Master's Programme in Manufacturing, Zero Defect Manufacturing for Circular Economies

Analysing production process influencing jar quality performance in injection of bio-materials.

Implementing FMEA and Design of Experiments for Thorough Process Analysis.

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Abstract

Sulapac, a pioneering company in biomaterials, is committed to delivering high-quality, sustainable packaging solutions. This thesis focuses on ensuring the injection moulding processes for Sulapac's 50 ml Premium Nordic Collection jar. Leveraging the opportunity to re-verify current processes with a new subcontractor, this study aims to ensure both the mechanical and aesthetic qualities of the product. Utilizing the Design of Experiments (DoE) methodology, key parameters such as holding pressure, cooling time, and filling speed are analysed to understand their impact on the quality and performance of the jars and lids. Additionally, Failure Mode and Effects Analysis (FMEA) is employed to identify and prioritize potential defects using the Risk Priority Number, providing actionable insights for corrective measures to elevate product quality.

The research presents a comprehensive approach, detailing step-by-step procedures for applying DoE and FMEA to rectify identified defects and streamline the manufacturing process. Findings highlight the critical importance of controlling manufacturing parameters and implementing re-verification at each step to ensure product quality consistency. The study also recommends the use of control charts for a refined monitoring of key parameters that significantly influence product quality. In addition, this systematic monitoring method enables for real-time adjustments and contributes to maintaining stability in the manufacturing process.

By understanding the interaction between key manufacturing parameters and proposing targeted improvements, this thesis equips Sulapac to meet its quality standards with their manufacturing subcontractor. The methodologies explored in this study provides a framework that can be applied to future implementation and research, contributing the Sulapac's continuous improvement.

Keywords Injection moulding, Sulapac, Design of Experiments, Failure Mode and Effects Analysis, Parameter validation, Closure Mechanism, Continuous improvement.

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Preface and acknowledgements

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Lastly, I want to thanks to EIT Manufacturing Master School for allowing me to live my dreams and study a masters abroad in European leading universities. Thanks for supporting me through scholarship sponsorship and selecting me as an agent of change. I will save this wonderful experience forever in my heart.

Otaniemi, 31 July 2024,
Oscar Fabrizio Valdivia Andrade

Symbols and abbreviations

Symbols

σ	Standard Deviation
μ	Mean
±	More or Less
$\bar{p}$	Adjusted Proportion
>	More than
<	Less than
≥	Equal or more to
≤	Equal or less to
×	Times value
√	Square
−	Minus
+	Plus
=	Equal to
≈	Approximate to

Abbreviations

DoE	Design of Experiments
FMEA	Failure mode and Effect analysis
O	Occurrence
S	Severity
D	Detection
RPN	Risk Priority Number
IC	Confidence Interval
UCL	Upper control limit
LCL	Lower control limit
SPC	Statistical Control Process
QA	Quality Assurance
TQM	Total Quality Management
MFI	Material Flow Index
MBc	Master Colour Batch
PDCA	Plan, Do Check, Act
cc/s	Cubic centimetres per second
Z	Confidence Level
kN	Kilo Newtons
°C	Celsius
N-m	Newtons meters
m/s	Meters per second

1 Introduction

1.1 Background

The practice of injection moulding was originated in the United States, initially finding application in metallurgical processes before gradually expanding to ceramics and plastics production (Kryachek, 2004). Plastic injection moulding has been considered one of the most cost-effective methods for mass-producing plastic parts. It involves injecting molten plastic into a mould tool and ejecting the solidified part. This process significantly reduces the cost per unit over repeated cycles, ensuring consistent quality across all parts (Singh & Verma, 2017). In addition, injection moulding is versatile, accommodating various materials, colors, cosmetics, polishes, and surface textures, extending beyond plastics to metals and glasses. However, as injection moulding established itself as a prominent mass production process, awareness of environmental issues has led to a significant shift towards developing and using more sustainable materials (Ivar Do Sul & Costa, 2014).

The effort to find sustainable solutions in packaging materials has gained significant relevance in recent years, driven by growing environmental concerns and the imperative to reduce plastic waste (Reichert et al., 2020). Biodegradable materials, which can benefit the environment, have emerged as promising candidates for addressing the plastic pollution crisis (Ibrahim et al., 2022).

Nowadays, the application of bioplastics includes packaging options for different industries such as cosmetics, pharmaceuticals, and food (Youssef & El-Sayed, 2018). These types of industries demand high-quality materials for product packaging, given that the components in each product are strictly analysed and used for human applications. Ensuring the quality of bioplastic packaging is essential to protect the product and prevent any contamination before it reaches the final consumer (R et al., 2021).

Sulapac Oy, founded in 2016 in Finland, is renowned for its innovative use of renewable raw materials, such as wood, and natural binders. This unique composition results in biodegradable materials that serve various packaging applications, making Sulapac a compelling choice for environmentally conscious industries. The company's biomaterials challenge conventional plastics, promoting their replacement to benefit the environment and align with a sustainable vision (Sulapac Ltd., 2024).

Sulapac has distinguished itself not only through the manufacturing of high-quality sustainable materials but also through the development of versatile final products for commercial applications. Their products cater to multiple

sectors, including cosmetics and food service industries. Furthermore, Sulapac has introduced the Nordic Collection portfolio, a high-end product line tailored for customers in these sectors (Sulapac Ltd., 2024).

The expansion of Sulapac in recent years can be attributed to diversification and enhancement in both materials and products. Their materials portfolio included distinct options such as Universal, Premium, and Barrier, along with variations within these categories that provide different properties and finishes tailored to specific production processes and product designs. In terms of finished products, Sulapac has distinguished itself through the high quality of its offerings across different sectors. Notably, they have established important manufacturing partnerships with various brands committed to environmental sustainability (Sulapac Ltd., n.d.). For further details, refer to the Appendices of the Nordic Collection. The focus of this research lies on specific models of the product portfolio.

Specifically, this study focuses on the 50 ml Nordic Collection jars and lids. The objective is to develop a plan to correlate injection moulding production parameters with the quality of the final product and the operations involved in manufacturing these jars and lids. Understanding this correlation is critical to maintaining high-quality packaging and ensuring the integrity of the packaged products. Key procedures in this study include quality and experimentations approaches to understand the behaviour of the final product when key parameters are modified, and a validation of these conducting fundamental tests as torque and leakage. Moreover, this proposal plan can be modified and applied to other models, such as the 30 ml and 15 ml jars and lids, pending further study and analysis.

Employing the Design of Experiments (DoE) methodology and Failure Mode and Effect analysis (FMEA), this study proposes a systematic approach to assess the current state of the manufacturing process and contribute to Sulapac's quality assurance.

1.2 Problem Statement

Sulapac's desire to move the manufacturing of the Nordic Collection jars to a new subcontractor offers an opportunity to understand the related parameters in the injection moulding process, improve related processes, and refine procedures. Although previous production trials were successful, establishing a robust process with the new partner is vital. Ensuring precise interaction between the lid and jar is critical for maintaining a tight and secure closure mechanism.

With the transition to a new subcontractor, it is essential to verify and adjust current process parameters to ensure consistent product quality. Sulapac already has a well-established quality control system for its material batches, and the focus now is on adapting these parameters with the new

subcontractor to maintain and enhance product standards. More than a problem, this transition is an opportunity to re-verify processes and apply methodologies to understand the correlation and behavior of the 50 ml Premium model on key parameters. Establishing robust quality procedures that can contribute to the quality assurance of the new subcontractor will ensure Sulapac continues to meet its high standards and achieve the desired consistency in its products.

1.3 Project Objectives

This study aims to use the current opportunity by the operations partnership of Sulapac with a new manufacturing subcontractor to re-verify procedures and gain a better understanding of the production process parameters of the 50 ml Nordic collection jar and lid. By employing methodologies such as FMEA and DoE, the research will enhance the comprehension and correlation of process settings that could improve product quality and production efficiency in a sustainable packaging solution. This research will contribute to Sulapac's commitment to high quality and continuous improvement in their operations. The main objectives of this study can be represented by the following bullet points:

- Comprehensive understanding of the correlation between key process parameters and the final product status.
- Suggest a quality and experimental plan for Sulapac's operations with the new subcontractor.
- Suggest methodologies that could be employed to systematically analyse and optimize the injection moulding processes for Sulapac's products.
- Propose quality tools for the new subcontractor to meet Sulapac’s quality standards.

1.4 Scope and Limits:

Although the study addresses various considerations, its scope is specifically limited to examining the current situation of the manufactured products with the new manufacturing subcontractor and proposing a plan to understand the correlations between key production parameters and the behavior of the final product. Identifying these correlations is crucial for the effective execution of the function and mechanical performance of the lids and jars of the Nordic Collection, all of which are manufactured through injection moulding.

The main concepts involved in this study revolve around the injection moulding process, manufacturing parameters, mechanical performance, and quality plan methodologies. This thesis is organized into several steps, each

addressing specific research objectives. The introduction focuses on outlining the background, goals, research questions, scope, and structure of the study. The second stage includes a literature review that comprehensively examines relevant literature on injection moulding processes, defect detection methodologies, parameter analysis, and closure mechanisms. Subsequent stages delve into the methodology employed, the results obtained, and discussions on the findings, culminating in conclusions and recommendations for future research.

2 Literature review

2.1 Quality Management in Manufacturing

The importance of quality in manufacturing is paramount within the industry, serving as a main pillar for success and competitiveness. As markets evolve and customer expectations rise, maintaining ambitious standards of quality becomes increasingly vital for businesses to remain competitive and meet the demands of their customers (Psarommatis et al., 2022). A high-quality manufacturing practices enhance overall the value of business relationships; this practice encompasses various aspects, including product performance, durability, reliability, and adherence to specifications. It not only enhances customer satisfaction but also improves trust and loyalty, ultimately contributing to long-term business success (Ulaga & Eggert, 2006).

The pursuit of high quality in finished products was originated back since the industrial revolution, marking the transition to mass production and the advent of standardized manufacturing processes. During this period, the importance on quality began to emerge as a critical factor in ensuring the reliability and consistency of mass-produced goods. Today, quality remains a central pillar of manufacturing, driving continuous improvement efforts and shaping the way companies operate and compete in the global market (Tambare et al., 2022).

The correct application of quality management covers a vary of aspects to enhance to ensure high quality standards in the manufacturing process. Different studies, and approaches have shown that quality management is essential in manufacturing considering not only the process itself but also the customer satisfaction(John S. Oakland, 2014).

2.1.1 Quality Planning

Quality planning is considered the foundation of quality management, essential for establishing the groundwork to manufacture products that meet or even exceed customer expectations. It involves setting clear, achievable quality goals and determining the necessary procedures and resources to meet these objectives. This phase ensures that every aspect of the production process aligns with the desired quality standards. It starts by understanding what the customer expects and translating these expectations into detailed, measurable quality targets. These targets form the basis for a comprehensive plan that outlines the processes, tools, and techniques needed to produce and maintain high-quality outputs.

A crucial part of quality planning is developing quality criteria and expectations. These standards serve as benchmarks for measuring the actual performance and quality of products. They include detailed descriptions of product characteristics, performance criteria, and acceptable tolerance levels. Setting these standards requires a thorough analysis of customer requirements, regulatory needs, and industry best practices. By establishing these benchmarks, organizations ensure consistency in their products and services, minimizing the risk of defects and non-conformance (M. Juran Joseph & A. De Feo Joseph, 2010).

Additionally, quality planning involves proactive measures to identify potential quality issues before they occur. This includes conducting risk assessments to identify areas where problems are likely to arise and implementing preventive actions to mitigate these risks. Tools like Failure Modes and Effects Analysis (FMEA) and Statistical Process Control (SPC) are commonly used to anticipate and address potential quality challenges. Integrating these tools into the planning process helps organizations consistently deliver high-quality products, thereby enhancing customer satisfaction and gaining a competitive edge in the market. Effective quality planning not only improves product quality but also fosters a culture of continuous improvement and operational excellence. Out of Crisis report from Edward deming exemplifies the importance of control to avoid any type of disruption in the process, the disruption is called crisis, and by preventing factors I possible to avoid the lack of quality ind products and processes (Edward Deming, 1986).

2.1.2 Quality Assurance and Standardization

Quality Assurance (QA) is a routine activity and procedure designed to instill confidence that quality requirements are being fulfilled. QA involves well-organized activities and procedures aimed at verifying whether manufacturing processes can produce products that meet the desired quality standards. Common techniques used in QA include the application of data analysis, defect detections, Total Quality Management (TQM), and manufacturing standards.

The standardization of production parameters is the continuous repeated use of specific numerical ranges in production equipment or machines to obtain a product with specific characteristics according to the required design. The importance of using specific parameters allows us to have a known production window, as well as knowledge of what are optimal results. Setting clear and practical standards that can be easily adhered to the production processes can deliver important results benefiting the production department and raising product quality by reducing the rejection possibilities (Cong Lin, 2009; Tambare et al., 2022).

Apart from a traditional approach, which relies on fixed parameters settings, there are studies that apply an adaptive approach. Strasser, Tripathi and Kerschbaumer demonstrated that by considering factors that could create variability and change the manufacturing conditions, a traditional approach is not enough to achieve the full standardization within processes. An adaptive approach can create optimal parameters by enhancing quality and reducing waste. This is a type of dynamic approach where parameters are standardized across the process but adjusted to the need of the production line to meet the specific requirements or characteristics of the final product (Strasser et al., 2018).

In manufacturing settings, the analysis results play a crucial role in optimizing and acknowledge the status of a process. By analysing data insights, organizations can identify opportunities for improvement, mitigate risks, and enhance strengths. For instance, in manufacturing, analysis results might reveal status of the manufacturing line, prompting to execute adjustments to the process by maximizing output while reducing costs (Tambare et al., 2022).

Additionally, these insights can help identify new opportunities, optimize operational efficiencies, and foster innovation within the organization. This approach not only ensures survival in a dynamic marketplace but also marks the path for the continuous development (Kim et al., 2015).

