evaluate a quarterly indicator with monthly collected data).

The frequency of data collection shall be adapted to:

— availability and time delay of the relevant data;

— changes over time (gradient, seasonality, etc.) of the measured performance;

— reactivity of the system to the actions undertaken.

### 7.4.2 Type of presentation

The utilisation of indicators generally requires a graphical presentation according to the required utilisation and to the importance of the series of data.

### 7.4.3 Test and validation

Before the calculation is used as a routine, each indicator will be calculated by using a representative sample during a significant period which will allow for validation of:

— methods of collecting and processing the data;

— methods of calculation and making graphical presentation;

— analysis and utilisation of these indicators.

### 7.4.4 Analysis of the results

One of the next steps, outside the scope of this standard, is to develop scorecards to analyse and to take the required actions.

# Appendix C: Breakdowns history of CAM 1

This database was extracted from Hakam' SAP, it illustrates the information about breakdowns of the CAM 1 line, in a period of four month, starting from January 1st, 2023.

| Equipment | | Notif.date | Created on | Start Malfn ) | Malfunction end | Breakdown dur. |
|---|---|---|---|---|---|---|
| HA-BLS02 | Sealing | 1/8/2023 | 01/08/2023 | 18:56:39 | 7:34:10 PM | 12:37:31 AM |
| HA-CRT04 | Charger | 1/10/2023 | 01/10/2023 | 12:35:00 | 1:20:00 PM | 12:45:00 AM |
| HA-BLS02 | Camera | 1/15/2023 | 01/15/2023 | 02:00:00 | 3:00:00 AM | 1:00:00 AM |
| HA-BLS02 | Charger | 1/18/2023 | 01/18/2023 | 02:45:00 | 3:53:00 AM | 1:08:00 AM |
| HA-BLS02 | Camera | 1/18/2023 | 01/18/2023 | 04:30:00 | 5:35:00 AM | 1:05:00 AM |
| HA-BLS02 | Camera | 1/18/2023 | 01/18/2023 | 15:38:09 | 19:30:00 | 3:51:51 AM |
| HA-CRT04 | Pusher | 1/21/2023 | 01/21/2023 | 17:27:58 | 6:04:43 PM | 12:36:45 AM |
| HA-CRT04 | Pusher | 1/21/2023 | 01/21/2023 | 21:45:00 | 10:17:00 PM | 12:32:00 AM |
| HA-CRT04 | Batch number | 1/21/2023 | 01/21/2023 | 09:00:00 | 11:30:00 AM | 2:30:00 AM |
| HA-CRT04 | Pusher | 1/22/2023 | 01/22/2023 | 18:00:00 | 6:32:30 PM | 12:32:30 AM |
| HA-BLS02 | Batch number | 1/24/2023 | 01/24/2023 | 09:14:36 | 12:28:00 PM | 3:13:24 AM |
| HA-CRT04 | Leaflet | 1/25/2023 | 01/25/2023 | 19:30:00 | 9:13:00 PM | 1:43:00 AM |
| HA-CRT04 | Sticker | 1/26/2023 | 01/26/2023 | 22:15:30 | 10:27:45 PM | 12:12:15 AM |
| HA-BLS02 | Charger | 1/29/2023 | 01/29/2023 | 11:00:28 | 12:17:00 PM | 1:16:32 AM |
| HA-BLS02 | Camera | 1/31/2023 | 01/31/2023 | 10:24:55 | 1:10:00 PM | 2:45:05 AM |
| HA-BLS02 | Charger | 2/6/2023 | 02/06/2023 | 14:50:00 | 4:10:00 PM | 1:20:00 AM |
| HA-CRT04 | Batch number | 2/8/2023 | 02/08/2023 | 22:47:47 | 11:49:00 PM | 1:01:13 AM |
| HA-BLS02 | Sealing | 2/8/2023 | 02/08/2023 | 22:45:57 | 11:41:07 PM | 12:55:10 AM |
| HA-BLS02 | Leaflet | 2/11/2023 | 02/11/2023 | 09:00:00 | 09:30:00 | 12:30:00 AM |
| HA-CRT04 | Leaflet | 2/12/2023 | 02/12/2023 | 10:46:44 | 12:46:00 | 1:59:16 AM |
| HA-CRT04 | Pusher | 2/16/2023 | 02/16/2023 | 19:29:38 | 7:45:05 PM | 12:15:27 AM |
| HA-CRT04 | Pusher | 2/19/2023 | 02/19/2023 | 14:37:00 | 3:20:20 PM | 12:43:20 AM |