2.1.3 Quality Control

Setting limits on defect ranges is critical for maintaining quality in manufacturing. By defining acceptable ranges for defects and deviations from designed specifications of the product. This helps companies to prevent the production of rejected goods and ensures that only products that meet quality standards are produced, and therefore, released to the market. This includes the development of specific quality control measures, defect identification methods, and inspection procedures to ensure correlation with established quality standards and specifications (Dhafr et al., 2006; Psarommatis et al., 2022).

By setting limits within the process, the improvement of quality in a manufacturing process is incredibly improved. The defect limits approach can be translated into tolerances; a high-grade quality product managing tolerances is critical. In addition, for some industries, automotive just to mention, the lack of control in tolerances can be derivate in safety issues and risk concerns for the user. Moreover, even if quality measurements remain in the tolerance range, the cumulative effect of minor deviations can risk overall product quality and specifications. Byun, in his research of process integration for

high quality in the steel industry, demonstrated that managing tolerances and the stack up of defects can bring substantial improvements to the total quality of the product and process when manufactured (Byun, 2019).

Effective defect detection mechanisms are crucial not only for identifying and addressing quality issues early in the manufacturing process, but to guarantee the quality of industrial production (He et al., 2020). By implementing a strict inspection and testing procedures, companies can detect and rectify defects before they escalate into more significant problems. This proactive approach not only minimizes the risk of defective products reaching customers but also enhances overall process efficiency and reliability (Vo et al., 2020a).

This involves the use inspection methodologies that creates problem solving capabilities after the identification and resolution of the quality issues. Finding the root cause can simplify and eliminate the defects in the process. An adequate root cause problem solving approach can create integrated solution within a company since cross functional collaboration needs to be applied to fix the problem. Nowadays, the integration of people, factors and processes are essential to develop a high-quality product (Vo et al., 2020b).

2.1.4 Continuous Improvement

Continuous improvement is a fundamental principle in manufacturing and operations that focuses on consistently enhancing processes, products, and services. This philosophy is embodied in methodologies such as Lean Manufacturing, Six Sigma, and Kaizen. These approaches create an environment where small, incremental changes can lead to significant improvements over time. By continuously seeking ways to enhance efficiency, quality, and customer satisfaction, organizations can stay competitive and adapt to changing market demands (Oakland, 2014).

One key aspect of continuous improvement is its focus on incremental changes rather than major overhauls. This approach encourages employees at all levels to identify and implement small, manageable improvements in their daily tasks and processes. These changes might involve streamlining workflows, reducing waste, or optimizing resource utilization. For example, Lean Manufacturing aims to eliminate non-value-added activities, thereby improving the overall efficiency of production processes (Juran & De Feo, 2010).

Continuous improvement also heavily relies on data and feedback. Tools like Statistical Process Control (SPC) are commonly used to monitor processes, identify potential issues, and prevent defects. SPC uses statistical methods to analyse and control process variations. By leveraging quality tools, manufacturers can proactively address problems before they escalate, ensuring consistent quality and performance. This data-driven approach is crucial for

maintaining high standards and achieving operational excellence (Deming, 1986).

Furthermore, continuous improvement promotes a culture of collaboration and employee engagement. It empowers workers to contribute ideas and take ownership of improvements in their areas. This empowerment leads to a more motivated and productive workforce, as employees can see the direct impact of their efforts on the organization's success. Companies like Toyota have exemplified this culture through their Toyota Production System, where continuous improvement is ingrained in every aspect of operations. By valuing employee input and encouraging ongoing learning, organizations can create a dynamic environment where innovation and improvement thrive (Crosby, 1979).

2.2 Overview in Injection Moulding

Injection moulding is situated within the most important manufacturing processes for mass production of parts with high dimensional complexity (Cardozo, 2009). Injection moulding is a cyclic manufacturing process. A cyclic manufacturing process is when there the existence of an elapsed time to move a unit of work from the beginning to the end of the process, and subsequently repeat the process with a new work unit (Nadarajah & Kotz, 2008). The precision of final products in injection moulding enables companies to establish a scalable increase of production and reduce productions costs overtime. However, injection moulding requires high quality control actions to ensure consistency and consequently reduce waste along the process (Kumar et al., 2020; Song et al., 2007).

Injection moulding involves several stages. Initially, raw material is fed into a heated barrel via a hopper. Inside the barrel, the raw material melts and becomes homogenized. Then, the molten material is injected through a retention valve into the mould cavity. After the mould cavity is filled, the material cools and solidifies. Finally, the mould opens, and the finished part is ejected, ready for the next cycle Figure 1 illustrates the distinct phases of the injection moulding process.

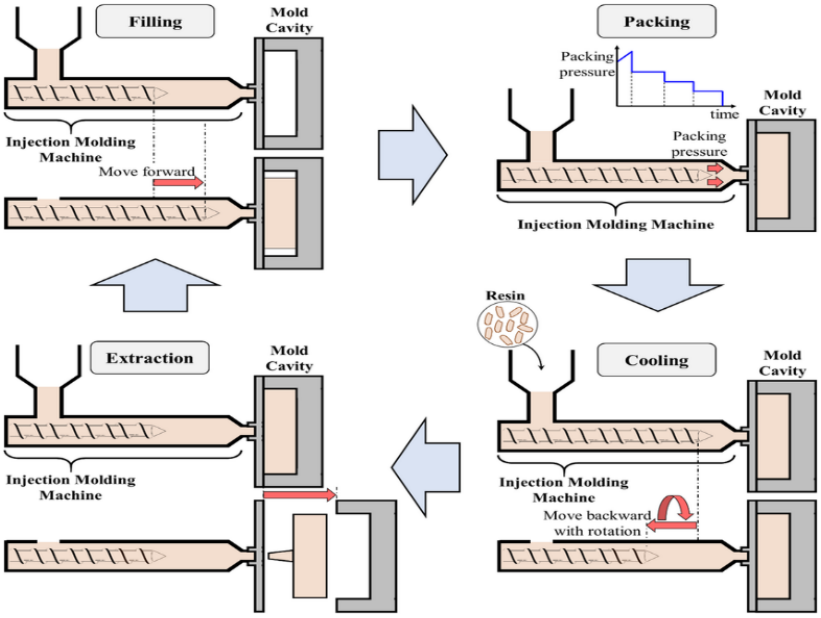

Figure 1: Injection moulding phases in manufacturing (Jung et al., 2023)

2.2.1 Filling phase

The filling stage in injection moulding involves injecting hot, molten material into a thin, cold mould, forming a layer of solid plastic (or manufactured material) along the mould's walls (Hill, n.d.). During this step the mould is closed, and the melted material fills into the cavity part, moving through the rotational screw to the mould cavity. The following Figure 2 exemplifies the operation.

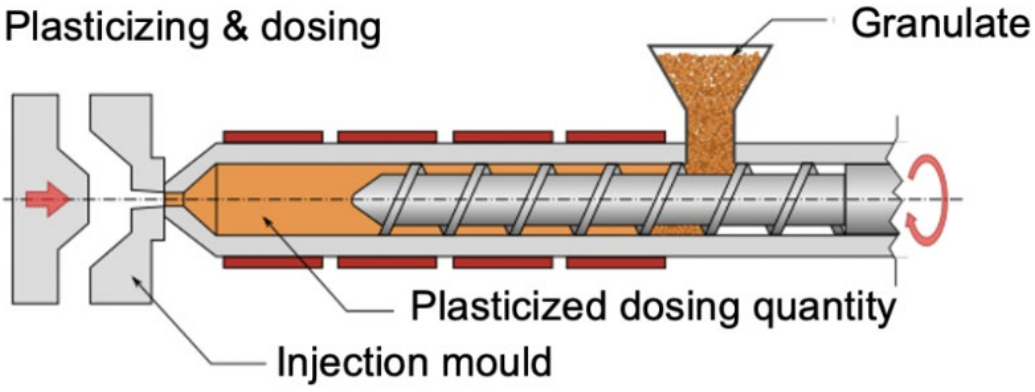

Figure 2: Filling phase in injection moulding (HVS - Technical moulded parts, 2023).

The filling phase is crucial during the process since is the phase where material properties can be compromised to change, hence the thermal properties of the materials should be carefully studied, just to mention one: Material

Flow Index (MFI). The filling phase enables the material to fluid into the cavity part and undergo to the packing phase.

2.2.2 Packing phase

The packing phase refers to the injection moulding stage, where after the cavity is filled, specific high pressure is performed to fulfil the entirely mould and start the formation of the desired product design (Shen et al., 2007). The following Figure 3 shows this mentioned phase.

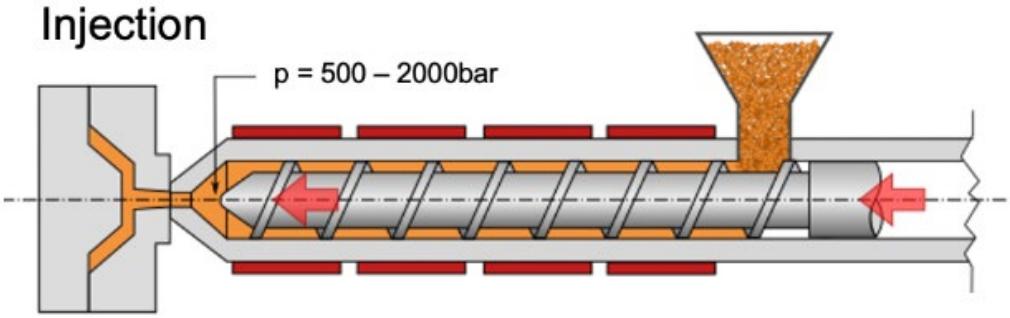

Figure 3: Packing phase in injection moulding (HVS - Technical moulded parts, 2023).

The Packing phase in injection moulding plays a crucial role since it is where temperature and pressure should be accurate, because of the criticality of this phase, the material is prompt to create defects in the manufacturing process if parameters are not well controlled. However, it is important to state that. According to every material, there are different properties and behaviors can vary from one to another (Cardozo, 2009).

The flow material factor in this phase can affect directly to the quality of the final product, since the smoothness of filling the action should be well done. The defects starts when the injection rate, holding time or pressure are out of the upper and lower limits (Liparoti et al., 2015).

2.2.3 Cooling phase

The cooling phase is the stage that immediately begins when packing phase has ended; this phase the material starts to solidify taking, permanently, the shape of the mould (Rapid MFG, 2020). The peculiarity of the cooling phase is that is the stage were most productivity adjustments can be done, since it takes around the 60% to 70% of the entire cyclic time of the injection moulding process. If productivity is the focus, just by applying small reductions to the cycling time, the productivity, overall, can be improved (Hassan et al., 2009). Figure 4 exemplifies graphically this phase.

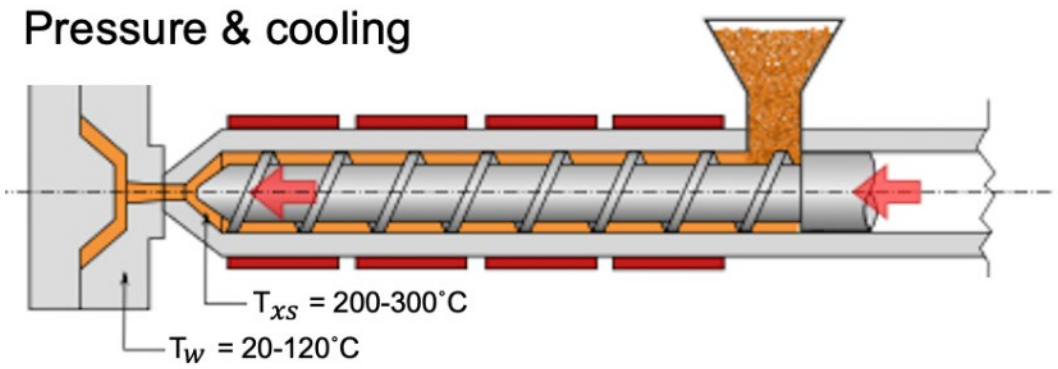

Figure 4: Cooling phase in injection moulding (HVS - Technical moulded parts, 2023)

The cooling action system can be performed through two different methods in injection moulding, by fluids or air channels in the moulds. Because injection moulding parameters is fully driven materials properties, the cooling method in the process varies from one to another. A proper election of the cooling system can deliver not only a high product quality but also decrease production costs and energy consumption (Xu Chun-long, 2010).

2.2.4 Ejection phase

The ejection phase in injection moulding involves of ejecting the moulded material when the mould opens, once the mould is full open the moulded part drops to, therefore, be stored. This phase is crucial since a proper ejection phase ensures the integrity of the final product; this mostly depends on the friction generated in between the tooling and the material, this is called friction coefficient. (Pouzada et al., 2006). Figure 5 shows this phase.

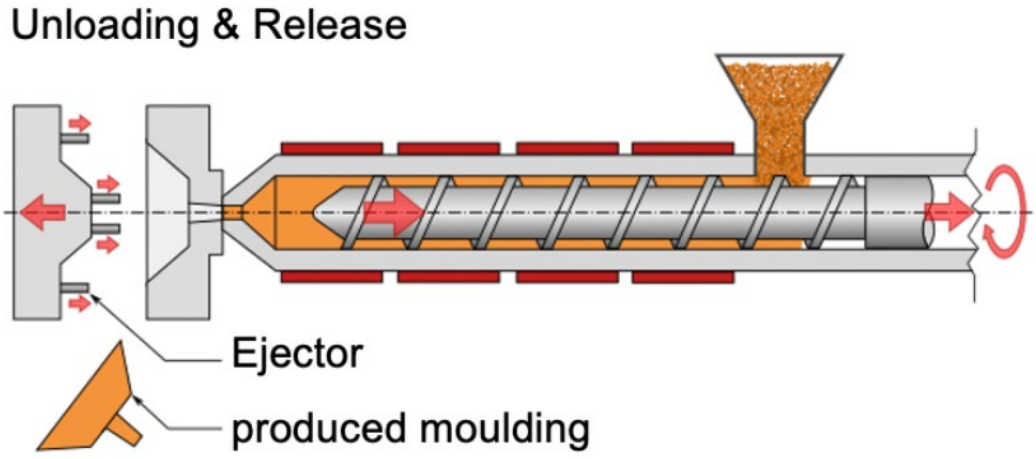

Figure 5: Ejection phase in injection moulding (HVS - Technical moulded parts, 2023).

2.3 Parameters Influencing Product Design in Injection Moulding

In various manufacturing processes, specific parameters critically influence the outcome of the designed and subsequently produced products. Within the realm of injection moulding, key parameters substantially impact the quality of the manufactured product. Each factor may exert one or more direct effects on the final product quality. As an example, cycle time, which significantly influences productivity, is determined by a combination of several factors. Furthermore, certain factors contribute cumulatively to the overall process, thereby affecting the total outcome. To continue, the following parameters are crucial in injection moulding.

2.3.1 Holding pressure and time.

Holding pressure is the sustained pressure applied to a molten material in a mould cavity. The Holding pressure is applied after the initial filling phase is complete. This pressure is maintained during both cooling and packing phases of injection moulding. The maintained time of pressure in the mould is called Holding time, which both of this reflects an important consequence in the cycling time, therefore productivity (Hassan et al., 2009; Kuang et al., 2023).

A correct application of holding pressure and time can minimize potential defect in the manufacturing, sink marks and voids, mainly. Since then, main purpose of this parameter is to compensate for material shrinkage as the molten material cools and solidifies, ensuring that the mould cavity has being filled property. Therefore, holding pressure is a critical parameter in determining the quality of the injection moulded part, as it influences the material's density and mass, and the replication of this along the whole manufacturing process when producing items with a detailed design.

2.3.2 Injection Speed

The injection speed relies in the velocity which the material is filled in the mould. A correct filling of material and packing formation depends on the speed of the filaments once they start to pack in the mould. This factor is pivotal as a parameter in the injection moulding process; by setting the correct injection speed could bring advantages by manufacturing precise products. However, if it is not studied properly this could significantly affect the quality and precision of the final moulded products. In addition, according to Hong Lin Li and Z. Jia (2012), this method not only enhances product

quality but also can contribute to significant cost savings by improving the structure and reducing defects (Hong Lin Li, 2012).

To effectively manage the injection speed in the process, some adaptive control techniques have been performed in different studies. These methods utilize different control schemes like regulators that can predict and control the moulding conditions to regulate the speed when parts are manufactured, hence this will create an accurate process with a steadily repeatability (Yang & Gao, 1999).

The significance of injection speed, defined as the injection rate, is usually measured in volume per unit time, such as cubic centimeters per second (cc/s) or cubic inches per second (in^3/s). The injection rate is a crucial factor that directly relates to the optimization of the injection moulding process. By optimizing the injection rate, the efficiency and quality of the final products are directly impacted. The injection rate is determined by the speed at which the molten material is injected into the mould. When studying the injection rate, three important aspects need to be considered: filling time, part quality, and process stability. According to Gu Yuanxian and Shen Chang-yu (2003), optimizing the injection rate during the filling phase, by controlling the filling time, can minimize defects such as over-packing, residual stresses, shrinkage, and warpage (Gu Yuanxian, 2003).

2.3.3 Mould Temperature

In injection moulding, the mould temperature is a crucial factor than can influence in the quality and characteristics of the final plastic products. Exemplified by Karagoz (2021), the mould surface temperature can impact directly in the mechanical properties of a product. The mentioned study, highlights that an optimal mould temperature setting can enhance crystallization rates and can reduce defects like warpages. This remarks the importance of an accurate mould temperature control to ensure properties of the material meet the selected standards (Karagöz, 2021).

In injection moulding, managing mould temperature with precision is key to ensure quality production. The control of the mould temperature allows for the on-real time control of the injection. The control of this is crucial for achieving optimal surface morphology and dimensional structure. As Lipatori demonstrated in his research, today in manufacturing processes mould temperature management is a must in the injection moulding industry (Liparoti et al., 2015).

2.3.4 Cooling Time

The cooling time in injection moulding is considered to be the most major factor for both cycle time and quality of the finished product. Understanding and improving cooling time is fundamental for increasing the efficiency in production and reducing manufacturing costs. The design of the cooling system in injection moulding plays a crucial role and affects significantly to the cycle time by heat transfer from the moulded material and the mould (Yielgady, 2022).

The optimization of cooling time relies directly on the cooling system, by adjusting cooling flow rates, temperatures, and layout it is possible to reduce the cooling time of the molten material, therefore, the cycle time which is translated in productivity. A. Chaabene utilized additive manufacturing to create moulds with a better performance cooling time. His approach allowed to optimize the cooling phase and significantly reduce the cooling time of the process (Chaabene et al., n.d.).

2.3.5 Cycle time

Cycle time in injection moulding refers to the total time required to complete one cycle of the injection moulding process when manufacturing product. The cycle begins when the mould closes and ends when the final product is ejected, and the mould is ready to receive more material for the next cycle. The cycle time can be stated as the sum of time within different phases Figure 6 shows the time distribution of cycle time. The phases that involve directly into the cycle time are injection phase, filling phase, cooling phase and the mould opening and ejection phase (Zink et al., 2017).

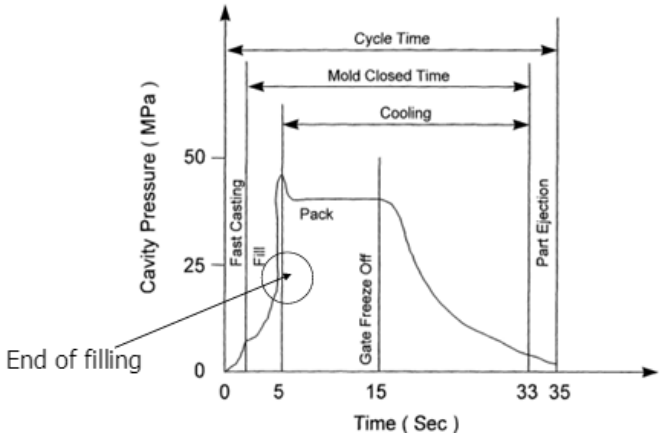

Figure 6: Cycle time and parameters diagram (S. Kim et al., 2008).

To understand better, the cycle can be defined as the accumulation of time of different action parameters that occur in different phases. Just to exemplify, the injection speed, which is related to the injection rate, occurs in the filling phase of the process, where other parameters are involved too, like holding

pressure and time. The injection moulding landscape involves a subsequence of parameters that result in major results (Mukras, 2020).

When we talk about cycle time is important to also consider cooling phase since is the most-time consuming phase for the cycle time, enhancements in the cooling systems could reduce completely significantly the cycle time of the process (Zink et al., 2017).

2.4 Importance of Torque in Sealing Products

The significance of torque in sealing is crucial to maintaining product integrity, preventing leaks, and ensuring product longevity. Gabor Szakacs discusses the critical aspects and variables influencing torque testing in bottle caps. The primary concern in manufacturing operations regarding sealing products is ensuring that the closures effectively prevent issues within the product (MesaLabs, 2006).

MesaLabs states that, in addition to torque measurements, there is a significant sequence of variables that can affect the torque of a closure action in a product. During various studies and measurements, the author highlights several key factors that should be considered in torque testing:

- Excessive pressure: Excessive load during the closing action can alter the torque measurements of a product. Indeed, an excess of pressure when applying torque can malfunction or damage the thread structure that facilitates the closing action.
- Material Properties: The material properties play a crucial role in determining the density and structure needed to generate appropriate torque during the closure action. Different materials can significantly affect the torque required and the effectiveness of the seal resulting in a risk to create damage in the inner area.

Additionally, MesaLabs emphasizes the importance of calibration when performing torque testing and measurements. Variations in calibration can lead to inaccurate performance measurements and potentially compromise product quality if the values are incorrect (MesaLabs, 2006).

To further support these findings, Szakacs suggests implementing regular torque testing protocols and training for personnel to ensure consistency and accuracy in torque application. Continuous monitoring and adjustment based on real-time data can help maintain optimal torque levels and prevent issues related to under- or over-tightening closures.

2.5 Sealing to prevent Leakage

In different industries, a critical aspect of packaging is the sealing and closure action to prevent leakage. A failure related to leakage in packaging can lead to potentially ruin the consumer's experience and manufacturer reputation.

Effective sealing is able to prevent contamination and spoilage, since it works as the principal barrier against external elements such as air, moisture and microorganisms. This is particulary important for products that are sensitive to environmental changes. A properly sealed cap ensures that the product inside the packaging remains in its ideal state from the point of manufacture until it reaches the final consumer (Moghimi et al., 2016). In addition, it is important to mention storage conditions of materials before being manufactured.

The condition of raw materials before being manufactured can impact the final product mechanical properties, in this study, the closure action between jars and lids. For instance, impurities or inconsistencies in the raw material can bring to a lack of performance of the final product, affecting its durability to maintain a proper seal. High quality raw materials, plus, the proper manipulation of them possess a high role in the mechanical strength and the flexibility to be mechanically reliable (Garavand et al., 2017).

Several factors influence the effectiveness of leakage testing. The type of material used for both the cap and container is a primary factor. Different materials have varying different levels of flexibility, mechanical and sealing properties. In addition, the degradation of the packaging over time or under certain conditions can, such as exposure to temperatures, can lead to a leakage. Therefore, is a must to ensure that the properties of materials are not altered in order to perform a correct sealing in packaging (Feng et al., 2022).

The design of the cap and the sealing mechanism also play a critical role. The compatibility of between the cap and the container's neck finish must be considerer to ensure a correct seal. Furthermore, the application of torque to execute the sealing should be consider when analysing the involved factors.

Another critical component in the sealing process is the use of liners. Liners are materials placed between the cap and the container to enhance the seal. They are essential in ensuring the integrity of the seal by compensating for minor irregularities on the sealing surfaces and providing an additional barrier to leakage. Different types of liners, such as foam liners, pressure-sensitive liners, and heat induction liners, are used based on the product's requirements and the type of cap used. Foam liners are commonly used for their cushioning properties, while pressure-sensitive liners are suitable for

tamper-evident applications. Heat induction liners provide a hermetic seal that is ideal for liquid products (Al-Jadaa et al., 2015).

2.6 Failure Mode and Effects Analysis (FMEA)

Failure Mode and Effects Analysis (FMEA) is a systematic method used in manufacturing processes to identify and address potential failures and their consequences on products or processes. FMEA contributes on considering possible ways in which a product or process might fail (Tsai et al., 2017).

By assessing the relevance and occurrence of failures, FMEA allows to hierarchically organize risks based on their impact on operations or final product (Chiozza & Ponzetti, 2009). Moreover, FMEA is wide used to enhance the reliability of a product, by exploring all the potential; failures and their causes; this type of approach can be highly useful for process too, since it can reduce the possibilities of errors or undesired parameters (J. Enright, n.d.).

Furthermore, FMEA can provide a structured approach from the root cause analysis, up to the effect in the process by prioritizing risks which facilitates the implementation of optimization approaches to a process, therefore a final product or service (J.E. Hunt, 1993).

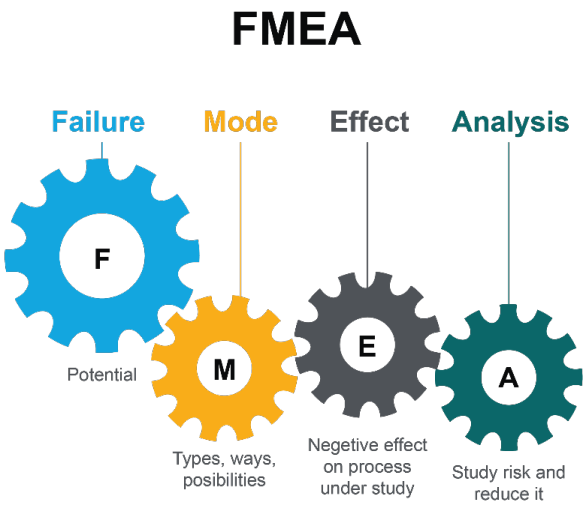

Figure 7: FMEA illustration (Advance Innovation Group, 2024).

2.6.1 Application of FMEA in Injection Moulding

As a complex manufacturing system, it is a widespread practice to apply FMEA to injection Moulding. A manufacturing system that is demanded to produce high-end products and massively, involves plenty of parameters, therefore, the parameters that are directly involved to the manufacture of the product are crucial (Mansur et al., 2016).

The FMEA approach can be applied in different circumstances into the injection moulding process. Is the user interests that drives the application of FMEA to the injection moulding process. Different studies present different approach according to the interests of the researcher or the Company; Improvements in mould performance in production, exploration of critical parameters in the production of final products, and wear approaches in system equipment are clear examples of this (Gopal & Dessalegn Dejene, n.d.).

2.7 Design of Experiments (DoE)

Design of Experiments is a fundamental statistical tool mostly used in engineering and manufacturing to identify the factors that influence product quality and process efficiency. By systematically testing variations in input variables, DoE helps to determine the conditions that optimize the output of processes.

2.7.1 Fundamentals of DoE

The principal goal of DoE is to understand the relationship between process variables (inputs) and output variables (responses) in a controlled manner. This method provides a structured approach to planning experiments, which can help to distinguish the effect of different variables by varying them simultaneously and having different results in the final product. The key principles of DoE include randomization, which helps ensure that the data obtained is free from bias; replication, which increases the accuracy of the data; and blocking, which reduces the impact of nuisance variables (Statistical Manufacturing Journal, 2002).

When principles are properly applied, DoE can be the key tool to improve the entire process. In addition, the benefits in preventing defects or failures are useful. For example, a study in the pharmaceutical industry demonstrated a 14.5% improvement by applying DoE techniques, which validated the effectiveness in achieving the customer requirements (Sharad Chaturvedi, 2017).