| HA-CRT04 | Goudet | 2/21/2023 | 02/21/2023 | 16:45:00 | 17:15:00 | 12:30:00 AM |
| HA-BLS02 | Programming | 3/1/2023 | 03/01/2023 | 02:00:00 | 2:10:00 AM | 12:10:00 AM |
| HA-BLS02 | Camera | 3/1/2023 | 03/01/2023 | 18:30:26 | 7:45:30 PM | 1:15:04 AM |
| HA-BLS02 | Camera | 3/1/2023 | 03/01/2023 | 18:12:25 | 7:42:08 PM | 1:29:43 AM |
| HA-CRT04 | Batch number | 3/1/2023 | 03/01/2023 | 14:00:00 | 4:47:00 PM | 2:47:00 AM |
| HA-CRT04 | Barecode | 3/9/2023 | 03/09/2023 | 09:45:26 | 10:30:00 | 12:44:34 AM |
| HA-CRT04 | Pusher | 3/11/2023 | 03/11/2023 | 11:11:04 | 11:40:00 | 12:28:56 AM |
| HA-BLS02 | Aluminum | 3/12/2023 | 03/12/2023 | 10:13:34 | 11:45:00 | 1:31:26 AM |
| HA-CRT04 | Charger | 3/15/2023 | 03/15/2023 | 14:20:20 | 15:40:00 | 1:19:40 AM |
| HA-BLS02 | Charger | 3/15/2023 | 03/15/2023 | 07:10:00 | 7:50:00 AM | 12:40:00 AM |
| HA-BLS02 | Cooler | 3/18/2023 | 03/18/2023 | 22:55:00 | 11:47:00 PM | 12:52:00 AM |
| HA-CRT04 | Leaflet | 3/19/2023 | 03/19/2023 | 10:00:00 | 10:30:00 | 12:30:00 AM |
| HA-BLS02 | Camera | 3/20/2023 | 03/20/2023 | 09:50:18 | 11:42:00 AM | 1:51:42 AM |
| HA-BLS02 | Cooler | 3/20/2023 | 03/20/2023 | 01:55:00 | 2:30:00 AM | 12:35:00 AM |
| HA-BLS02 | Charger | 3/20/2023 | 03/20/2023 | 12:00:34 | 3:30:00 PM | 3:29:26 AM |
| HA-CRT04 | Charger | 3/26/2023 | 03/26/2023 | 17:00:00 | 5:51:00 PM | 12:51:00 AM |
| HA-BLS02 | Sealing | 3/26/2023 | 03/26/2023 | 11:15:10 | 11:45:00 | 12:29:50 AM |
| HA-CRT04 | Batch number | 3/29/2023 | 03/29/2023 | 16:40:00 | 7:54:00 PM | 3:14:00 AM |
| HA-CRT04 | Leaflet | 4/4/2023 | 04/04/2023 | 23:00:00 | 23:30:00 | 12:30:00 AM |
| HA-CRT04 | Leaflet | 4/4/2023 | 04/04/2023 | 17:10:52 | 6:51:00 PM | 1:40:08 AM |
| HA-CRT04 | Pusher | 4/5/2023 | 04/05/2023 | 2:30:00 AM | 3:12:42 AM | 12:42:42 AM |
| HA-CRT04 | Pusher | 4/5/2023 | 04/05/2023 | 9:52:45 AM | 10:46:56 AM | 12:54:11 AM |
| HA-CRT04 | Box | 4/6/2023 | 04/06/2023 | 14:00:00 | 4:00:00 PM | 2:00:00 AM |
| HA-CRT04 | Box | 4/9/2023 | 04/09/2023 | 11:55:00 | 12:05:00 | 12:10:00 AM |
| HA-BLS02 | Charger | 4/11/2023 | 04/11/2023 | 14:00:33 | 3:09:00 PM | 1:08:27 AM |
| HA-BLS02 | Camera | 4/12/2023 | 04/12/2023 | 16:40:00 | 5:10:00 PM | 12:30:00 AM |
| HA-CRT04 | Box | 4/16/2023 | 04/16/2023 | 02:44:14 | 02:55:00 | 12:10:46 AM |
| HA-BLS02 | Charger | 4/27/2023 | 04/27/2023 | 00:40:00 | 03:40:00 | 3:00:00 AM |
| HA-CRT04 | Leaflet | 1/25/2023 | 01/25/2023 | 19:30:00 | 8:00:00 PM | 12:30:00 AM |
| HA-BLS02 | Leaflet | 2/11/2023 | 02/11/2023 | 09:00:00 | 9:30:00 AM | 12:30:00 AM |
| HA-CRT04 | Leaflet | 2/12/2023 | 02/12/2023 | 10:46:44 | 11:27:00 AM | 12:40:16 AM |
| HA-CRT04 | Leaflet | 3/19/2023 | 03/19/2023 | 10:00:00 | 10:30:00 | 12:30:00 AM |
| HA-CRT04 | Leaflet | 4/4/2023 | 04/04/2023 | 23:00:00 | 23:30:00 | 12:30:00 AM |
| HA-CRT04 | Leaflet | 4/4/2023 | 04/04/2023 | 17:10:52 | 6:00:00 PM | 12:49:08 AM |
| HA-CRT04 | Leaflet | 1/7/2023 | 1/7/2023 | 2:04:00 PM | 2:13:00 PM | 12:09:00 AM |
| HA-BLS02 | Sealing | 4/9/2023 | 04/09/2023 | 3:20:10 PM | 3:53:00 PM | 12:32:50 AM |
| HA-BLS02 | Programming | 3/21/2023 | 03/21/2023 | 8:10:00 AM | 8:18:20 AM | 12:08:20 AM |
| HA-BLS02 | Programmig | 3/15/2023 | 03/15/2023 | 5:16:08 PM | 5:23:00 PM | 12:06:52 AM |
| HA-BLS02 | Programming | 4/18/2023 | 04/18/2023 | 2:43:56 AM | 2:50:00 AM | 12:06:04 AM |