2.7.2 Step-by-step Process of Results and Factors

Uy and Telford provide a thorough explanation of how to approach a DoE. By correctly applying DoE techniques, systems can be understood with robust statistical data, simplifying decision-making processes. Their study emphasizes the importance of initial and final optimization design (Uy & Telford, n.d.).

- Initial Screening: This step involves identifying potential factors that might influence the process outputs. A comprehensive approach is

applied to recognize the most noticeable impacts of these selected factors on the responses. This step identifies the potential factors that might influence the response of the outputs form the process. This can be done by applying a comprehensive approach and understanding the most noticeable impacts on the response of these selected factors.

- Factor Ranking and Analysis: During this phase, the significance of different factors is evaluated. Factors are ranked based on their effects, providing a clear hierarchy of their importance.

- Results Analysis: After obtaining the results, a deeper investigation into the factors is essential to understand how significant factors interact and influence the response variables.

- Optimization: This step focuses on optimizing the analysed process. Optimization should be justified based on the output results and aligned with the primary objective of the DoE application.

- Model Validation: Ensuring that the model developed is consistent and optimal is crucial. This step verifies that the DoE has been conducted under conditions that support reliable and valid outcomes.

2.7.3 Type of factorial design

Factorial Designs are among the most used experimental designs in the DoE. They are particularly valuable for analysing the interaction effects between different factors. The main types of factorial designs include:

- Full Factorial Design: This design involves conducting experiments at all possible combinations of factor levels. It provides a thorough understanding of the effects of all factors and their interactions. However, if the number of factors is large, this approach can be resource-intensive and time-consuming.

- Fractional Factorial Design: Instead of using all possible combinations as in a full factorial design, fractional factorial designs select a subset of combinations. This reduces the number of experiments required, making it more practical for studies with many factors. The trade-off is that some interaction effects may be overlooked.

- Two-Level Factorial Design: In this design, each factor is tested at two levels, typically high and low. It is efficient for identifying significant factors and interactions but may not capture non-linear relationships.

- Response Surface Methodology (RSM): RSM is used to model and optimize processes where the relationship between factors and responses is complex and involves curvature. This methodology involves conducting experiments at various levels and fitting the data to a polynomial model, providing a more nuanced understanding of how factors interact.

2.7.4 Interpreting Results from DoE

In the paper by Uy and Telford (2009), the application of regression and Pareto analysis is demonstrated through comprehensive approach The interpretation of the DoE can be interpreted with different tools, this thesis will use the Regression model and Pareto analysis.

- Regression Analysis: The regression analysis can be performed on the collected data to model the relationship between the response variable and the experimental factors. The regression model is able to quantify the effect of each factor providing coefficient that indicate the relevance and direction of the output effects.

- Pareto Analysis: The pareto analysis is generated to visualize the ranked factors on their cumulative impact on the response variables. This chart can reveal which are the key few factors in the variation response, highlighting where the decision maker should focus to lead optimization and data validation.

By applying regression and Pareto analysis Uy and Tlefor effectively narrowed down the factors that were affecting system performance, focusing on those with the most significant impact. This approach is able to ensure that any analysis or optimization is targeted efficiently, with a minimal resource expenditure (Uy & Telford, n.d.).

3 Methodology

This section presents a comprehensive analysis of Sulapac's current situation based on collected and analysed information. It begins with the information collection structure, which includes literature reviews of past studies, initial or kick-off meetings, and weekly meetings, as well as direct observations. Following this, it details the collaboration with the new subcontract manufacturer. Additionally, it includes Sulapac's quality assessment, the design of the 50 ml Premium model, current operations, and an analysis of the production parameters and final product quality. This analysis provides an integral view of the current state of Sulapac's manufacturing processes, emphasizing the importance of re-verifying, and refining these processes with the subcontract manufacturer to meet Sulapac's high-quality standards and identify potential improvements. Based on the findings presented in this section, proposals for Sulapac's implementation strategies will be developed.

3.1 Data Collection Methods

The data collection process was systematically organized, considering all the relevant aspects so that problems can be identified within the stipulated time. The methods used for data collection are as follows:

- **Literature Reviews of Past Studies:** The past comprehensive reviews of research were done for setting up the state of the art, knowledge base, and background. This included studies on injection moulding, total quality management, quality manufacturing, DoE, and FMEA.
- **First Meetings or Kick-Off Meetings:** These meetings were arranged at the initiation of the study with stakeholders from Sulapac and the subcontract manufacturer. The aim was to agree on the project goals, expectations, and approach, and to get first insights of the process and their involved aspects.
- **Weekly Meetings:** Weekly meetings were held to monitor progress, follow up on emerging issues, and ensure that all parties involved to kept in regular contact. Such meetings facilitated periodic data gathering for any review of the project work plan.
- **Direct Observation:** Observation has been conducted at the subcontractor's premises to establish data collection on the manufacturing processes. This provides valuable inferences from the real operations that identify potential areas of improvement and validate information from other sources.

The findings were reported, and implementation proposals were developed based on these results. The following diagram illustrates the comprehensive data collection plan and steps taken throughout this process:

Figure 8: Data collection scheme (Zink et al., 2017)

3.2 Current Product Design

In 2018, Sulapac successfully launched the Nordic Collection portfolio, its first range of cosmetic jars. This expansion of their product line was met with considerable success and resulted in high customer satisfaction over the past few years. The 50 ml Premium model offers a luxurious finish, an effective seal, and a smooth surface to end-users. The figure 9 below exemplifies a general 2D drawing of this model.

The jars feature a uniform surface with an interior made from Barrier material and an exterior crafted from Premium material, customizable in diverse colors to meet customer needs. The design principles of the lids mirror those of the jars, combining aesthetic appeal with functional durability.

By maintaining consistent design and material choices, Sulapac ensures superior quality and versatility, aligning with their commitment to eco-friendly

and customizable packaging solutions. These established quality standards enable the manufacturing subcontractor to effectively follow and implement Sulapac's guidelines, ensuring the efficient production of this model.

Figure 9: Premium 50 ml design.

3.2.1 Inner and outer Material

To properly understand the coexistence of the two materials used in Sulapac's products, it is important to consider the properties and roles of each material.

Barrier Material

The Barrier material is recognized as an ideal choice for the cosmetics industry, specifically developed for injection moulding and used primarily for the internal surfaces of cosmetic jars. It acts as a protective layer that prevents the evaporation of water, making it highly effective for containing water-based cosmetics in a sustainable manner. Suitable for double injection or bi-injection moulding processes, the Barrier material has a 98% bio-based content, certified by the USDA and BPI, and complies with EU regulations for food contact materials. Its properties closely resemble conventional plastics, allowing for sustainable production without compromising performance. The processing conditions for this material highlight its adaptability and efficiency in the manufacturing process.

All the properties of the materials can be detailed in the appendices section. Regarding the Barrier material, it can be concluded that it is the ideal choice for storing and preserving the integrity of the product, thanks to its smooth and secure surface designed specifically for this purpose.

Premium Material

The Premium material provides a fine finish and has been thoroughly tested and approved by the USDA. Its main components are wood fibers and biodegradable polymers, offering a more sustainable alternative while maintaining conditions similar to conventional polymers. This material enhances the product's aesthetic appeal and aligns with eco-friendly practices. The

external part of Sulapac's products, made from Premium material, includes large wood chips to provide a distinctive look and feel. It can be customized in various colors to meet customer preferences. The use of colorants does not significantly affect the performance characteristics of the material, ensuring that the jars and lids maintain their high quality and functionality. Detailed property tables of the Premium material are available in the appendices.

Combined Benefits

Each material offers distinct characteristics that, when combined, result in a high-quality product with efficient processing and mass production capabilities. The Barrier material ensures the integrity and secure storage of the contents, while the Premium material adds a refined, aesthetic finish. Together, they provide a sustainable alternative for companies looking to reduce plastic use. It's important to highlight that these are not the only materials in Sulapac's portfolio. Sulapac offers a variety of other materials, each tailored to meet the diverse production requirements of different companies. This flexibility allows businesses to choose materials that best suit their specific production needs and sustainability goals.

3.3 Current Manufacturing Process

This section describes the current manufacturing process of Sulapac's jars and lids, in collaboration with the current subcontractor. It provides an overview of the manufacturing steps and focuses on the impact of key aspects on production quality and efficiency.

3.3.1 Current Production Parameters

Sulapac has well-established quality procedures for their materials, which ensures the production of high-quality jars and lids. These materials are meticulously stored and handled to prevent spoilage or deterioration, using only those that are suitable for the manufacturing process and within their quality range. This commitment to quality materials supports the overall excellence of the final products.

The current production parameters used by the subcontractor are designed to function effectively with the properties of Sulapac's materials to meet the required quality standards. Parameters such as holding pressure, holding time, cooling time, and filling speed are critical in achieving the desired quality products. Research conducted in Section 2 of this study indicates that these parameters are potentially linked to the final product's quality and dimensions.

Although the manufacturing parameters are carefully managed by the subcontractor, variations can influence the consistency of product quality across

different production batches and orders. These variations are not due to external factors, as Sulapac ensures that all materials, before delivering to the manufacturing subcontractor, are processed at consistent conditions, even with changes in material properties due to humidity or climate. Any potential changes in the material properties are limited to a small fraction of the materials, as they are stored in controlled environments, thus affecting only a minimal fraction of the production batch.

By varying these manufacturing parameters, it is possible to interpolate and find the most optimal settings for holding pressure, holding time, cooling time, and filling speed. This approach helps the subcontractor to meet the high-quality standards set by Sulapac for the Nordic Collection Portfolio. This approach is fundamental as Sulapac transitions toward increased production quantities of jars and lids, ensuring that the high standards of product quality are upheld and supporting the efficient scaling of production.

3.3.2 Current Quality Assessment

At Sulapac, quality control of finished products involves a comprehensive procedure to ensure that each product meets the established quality standards. This process is divided into two main stages: visual inspection by the manufacturing subcontractor and a detailed quality control by Sulapac, including procedures that have been previously applied successfully with other subcontractors.

The subcontractor performs visual inspections according to a detailed checklist developed in collaboration with Sulapac. This checklist evaluates various aspects of the jars and lids to ensure they meet Sulapac's specific design standards and requirements.

In addition to visual inspections, Sulapac conducts thorough quality control procedures especially in the production validation phase that involves measurements of dimensions, torque tests for both tightening and untightening forces, and leakage tests, to ensure the mechanical characteristics function as intended. This dual approach ensures that the products meet high-quality standards of the customers.

This quality control process has been successfully applied with other subcontractors in the past. However, with the new subcontractor, it is necessary to re-verify and review these processes to ensure they are implemented as intended by Sulapac. This verification quality assessment employed by the subcontractor can be observed in the table below.

Table 1: Manufacturing subcontractor quality check

VISUAL INSPECTION OF READY-MADE LIDS AND BOTTOMS			
	Item does not have any of the following defects		**Notes**
	Injection molding defects		
1	Flashing	Ok	
2	Short shots – items are complete	Ok	
3	Burning	Ok	
4	Sink marks	Ok	
5	Shiny areas	Ok	
6	Matt areas	Ok	
7	Streaks	Ok	
8	Knit lines / joint marks	Ok	
9	Flow lines	Ok	
	Mechanical defects		
10	Scratches	Ok	
11	Deformations	Ok	
12	Distortion	Ok	
13	Ejector impressions	Ok	

This table covers a range of aspects and provides a comprehensive overview of the quality control checks performed after the production process is complete.

3.3.3 Current Final Product Quality

As presented in past studies regarding injection moulding processes, such as those by Cardozo and Hasan, the final quality of the product can be influenced by the variability in the production parameters. In the current manufacturing process executed by Sulapac's subcontractor, this variability may be reflected in the final product. Among the commonly observed defects are flow marks, sink marks, and incomplete filling in small dimensional parts (threads) on both the jar and the lid. These issues can increase the likelihood of variations in the functional performance of the product, such as the variation in the torque force needed for tightening and untightening both pieces.

The defects identified below were based on evaluations of samples provided by the subcontract manufacturer to Sulapac, as well as from various past production orders:

- **Sink marks (Shrinkage):** Noted in certain dimensions of the jars and lids, leading to potential structural and functional issues.
- **Flow Marks:** Particularly prominent around the filling gate, more noticeable on the lids than on the jars. This defect is especially evident in darker-colored models, such as Black and Blueberry.

- **Short shots:** Resulting in insufficient material packing in specific dimensions, which affects the completeness and integrity of the products.
- **Color-Dependent Defects:** The defects are found across almost all models, with their visibility varying significantly depending on the color of the model.

These observations highlight the importance of precise control and re-verification of the production process parameters to ensure a consistent and high-quality outcome. Samples and numerical data will be presented in the implementation section when evaluating the defects in the FMEA approach.

3.3.4 Current Operations

In the manufacturing sector, the goal of outsourcing production goes beyond operations streamlining. It supports growth, provides a beneficial supply chain according to the business needs, eliminates the need for capital-heavy investments, and provides access to top class technologies. For Sulapac, these are beneficial aspects that can maintain the efficiency and high-quality of their products. Moreover, when outsourcing is effectively managed, it enhances both time and resource efficiency.

While the current communication and operations for producing these jars and lids might seem straightforward, it is important to re-verify and refine the processes with the new manufacturing subcontractor. A key aspect to understand is the role of the manufacturing subcontractor. The subcontractor takes complete responsibility for the entire production process, meaning Sulapac cannot change or modify the parameters when production of jars and lids is being executed. Therefore, Sulapac evaluates the final products; this highlights the importance to define clear procedures and provide precise instructions to the subcontractor to maintain product quality.

Establishing a streamlined and effective communication channel between Sulapac and the manufacturing subcontractor ensures that all parties are aligned on the production goals, quality standards, and operational procedures. This alignment is key to meet Sulapac's quality standards and overcoming future challenges if they are presented.

4 Implementation Proposal

With the new subcontractor, there is an opportunity to review and re-verify the current parameters, establishing a plan to maintain and enhance Sulapac's quality standards. This process aims to address key quality aspects throughout the production process. In this section, a proposed quality plan for Sulapac will be presented. These proposals are based on the collected information by various studies. Both the FMEA and DoE are suggested approaches for Sulapac. These approaches will include step-by-step instructions and numerical values to exemplify their application. Numerous studies indicate that using quality tools not only helps in identifying defects but also in proposing improvements to current processes.

4.1 FMEA Approach Proposal

While the presence of defects in a manufacturing process is an inevitable occurrence, it is crucial to maintain them within strictly controlled and acceptable ranges to ensure high quality. By identifying and prioritizing the most common defects, the study can be guided towards a Design of Experiments that can be executed in collaboration with the new manufacturing subcontractor. With this said, the most common defects observed in the final product of the production process include:

- Sink marks.
- Flow marks.
- Short shots.

As executed in the study by Hanumantharaya and Madgule, prioritizing these defects is essential to understanding the critical issues in the process. This initial step in the FMEA involves detecting the defects, determining their severity, defining the probability of occurrence, counting the number of detected errors, and finally establishing the risk priority. This approach is also discussed in the study by Chiozza and Ponzetti. The FMEA process includes several variables, as mentioned in the stages of the process:

- **Occurrence (O):** This refers to the likelihood of the cause of the failure mode occurring.
- **Detection (D):** This pertains to the ability to identify the cause of the defects, which can be analysed through root cause analysis.
- **Severity Effect (S):** This measures the seriousness of the effects of the failure mode on a scale.
- **Risk Priority Number (RPN):** This is the product of S, O, and D, and it ranges between 1 and 1000, indicating the priority level of the risk.

The opportunity to refine and re-verify the parameters with the new manufacturing subcontractor is significant. Although the actual data provided by the current subcontractor provides partial information regarding the relationship of final product outputs and parameters, it can be supplemented to conduct an FMEA. It becomes possible to determine the estimation of defects identified and the corresponding ranges for each defect by estimating using a confidence level of 95%. This methodology enables making an approximate FMEA for understanding and quantification of the number of rejects, so that the basis for the use of DoE could be set.

4.1.1 Estimating and Prioritizing Defects Using FMEA

To prioritize defects using the Failure Mode and Effects Analysis (FMEA), it is needed to estimate the occurrence of defects and evaluate them in terms of severity, occurrence, and detectability. As mentioned earlier, these factors allow us to calculate the Risk Priority Number (RPN).

As a first step, establish defect data from 20 samples obtained from the 50 ml Premium models. It is important to note that this process can be replicated across all models since they all exhibit similar defects such as flow marks, sink marks, and short shots.

With this approach, its possible to systematically analyse the defects and prioritize them based on their impact and frequency. This method provides a structured way to address quality issues and helps in focusing on the most critical areas for improvement. The mentioned defects can be appreciated in the following table:

Table 2: Defects in samples.

DEFECTS	QUANTITY
Flow marks only	10 units
Short shots only	2 units
Sink marks only	1 units
Flow marks and Short shots	4 units
Flow marks and Sink marks	1 unit
Short shots and Sink kmarks	1 unit
Flow marks, Short shots and Sink marks	1 unit

In some cases, products exhibit two defects simultaneously, which is considered an overlapping of defects. This is important to account for the estimation of defect occurrences. In the FMEA model, each defect is typically treated independently. However, in practice, some products may present multiple defects. Ignoring this overlap could lead to an overestimation of the total number of defective units and affect the accuracy of the severity,

occurrence, and detection evaluations. Consequently, this would impact the prioritization of defects to be addressed with tools like DoE.

Description of the Adjusted Approach:

1. **Identification of Overlapping Defects:** Using the 20 samples, it is possible to identify how many units in the sample exhibit multiple defects and their types. For example, if a unit has both flow marks and short shot defects simultaneously, it is counted in both categories but also recognized as an instance of overlap.
2. **Adjustment of Defect Proportions:** It is necessary to apply adjustments to reflect the presence of multiple defects in a single unit. Instead of simply summing the defects, it is needed to calculate the proportion of each defect, considering units that show more than one type of defect.
3. **Calculation of Confidence Intervals:** Using the data, we recalculate the confidence intervals for each type of defect. This will help provide a more accurate range and allow for a more specific RPN.
4. **Calculation of S, O, D, and RPN:** Based on the adjusted proportions, it is possible to calculate a more accurate RPN, as well as other variables.

By applying this method of estimation, it is possible to benefit from improved accuracy, effective prioritization, and a more practical approach. Once it is understanding the differentiation of defects, this proceeds to calculate the adjusted proportions. The following table provides this adjustment.

Table 3: Adjusted defects in samples.

TOTALS TYPE DEFECTS	TOTAL AMOUNT
Total units with Flow marks	16
Total units with Short shot	8
Total units with Sink Marks	4

As second step, calculate the proportion of each defect in the sample of 20 units:

1. Proportion of Flow marks $\hat{P}Flow\ Marks$

$$\hat{P}Flow\ Marks = \frac{16}{20} = 0.80$$

2. Proportion of Short Shot $\hat{P}Short\ Shots$

$$\hat{P}Short\ Shots = \frac{8}{20} = 0.40$$

3. Proportion of Sink marks $\hat{P}Sink\ Marks$

$$\hat{P}Sink\ Marks = \frac{4}{20} = 0.20$$

As a third step using the formula for the 95% interval confidence for a proportion of P, the formula is the following:

$$IC = \hat{p}\ \pm Z\ \times \sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

Where Z = 1.96 for a 95% confidence level.
With this, it is possible to calculate the confidence interval for Flow marks, Short Shot and Sink marks:

1. Confidence interval for Flow marks:

$$\text{IC Flow marks } = 0.80\ \pm 1.96\ \times \sqrt{\frac{0.80 \times (1-0.80)}{20}}$$

$$IC\ Flow\ marks\ = 0.80 \pm 1.96 \times \sqrt{\frac{0.16}{20}}$$

$$IC\ Flow\ marks\ = 0.80 \pm 0.175$$

$$IC\ Flow\ marks = \ (0.625|0.975)$$

2. Confidence Interval for Short Shot:

$$\text{IC Short Shots } = 0.40\ \pm 1.96\ \times \sqrt{\frac{0.40 \times (1-0.40)}{20}}$$

$$IC\ Short\ Shots\ = 0.80 \pm 1.96 \times \sqrt{\frac{0.24}{20}}$$

$$IC\ Short\ Shots\ = 0.40 \pm 0.218$$

$$IC\ Short\ Shots = (0.182|0.618)$$

3. Confidence Interval for Sink Marks

$$\text{IC Shorts Shots } = 0.20 \pm 1.96 \times \sqrt{\frac{0.20 \times (1 - 0.20)}{20}}$$

$$IC\ Short\ Shots = 0.20 \pm 1.96 \times \sqrt{\frac{0.16}{20}}$$

$$IC\ Short\ Shots = 0.20 \pm 0.175$$

$$IC\ Short\ Shots = (0.025|0.375)$$

As the fourth step, estimate the occurrence of defects. For this purpose, a total production quantity of 5000 units, which represents a medium production order received from a customer to date. The choice of 5000 units is intended to demonstrate the significance of defects in a close approximation to the largest production batches.

In this context, the term "population" is used to refer to the total set of items under consideration—in this case, the 5000 units.

1. Flow marks:
$$(0.625 \times 5000|0.975 \times 5000) = (3125|4875)$$

2. Short Shot:
$$(0.182 \times 5000|0.618 \times 5000) = (910|3090)$$

3. Sink marks:
$$(0.025 \times 5000|0.375 \times 5000) = (125|1875)$$

As a fifth step, assign and give numerical values according to severity, occurrence, and detection. With these values, it will be possible to calculate the Risk Priority Number (RPN).

These ratings are critical for evaluating each potential failure. They help prioritize which defects to address based on their impact, likelihood, and difficulty of detection. To determine these values, we refer to the "FMEA Manual" from AIAG's study, where they provide a ranking reference type for each of these factors.

1. Severity: Severity in manufacturing considers how the defect affects the functionality. In this case the functionality will be the mechanical property of the Jar and Lid when applying torque to seal the product. The scale is the following:
    - 1-3: Minor defect that do not affect the functionality or safety.
    - 4-6: Moderate issues that affect the performance but do not compromise safety.
    - 7-8: Major issued that significantly impact performance.
    - 9-10: Critical issued those results in product failure.

2. Occurrence: Ocurrrence evaluates how frequently a defect is likely to occur or occurred during production.
    - 1: Extremely unlikely to occur
    - 2-3: Low likelihood of occurrence
    - 4-6: Moderate likelihood
    - 7-8: Likelihood
    - 9-10: Almost certain to occur (Extreme frequent issue).

3. Detection: Detection is measured within the possibility to idently the defects, identified from Sulapac and Customer.
    - 1-2: Almost certain to be detected.
    - 3-4: High likelihood of detection.
    - 5-6: Moderate likelihood.
    - 7-8: Low likelihood.
    - 9-10: Very unlikely to be detected (almost impossible to detect).

The ranking of S, O and D for each defect are the following:

1. Flow marks:
    - Severity: 6
    - Occurrence: 8
    - Detection: 5
2. Short Shot:
    - Severity: 8
    - Occurrence: 6
    - Detection: 6
3. Sink marks:

- Severity: 5
- Occurrence: 4
- Detection: 4

Which allows to perform the RPN calculations:

1. Flow marks:

$$RPN \text{ Flow marks} = S \times O \times D = 6 \times 8 \times 5 = 240$$

2. Short Shot:

$$RPN \text{ Short Shot} = S \times O \times D = 8 \times 6 \times 6 = 288$$

3. Sink Marks:

$$RPN \text{ Sink marks} = S \times O \times D = 5 \times 4 \times 4 = 80$$

The RPN values can be appreciated in the following table:

Table 4: Risk Priority Number values.

Defect Type	Severity	Occurrence	Detection	RPN
Flow marks	6	8	5	240
Short Shots	8	6	6	288
Sink marks	5	4	4	80

The results indicate that Short Shot is the most critical defect among the three. This suggests that prioritizing this defect should be the focus when applying quality improvement tools.

4.1.2 Analysis and Interpretation of FMEA results.

Short Shot:

The Short Shot defect has the highest RPN of 288, indicating it is the most critical defect to address. Its high severity and significant occurrence make it a top priority for corrective action. The Short Shot defect, as previously mentioned, refers to the incomplete formation of threads when the material is injected into the mould. This is particularly critical because the threads are essential to the main function of the jar and lid, especially for products intended to seal items for human consumption. Furthermore, the defect can impact the torque, which is crucial for ensuring a secure seal.

Flow marks:

With an RPN of 240, flow marks is the second highest priority defect to address. The flow marks directly impact the aesthetic quality of the external surface of the final product. As detailed in the defects table, these marks are typically found near the injection gate, occurring during the mould filling process and thus affecting surface quality.

Flow marks can be influenced by high pressure during the holding phase and excessive mould temperature, which can affect the material's flow properties, leading to inconsistent flow patterns and visible defects. Therefore, it is crucial to further investigate the exact conditions contributing to the formation of flow marks and implement appropriate measures to control this defect effectively.

Sink marks:

Sink with a RPN of 80, is the defect that possess less risk compared the two other defects. However, this does not mean that should not be addressed; during the defects analysis the sink marks are observed in certain jars. Despite the effect of sink marks are not a critical cause, if not addressed to be corrected, this could increase its occurrence level.

As result of a successful FMEA, it is possible now to understand the criticality of each defect and the approach that should be applied to them, as this study aims to propose methodology to concrete the objectives, this result allows to go further, as in this, now conform a Design of Experiments that can address these quality aspects.

4.2 DoE Approach Proposal

The identified defects have been prioritized through the FMEA, providing a clear direction for addressing these problems. To implement the DoE, a sequence of systematic steps must be followed, as outlined in previous studies. Conducting the DoE involves following a structured and organized approach.

It is important to note that this DoE section is presented as a proposal, considering the various factors involved, such as costs for materials, production, labor, and time, especially in cases of outsourced manufacturing. Despite these considerations, the study offers a solid and well-supported plan.

4.2.1 Factors Selection

Defects have been identified and prioritized by their RPN. To address these defects, it's essential to define the process inputs for correction. Previous studies help identify the injection moulding process parameters that mostly are related to these defects.

Short Shot Defect:

- Filling Speed: The speed at which the molten material is injected into the cavity can correct the short shot defect. A direct influence exists on improving the material's ability to fill the mould before it starts to solidify. This is particularly important for complex geometries or thin sections where the material needs to flow adequately and in the correct timeframe to solidify properly. As noted by Hong Li and Zia in their study, insufficient flow increases costs because the material solidifies prematurely, causing short shots.

- Cooling Time: Cooling time is closely related to filling speed, as premature solidification in the cavity before it is fully filled can occur. Selecting the correct cooling time will ensure proper solidification with the necessary details of the mould.

- Holding Time: Holding time is the period during which pressure is maintained to compensate for material shrinkage as it cools, ensuring the mould cavity is fully filled. Insufficient holding time results in incomplete filling, especially in areas far from the injection gate, leading to short shots.

Flow marks Defect:

- Holding Pressure: Holding pressure is applied after initial filling to maintain the material in the cavity while it solidifies. This pressure ensures the material continues to fill the cavity. High holding pressure increases the risk of flow marks because it forces material to escape through gaps. Reducing holding pressure can help prevent this defect, but if it’s too low, it won't adequately compensate when the material solidifies.

- Cooling Time: Inadequate cooling time can cause partially molten material to flow through parting lines when the mould opens. This can depend on the mould design and the position of complex areas and surfaces. Proper cooling time ensures the material solidifies completely before the mould opens, reducing the risk of flow marks.

Sink marks Defect:

- Cooling Time: A short cooling time can lead to insufficient solidification before the mould opens, causing the material to shrink after being removed from the mould.

- Holding Time: Without enough holding time, the material may not stabilize, leading to visible gaps and geometric deformities as it shrinks.