## Abstract

Our graduation project took place at the pharmaceutical company Hikma. Our mission was to carry out an analysis of the most critical production system, to then propose Poka Yokes to improve product quality and equipment operation, and to see the impact of these solutions on maintenance KPIs. In the first part of this manuscript, we reviewed the state of the art on PYs and KPIs. In the second part, we began by presenting our host organization, then carried out an analysis of the most critical production system (CAM 1), using various analysis methods to determine the root causes of downtime problems, and then proposed PYs, solutions and recommendations. The proposed solutions were implemented in fuzzy logic to evaluate the evolution of MTBF and MTTR.

Finally, we analyzed and interpreted the results to prove the effectiveness of these solutions.



**Key words:** Poka Yoke, KPIs, Fuzzy Logic, MTBF, MTTR, Maintenance.



## Résumé

Notre projet de fin d'étude s'est déroulé à l'entreprise pharmaceutique Hikma. Notre mission était de faire une analyse du système de production le plus critique, pour ensuite proposer des Poka Yokes pour améliorer la qualité des produits et le fonctionnement des équipements, et voir l'impact de ces solutions sur les KPIs de la maintenance. Dans la première partie de ce manuscrit, nous avons fait un état de l'art sur les PY et les KPIs. Dans la seconde partie, nous avons abordé les outils qui seront utilisés pour notre analyse et simulation. Et dans la troisième partie nous avons commencé par présenter l'organisme d'accueil, ensuite nous avons fait une analyse du système de production le plus critique (CAM 1) en utilisant les différentes méthodes d'analyses pour déterminer les causes racines des problèmes d'arrêts ensuite proposés des PYs, solutions et des recommandations. Les solutions proposées ont été implémenté dans la logique floue pour évaluer l'évolution du MTBF et MTTR. Finalement, nous avons fait une analyse et une interprétation des résultats pour pouvoir prouver l'efficacité de ces solutions.



**Mots clés :** Poka Yoke, KPIs, logique floue, MTBF, MTTR, Maintenance.



## ملخص

قمنا بتنفيذ مشروع تخرجنا في شركة الأدوية حكمة. حيث تمثلت مهمتنا في إجراء تحليل لأكثر أنظمة الإنتاج أهمية ، ثم اقتراح مجموعة من البوكا يوكي لتحسين جودة المنتجات وضمان التشغيل السليم للمعدات ومعرفة تأثير هذه الحلول على مؤشرات الأداء الرئيسية للصيانة. في الجزء الأول من هذا العمل، راجعنا أحدث التطورات في البوكا يوكي و مؤشرات الأداء الرئيسية. في الجزء الثاني، تناولنا الأدوات التي سيتم استخدامها في التحليل والمحاكاة لدينا. في الجزء الثالث، بدأنا بتقديم منظمتنا المضيفة، ثم قمنا بتحليل نظام الإنتاج الأكثر أهمية (كام 1) ، باستخدام طرق تحليل مختلفة لتحديد الأسباب الجذرية لمشاكل التوقف ، ثم اقترحنا PYsوالحلول والتوصيات .تم محاكاة الحلول المقترحة بمنطق غامض لتقييم تطور متوسط الوقت بين الإخفاقات و متوسط وقت الإصلاح. أخيرًا، قمنا بتحليل وتفسير النتائج لإثبات فعالية هذه الحلول.



**الكلمات المفتاحية:** بوكا يوكي، مؤشرات الأداء الرئيسية، المنطق الغامض، متوسط الوقت بين الإخفاقات، متوسط وقت الإصلاح، صيانة.