4.2.2 DoE Model

The selected inputs will be four, representing a full factorial level across the four dimensions of the systematic process cube. This approach allows for a comprehensive planning of the DoE. As for the outputs, based on the identified defects, the chosen outputs will be:

- Dimensions: (Height and Inner/Outer Diameter)
- Surface Quality: (Flow marks)
- Mould Filling: (Short Shot)

With this approach, the following analysis can be established:

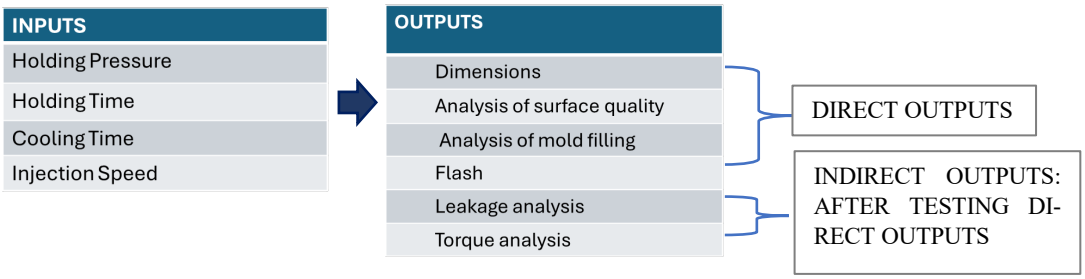

Figure 10: DoE analysis approach.

To better illustrate this approach of addressing both types of outputs:

- Direct Outputs: These include aspects like the dimensions of the jars and lids (height, weight, and inner/outer diameter) and surface quality, which are immediate indicators of product quality.

- Indirect Outputs: These encompass the performance of the products in terms of their mechanical functions, particularly how well they close and seal, which are critical for their use.

This dual focus ensures not only the correction of current defects but also the maintenance of the primary functionality of the products.

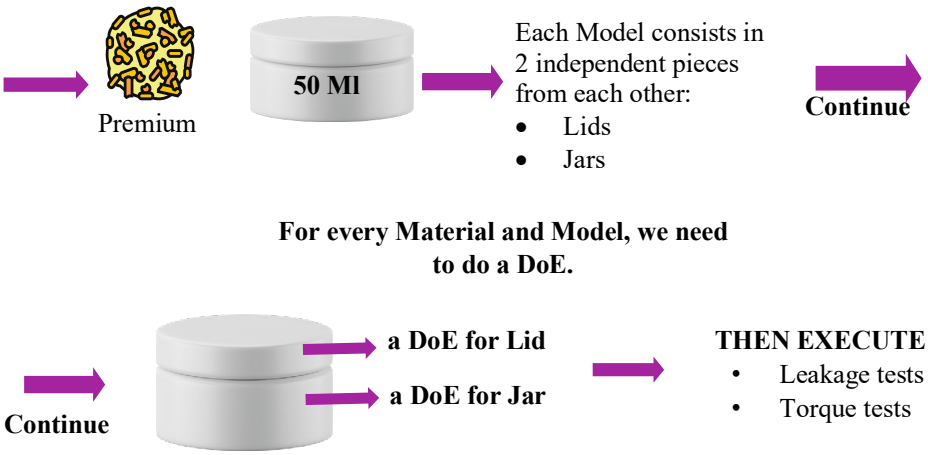

Figure 11: DoE Plan and validation scheme.

4.2.3 DoE Planning

The execution of the Design of Experiments must be carefully planned. A poorly planned DoE can result in high costs for money, labor, and materials. Master planning of the DoE is crucial to utilize time and budget optimally without incurring excessive costs for improvement. Below, the planning table for the 50 ml.

Table 5: DoE plan execution

Model	Cycle time (seconds)	Settings quantity for DoE	Time per Parameter Setting (min)	Total Time per Material (minutes)	Total Time per material (hours)
Lids 50 ml	30.40	17 settings	55	935	15.58
Jars 50 ml	48.96	17 settings	55	935	15.58

Since the DoE plan is to execute 17 runs per lid or jar of each model, according to the cycle time of each item, it is suggested to run 30 minutes per setting and take samples for every cycle from different shots. Running each DoE setting for 30 minutes, with 5 minutes for stabilization and 25 minutes for data collection, is justified by the need to:

- Allow the system to stabilize after parameter changes.

- Collect an at least representative sample size of 20 items over the 30-minute period.
- Ensure process stability and detect variability.
- Efficiently manage time and resources while obtaining reliable and meaningful data.

The approach will not be on piece sampling (i.e., reaching 20 pieces and then changing the parameter), but rather on sampling at every cycle interval, to better simulate the production process higher quantities and continuous time.

4.2.4 DoE Factorial Design

To select the variability of the factors to be introduced, it is first necessary to define the levels of the DoE. The DoE will have 2 levels (Low and High), where two distinct values for each factor will be set.

Table 6: DoE Inputs and Levels model.

	OrdenEst	OrdenCorrida	PuntoCentral	Bloques	Filling Speed	Cooling Time	Holding Pressure	Holding Time
1	12	1	1	1	97.62	12	380	3.8
2	4	2	1	1	97.62	12	380	2.2
3	10	3	1	1	97.62	8	380	3.8
4	9	4	1	1	84.88	8	380	3.8
5	8	5	1	1	97.62	12	450	2.2
6	7	6	1	1	84.88	12	450	2.2
7	6	7	1	1	97.62	8	450	2.2
8	14	8	1	1	97.62	8	450	3.8
9	3	9	1	1	84.88	12	380	2.2
10	17	10	0	1	91.25	10	415	3.0
11	16	11	1	1	97.62	12	450	3.8
12	1	12	1	1	84.88	8	380	2.2
13	2	13	1	1	97.62	8	380	2.2
14	11	14	1	1	84.88	12	380	3.8
15	15	15	1	1	84.88	12	450	3.8
16	5	16	1	1	84.88	8	450	2.2
17	13	17	1	1	84.88	8	450	3.8

The factorial design consists of 4 factors in a full factorial design, with one replication. This is done considering material and time costs. This can be seen in the following table of 17 randomized runs. The initial plan is to find the quantity that simulates the optimal design; the replicability of the products will be analysed once the optimal characteristics that provide the desired product quality are identified. The production plan, as mentioned earlier, involves the sampling and analysis as required, resulting in the following values:

Table 7: DoE model results.

Filling Speed	Cooling Time	Holding Pressure	Holding Time	Inner Diameter	Outer Diameter	Height	S. Qua Rugosity	Weight
97.62	12	380	3.8	54.701	55.200	10.305	0.691	128.00
97.62	12	380	2.2	54.708	55.299	10.290	0.764	125.00
97.62	8	380	3.8	54.333	55.200	10.300	0.552	124.50
84.88	8	380	3.8	54.790	55.200	10.300	0.284	125.00
97.62	12	450	2.2	54.701	55.208	10.310	0.550	125.20
84.88	12	450	2.2	54.622	55.199	10.290	0.564	125.10
97.62	8	450	2.2	54.238	55.201	10.333	0.578	125.11
97.62	8	450	3.8	54.699	55.200	10.310	0.384	125.09
84.88	12	380	2.2	54.700	55.201	10.297	0.460	125.06
91.25	10	415	3.0	54.700	55.200	10.310	0.223	125.09
97.62	12	450	3.8	54.700	55.200	10.300	0.198	125.37
84.88	8	380	2.2	54.701	55.198	10.330	0.655	125.66
97.62	8	380	2.2	54.700	55.200	10.300	0.781	125.99
84.88	12	380	3.8	54.612	55.300	10.310	0.297	125.79
84.88	12	450	3.8	54.633	55.399	10.291	0.633	125.33
84.88	8	450	2.2	54.699	55.402	10.297	0.222	125.78
84.88	8	450	3.8	54.701	55.200	10.300	0.389	123.22

5 Outputs to analyze each with different values

Lid/Jar with this outputs
Lid/Jar with this outputs
Lid/Jar with this outputs
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Lid/Jar with this outputs

Factor 1 Filling Speed (mm/s)
Factor 2 CoolingTime (Seconds)
Factor 3 Holding Pressure (Bars)
Factor 4 Holding Time (Seconds)

Introduce these settings in the injection molding equipments parameters

We get this values from measuring, the inner/outer diameter, weight, rugosity and Height by taking samples in each run

The results obtained from the statistical software allowed for identifying the factors with the greatest impact on the production process. This enabled the identification of where to implement corrective actions and narrow the process window to further adjust the parameters. The following Figure 12 demonstrates how the factors were identified.

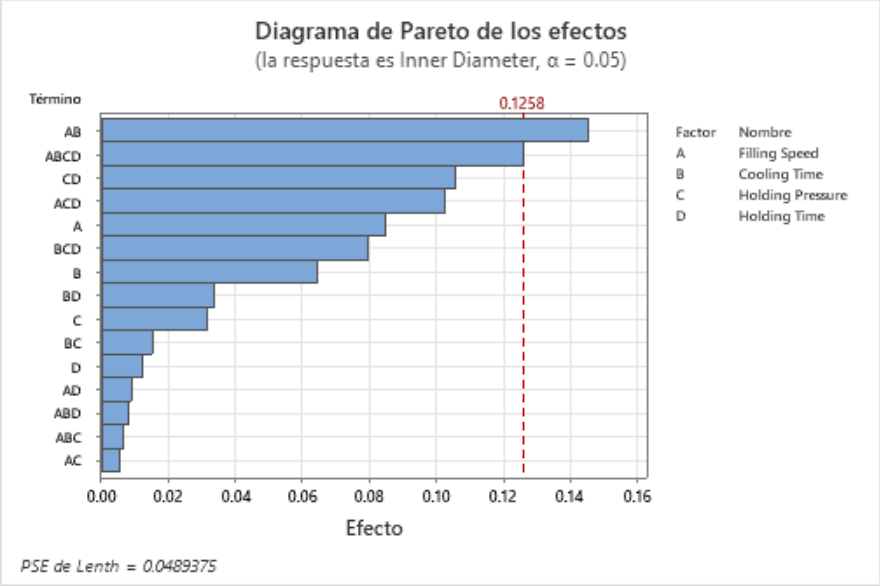

Figure 12: Pareto regression analysis.

The factorial regression could allow for the identification of all combination factors that most significantly affect the outputs. This regression can be executed for each of the outputs, understanding the comparison of factors versus outputs within the production process. Once the parameters are detected

based on the sampling and collected data, it is necessary to proceed with analysing and narrowing the tolerance curve. After defining the important factors, the next step is to establish the lower control limits and the upper control limits. However, it is essential to verify the adequate performance of the mechanical properties of the jar and lid before proceeding.

4.2.5 Torque/Leakage Assurance

As mentioned earlier, the importance of an effective mechanical performance is crucial, and it is considered a relevant factor. Torque measurement is necessary to assess the precision of thread formation during the manufacturing process. Additionally, reference tables for optimal torque values for caps and closures, based on their diameter and storage capacity, are available to guide this assessment.

Torque:

The torque measurement can be executed using the current equipment that Sulapac possesses, the Sauter Model DA-500. This device allows for measuring torque both during tightening and release, ensuring that the models are within the acceptable torque range.

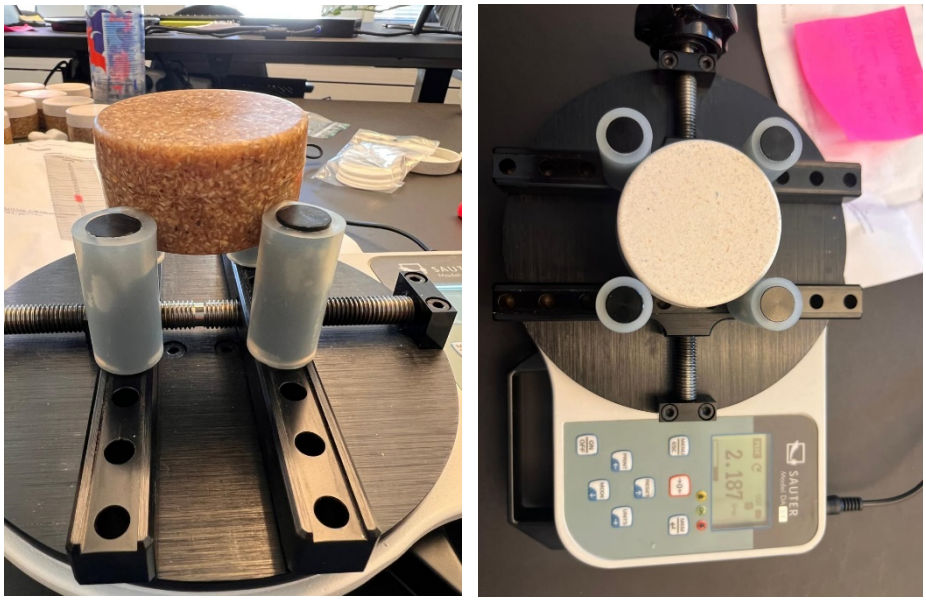

Figure 13: Jars and Lids torque testing.

The torque measurement process is quite straightforward and involves the following steps:

Measurement Procedure

Setting the Device:

- Configure the torque meter to the measurement mode.
- Set the device to record the peak torque value, which is the highest force applied during the opening or closing process for both jar and lid.

Measuring Opening Torque:

- For opening torque, turn the lid counterclockwise.
- Apply a steady and even force until the lid begins to move.
- Record the maximum torque value shown on the torque meter, and then rest values to zero.

Measuring Closing Torque:

- For closing torque, turn the lid clockwise.
- Apply a steady and even force until the lid is securely closed.
- Record the maximum torque value shown on the torque meter, then reset values to 0 for next sample.

Repeat for Accuracy:

- Perform multiple measurements (usually at least 3-5 times) to ensure data consistency and reliability.
- Calculate the average torque value from these measurements for a more accurate assessment.

Torque results will be able to be recorded like in the following table:

Table 8: Premium 50 ml torque results.

Specification (N-m) 50ML Premium													
Torque		Min	Max	1	2	3	4	5	6	7	8	9	10
Range table of reference	Tightening Torque (Closing)	2.1	3.3	2.373	2.457	2.223	2.402	2.474	3.045	2.411	2.551	2.582	2.768
	Untightening Torque (Release)	1.2	2.7	2.161	2.282	2.187	2.125	2.059	2.925	1.515	2.426	2.105	2.255

This table has been elaborated with Sulapac samples from the last production batch, the same ones that presented all the mentioned defects in the data collection, to exemplify how the torque measurement works. It can be observed that despite the external defects, the majority are within the desired torque ranges. Each sample has been measured 3 to 4 times to ensure the accurate numerical value of the torque.

Leakage

The crucial part of sealing a lid and jar is ensuring it is properly closed and that there is no leakage. The need to measure leakage is extremely important. Leakage measurement is performed using a vacuum chamber and a set pressure.

Post-Test Analysis:

Evaluate the Results:

- Assess the integrity of each jar and lid based on the observations during the test.
- Identify which samples passed or failed the leakage test.

Investigate Leaks:

- For any samples that failed, examine the specific areas where leaks were detected.
- Determine the possible causes of the leaks, such as manufacturing defects or improper sealing.

Implement Corrective Actions:

- Take steps to address the causes of leakage.

Document and Report:

- Record detailed test results for each sample.

4.2.6 Mechanical Validation Plan

With a significant number of samples, it is important to reject and select those that meet the desired expectations and requirements. Additionally, it is necessary to narrow the curve to establish the upper and lower limits to produce the jars and lids. The following Figure 14 exemplifies what is being described.

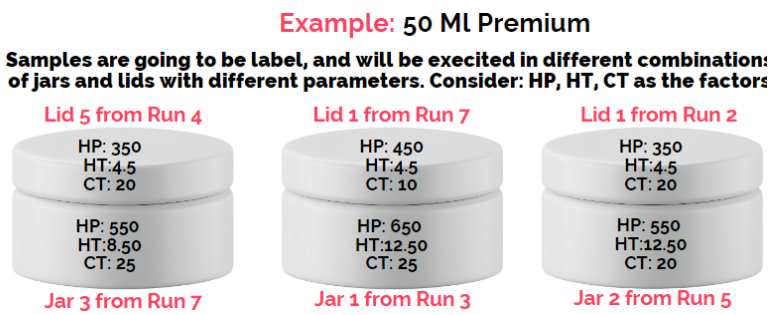

Figure 14: Jars and Lids labeling for test validation.

Each sample, along with its different parameters, will be labeled and recorded with the outputs (characteristics) they possess and the parameters under which they were manufactured. Samples with significant defects will also be labeled. Combinations will be made by prioritizing those samples within the permitted tolerance ranges for dimensions, those that meet the average weight, and those without defects. In other words, samples with ideal characteristics will be prioritized. Once this is done, mechanical tests will be performed.

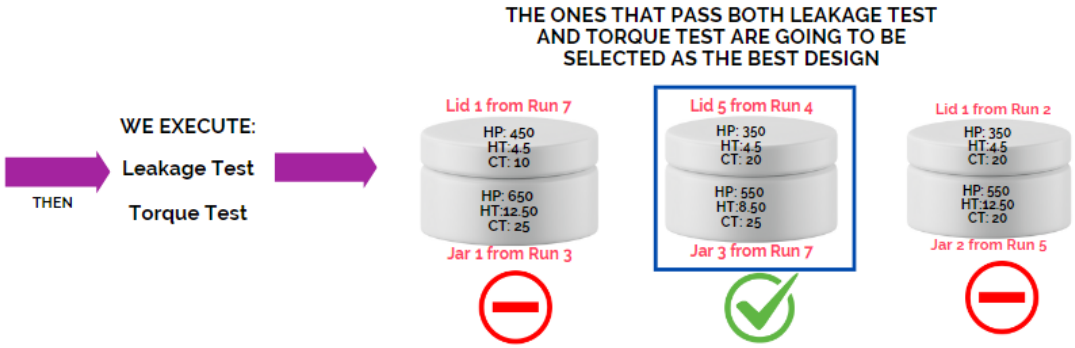

Figure 15: Jars and Lids mechanical test validation.

The selection of ideal samples will allow for the identification of those that do not have visual defects and meet the mechanical requirements. Validating these "ideal" samples will enable the modification of parameters in the production process, thereby applying replicability and studying the "optimal" parameters. With this, it is justified and demonstrated that certain combinations of parameter modifications in the injection moulding process can ensure superior quality in dimensions, design, torque tests, and leakage tests for Sulapac customers.

4.3 Control Charts Proposal

It is essential to establish upper and lower control limits (UCL and LCL). Implementing these controls on parameters helps prevent production errors that can lead to defects in jars and lids. This is especially important when manufacturing is outsourced, as excessive defective products increase time and costs. Once models are validated with optimal parameters, UCL and LCL can be set at these ideal levels. This benefits production quality, saves costs, and makes error identification easier. Additionally, it allows Sulapac and the subcontractor to monitor quality more effectively and project product quality for larger orders and higher specifications based on customer needs.

4.3.1 Implementation of UCL and LCL

For a correct implementation of UCL and LCL, the precise steps to establish them should be specified as follows:

- **Collect Data at Optimal Settings:** Once the optimal settings are identified, collect enough data points for each parameter during actual production runs. This data will help calculate the mean and standard deviation for each parameter.

- **Calculate Mean and Standard Deviation:** Calculate the mean (μ) and standard deviation (σ) for each parameter based on the collected data.

- **Determine Control Limits:** Use the mean and standard deviation to propose the Upper Control Limit (UCL) and Lower Control Limit (LCL) for each parameter. Typically, control limits are set at ±3 standard deviations from the mean.

Example Calculation Steps:

Collect Data at Optimal Settings:
As to exemplify, lets establish that the optimal setting for filling speed is identified as 5.4 units/sec. The data collection will be the following at this setting: [5.38, 5.42, 5.40, 5.41, 5.39, 5.42, 5.40, 5.41, 5.39, 5.40].

Calculate Mean and Standard Deviation:

- Mean (μ) = (Sum of all data points) / (Number of data points)
- $\mu = (5.38 + 5.42 + 5.40 + 5.41 + 5.39 + 5.42 + 5.40 + 5.41 + 5.39 + 5.40) / 10$
- $\mu = 5.402$
- Standard Deviation (σ) = $\sqrt{[\Sigma(xi - \mu)^2 / (n - 1)]}$
- $\sigma \approx 0.012$
- Xi represents each individual data point.
- N is the total number for data points.

Determination of Control Limits:

- $UCL = \mu + 3\sigma = 5.402 + 3(0.012) = 5.438$
- $LCL = \mu - 3\sigma = 5.402 - 3(0.012) = 5.366$

As it follows, this should be applied for all 4 key factors that were used in the DoE.

Filling Speed:

- Optimal Setting: 5.4 units/sec

- Mean (μ): 5.402
- Standard Deviation (σ): 0.012
- UCL: 5.438
- LCL: 5.366

Cooling Time:

- Optimal Setting: 15.3 seconds
- Collect data at optimal setting and calculate mean and standard deviation.
- Calculate UCL and LCL using the same method.

Holding Time:

- Optimal Setting: 7.3 seconds
- Collect data at optimal setting and calculate mean and standard deviation.
- Calculate UCL and LCL using the same method.

Holding Pressure:

- Optimal Setting: 50.3 kN
- Collect data at optimal setting and calculate mean and standard deviation.
- Calculate UCL and LCL using the same method.

It is necessary to integrate in this quality plan, the collection of data at the identified optimal settings during regular production to monitor process stability is substantially beneficial to establish limits. With the use of the calculated UCL and LCL to control each key parameter, with this is possible to ensure the correct prevention and monitoring of control charts to ensure the process remains within the desired quality.

4.4 Continuous improvement Proposal

Continuous improvement is essential for maintaining Sulapac's product quality and ensuring that processes consistently meet high standards. Since 2018, Sulapac has held the ISO-9001 quality management certification, highlighting its dedication to continuous process improvement and quality management. To further contribute to their improvement commitment, Sulapac can implement the PDCA (Plan-Do-Check-Act) cycle, also known as the Deming Cycle. This cycle provides a structured approach for systematically analysing processes, identifying areas for improvement, and implementing effective changes to sustain and elevate the product quality.

- **Plan** The first step involves thorough planning. Identify specific quality issues through data analysis and feedback from production runs. For instance, use control charts to pinpoint recurring defects such as flow marks or short shots. Set clear, measurable objectives and

develop an action plan detailing resources, timelines, and personnel. Planning may also involve researching new technologies or methodologies to improve the production process.

- **Do** Next, implement the planned changes on a small scale to test their effectiveness. Adjust production parameters, such as modifying the filling speed or cooling time, based on insights from the planning phase. Document each change and its impact meticulously. Small-scale implementation helps mitigate risks and allows for real-time adjustments without disrupting the entire production line.

- **Check** Monitor and evaluate the impact of changes on product quality. Use the same metrics and data collection methods to assess whether the changes lead to improvements. Collect new data points and compare them against established control limits to determine if defects are reduced and overall quality improved.

- **Act** Based on the evaluation, decide whether to adopt the changes on a larger scale or make further adjustments. If successful, standardize the new processes and update operating procedures. Share results with the team to ensure everyone follows the improved practices. If the desired outcomes are not achieved, revisit the planning phase to devise alternative strategies and repeat the cycle.

By continuously applying the PDCA cycle, Sulapac can maintain high-quality standards and foster a culture of continuous improvement. This proactive approach, supported by leadership and operations, enhances product quality, increases operational efficiency, and boosts customer satisfaction.

4.5 Refining Operations and Communication

Clearly defined operations and communications are essential for achieving efficient processes without bottlenecks, especially when operations are outsourced. Establishing procedures and workflows is key for effective offshore communication, ensuring smooth time management and role independence. Sulapac already has optimal operations and established communication standards, and the proposed improvements in this section aim to refine current operations and adapt processes to better meet their evolving needs. These procedures will not only facilitate better communication and operation but also act as a safeguard against defects in the manufacturing process. Additionally, they make it easier to manage any disruptions in the supply chain.

4.5.1 Quality Procedures Proposal

The roles within the current operations are clear and well-defined. To further enhance coordination and decision-making processes, it is beneficial to

address areas where additional clarity can support quality prevention aspects. Creating flowcharts could contribute to maintain product quality and proactively address any potential issues.

Color variation:

The operator at the subcontractor's facilities already performs visual color variation control, which should be relatively continuous. A box sheet consists of approximately 30 samples, meaning that upon completing each layer of the box, the operator must visually verify the color. During the production process, it is common to encounter color differentiation between the jar and the lids. This can result in irregularities between pieces because the dosing for the lids is different from that for the jars.

Although excessive color variation has not yet led to rejections beyond acceptable ranges, addressing this issue is crucial as the production of the Nordic Collection expands. It is essential to further develop these procedures in collaboration with the manufacturing subcontractor to manage and prevent excessive color variation. While the subcontractor already implements this procedure, intensifying the control will ensure greater consistency. This collaborative approach aligns with the subcontractor's established processes, promoting smoother production and better-quality control. Implementing these procedures will help maintain product quality and avoid potential conflicts related to production rejection and acceptable ranges. It is important to consider these procedures under normal and everyday production conditions to ensure their effectiveness and practicality.

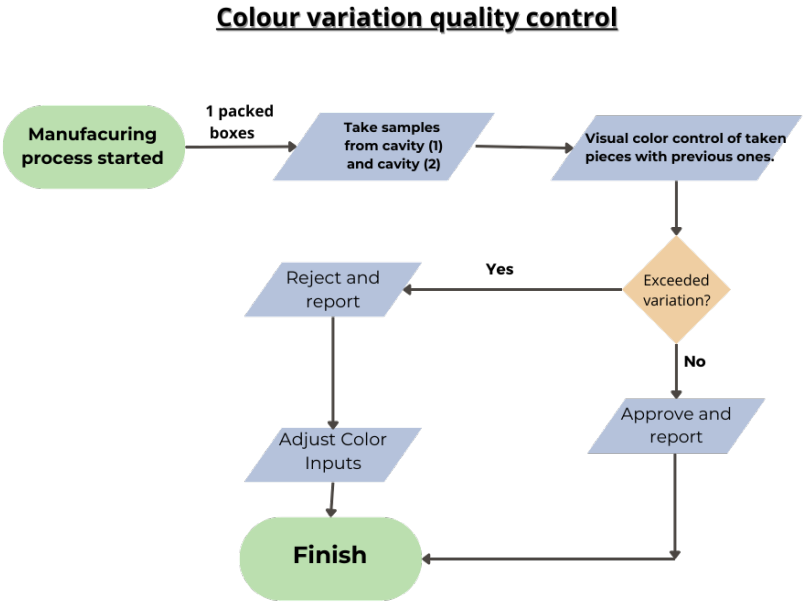

Figure 16: Color quality control procedure

Design and defect control:

Unlike color quality control, design and defect control do not need to be as frequent. The operators at the subcontractor's facilities already monitor the ranges and behaviors of the parameters that most influence defects, using established control limits. Samples are taken every two hours from different cavities and from various boxes, ensuring random sampling.

Even when parameter indicators are within range, maintaining an additional visual check is important for prevention, particularly in outsourced production. This type of production is conducted at the client's request, based on established production orders rather than continuous production. Therefore, emphasizing and controlling the manufacturing process is crucial.

To enhance this process, it is suggested to implement a systematic review and adjustment procedure to further refine quality control aspects.

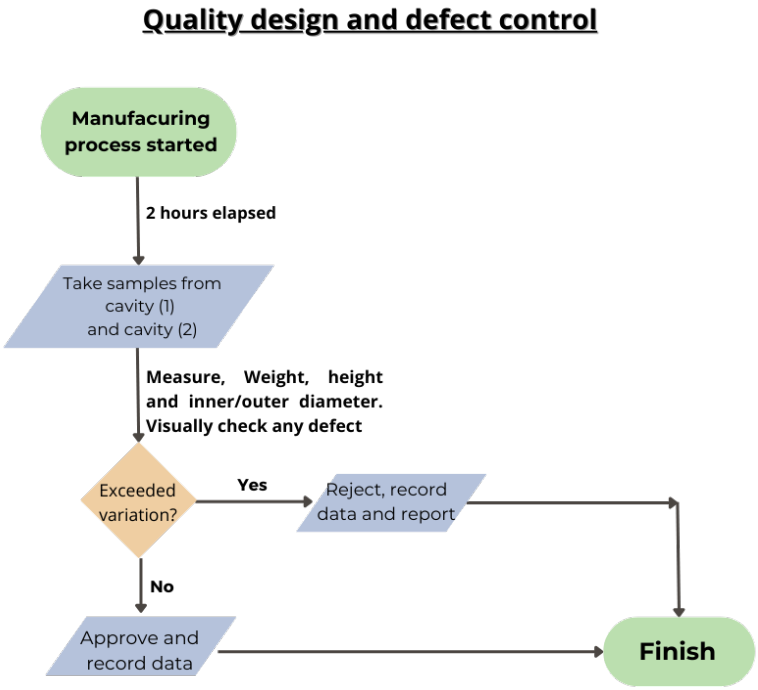

Figure 17: Quality design procedure

Operations Workflow Proposal

The direct stakeholders include the supply chain lead, the injection moulding lead, the product development team, and the manufacturing subcontractor. While the current workflow functions effectively, establishing the following workflow is recommended to further verify and enhance the high standards set by Sulapac.

The proposed workflow diagram outlines the production process from order creation to final quality verification. It begins with the creation of a production order and checking if materials are in stock. If materials are not in stock, they are shipped to the manufacturing subcontractor. Production is then scheduled and proceeds to execution if on time. Any delays or issues are identified and coordinated with the supply chain lead or the manufacturing subcontractor.

During production, any manufacturing issues are addressed by the quality lead and the manufacturing subcontractor. After production, a report is generated. If quality issues are identified, the injection moulding lead resolves them with the manufacturing subcontractor. Finally, samples are sent to Sulapac for quality verification, ensuring efficient problem-solving.

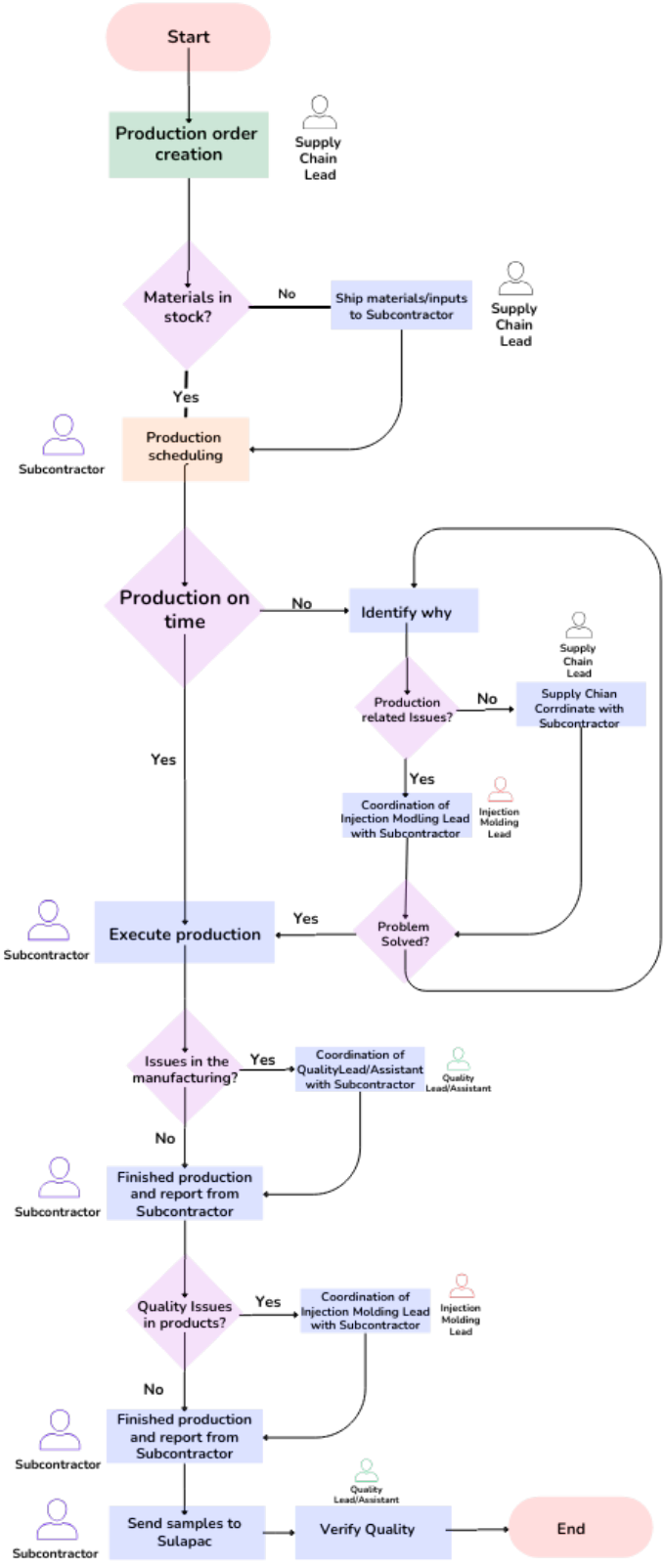

Figure 18: Operations flowchart procedure

In this section, hypothetical results for FMEA calculations and control limit charts will be analysed.

Failure Mode and Effect Analysis.

The FMEA results show that calculating the Risk Priority Number (RPN) is crucial for Sulapac's quality control. It helps identify and prioritize defects that most affect the quality of their products. For instance, short shots have a high RPN because poor thread formation can directly impact the mechanical properties of jars and lids. Mechanical failures may cause issues with torque, affecting both tightening and untightening, leading to leakage. If there is a liquid inside, it could escape through the back shot hole, causing deformations in such thin and detailed parts.

Understanding the priority of defects and their relation to mechanical failures is a key outcome of the FMEA. These calculations, despite being approximate, can be replicated with a real population, as demonstrated with a 5000-unit production order. This approach can be applied to larger populations with more samples, allowing for more specific priorities within narrower confidence intervals. Reprioritization is also possible if new defects arise or existing defects worsen, impacting the product's mechanical performance.

The statistical software Minitab was used to perform the FMEA, demonstrating its practical application in current operations. The following table shows the FMEA table results.

Table 9: FMEA table result.

FMEA

Step #	Item/Component	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Responsibility	Target End Date
1	Short Shots	Threads formation for ensuring mechanical property to execute smoothly	Leakage/ Torque	Spill of contained product / Closuring failure	8	Lack of Material in molding filling stage.	6	Filling Speed and Cooling time.	6	288	A research to study factors variability and optimal parameters. Study can be addressed with a Design of Experiments.	Mueller/ Sulapac Sulapac/Sub-contractor	12/12/2024
2	Flash Marks	Better visual appreciation on a fine surface ending for the final consumer.	Surface Roughness	Lack of uniformity in surface / Fine ending ruined	6	Leakage of material near injection gate.	8	Holding Pressure and Holding time.	5	240	A research to study factors variability and optimal parameters. Study can be addressed with a Design of Experiments	Mueller/ Sulapac Sulapac/Sub-	12/12/2024
3	Shrinkage	Correct dimensions for both jar and lid.	Dimension alteration	Lack uniformity in Jar and Lid dimensions	5	Not enough Cooling time.	4	Holding Pressure and Cooling time.	4	80	A research to study factors variability and optimal parameters. Study can be addressed with a Design of Experiments	Mueller/ Sulapac Sulapac/Sub-contractor	12/12/2024

As detailed in the implementations section, the Short Shot defect critically impacts thread formation, which is essential for sealing jars and lids in the cosmetic industry. It affects torque and sealing performance, making it a top priority for corrective action in scaling up production. Flow marks impact the product's aesthetic quality and are caused by high pressure and mould temperature, necessitating further investigation for control. The sink marks pose

the least risk but still requires attention to prevent increased occurrence and customer dissatisfaction. The FMEA results highlight the importance of addressing these defects and guide the development of a Design of Experiments to mitigate these issues.

Design of Experiments

Understanding the Design of Experiments approach is crucial for improving product quality. Selecting the right factors is the most critical aspect, as they form the foundation of the study. While outputs can be analysed or modified, the inputs cannot. Poor input selection leads to increased costs in materials, time, and labour. Although hypothetical results would lack credibility, selecting factors based on literary studies, collected data, and FMEA calculations provides strong support.

Control Charts

The simulation of control limit charts calculations demonstrates the ability to control parameters within the production process. Below, a control chart representing the filling speed is exemplified, as calculated in the implementation section. Control charts are essential for maintaining continuous production and monitoring once optimal parameters are found through DoE and validated by further testing.

Although control charts will be used exclusively with the subcontractor, maintaining these procedural standards will significantly contribute to consistent product quality. The presented graph shows sample collection over 14 different periods in a replica of 3. Using Minitab 22 Statistical Software, the calculation simulates the hypothetical behavior of data collection for filling speed, showing variables within limits and some samples approaching or exceeding the limits. These serve to alert when established limits are exceeded, indicating imperfections or possible defects that can be prevented by adjusting the ranges to more narrowed values.

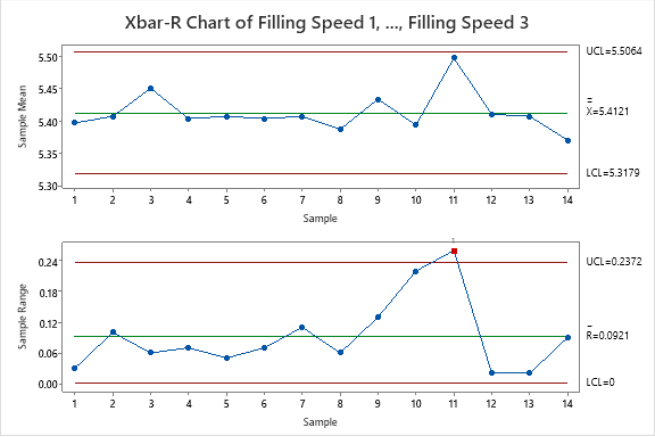

Figure 19: Control Charts

5 Scientific Discussion

To properly address the study, it must be understood that each model has two completely independent items that function mechanically together. Each study and calculation conducted can be replicated without issue in each item and as needed, adapted to other different models.

5.1 The FMEA and DoE approach

Starting with the FMEA calculations, the current situation of the defects has been understood. The levels of occurrence, severity, and detection have been evaluated according to the current state of the defects and how they affect performance in both leakage and torque under current manufacturing conditions. This allows for establishing, alongside confidence interval calculations, approximate data for larger production populations. The FMEA study can be applied to each different model to understand each defect and its impact more clearly. While the focus is on the 50 ml models, the FMEA study can be applied to provide values for occurrence, severity, and detection according to how each model is affected, as each piece is completely independent. As a proposal, FMEA can be a methodology not only applied to the Nordic Collection 50 ml but also to other types of products from raw materials to finished products. Sulapac, being part of the bioplastic industry, has ample opportunity to apply improvements in quality monitoring, which is the most critical point in the pursuit of company growth.

Being a theoretical proposal, data simulation and calculations are required to implement the proposals. There may be empirical alternatives to address current challenges, make decisions, and strictly delegate roles for defect resolution, or simply claim manufacturers to solve their defect issues. However, it must be understood that the approach of this study is to analyse previous studies' literature, focusing on optimization. The main objective is to find the correlation of the parameters with the final product design and its aesthetic and mechanical characteristics. This means that the true importance is understanding that varying a factor reflects a result in the characteristics of both the jar and the lid. However, the possibility of no result is possible, which may occur in the factors and is due to the interpretation of the regression models and the points interacting in the statistical model. According to studies and some current knowledge and everyday use in the manufacturing industry, the DoE has been selected to understand these factor changes and behaviors, both in how they can affect a factor's variability or not. By doing this, a complete understanding of the model is generated, and the correlation of each factor with each aspect of the jar and lid is understood.

While DoE is a method commonly applied today not only in plastic industries but also in chemical, pharmaceutical, and other industries, it is a costly approach. The workloads involve occupying production time in testing and

analysing the outputs. A DoE involves time and material costs just to validate the interaction of the factors and the data, which implies establishing standards. The benefit of DoE can only be beneficial if the goal is to understand all the factors properly. In the end, it is the current decision of each company to execute it; however, if the goal is business growth and portfolio expansion, it is necessary to establish a complete understanding to solidly support the final product quality and continuous improvement in the process.

The application of FMEA with the DoE approach has been applied in this study to understand the current situation and propose a model that can address the entire current process. The methodologies used could be questioned, perhaps the possible need for a statistical model before DoE, such as ANOVA. The answer lies in that FMEA not only takes a preventive approach but also an integral and current approach to the problems. The search for parameter correlation also involves prioritized corrective action to avoid future defects; DoE, apart from understanding the experimental results, covers the total interaction analysis to see how current defects replicate in future production batches and the damage they can cause, in this case, torque and sealing, fundamental mechanical properties in the current product.

Moreover, FMEA allows prioritizing current defects and can be executed with the small amount of data available. Not to undermine FMEA, which is a very adaptable approach, something essential for this study that proposes that Sulapac can continue collecting and implementing data. By prioritizing, it also guides DoE in knowing which factors need to be analysed to avoid overloading the model or making it more costly. It should be clear that DoE is necessary, but it should also be recognized that the manufacturer has knowledge of quality parameters, meaning that if a quality bar is set, it can be established that the subcontractor has the expertise to apply improvements empirically. However, DoE establishes a methodological approach that allows the subcontractor to find the product correlations efficiently. Considering the costs of doing a DoE with many replicas, the quality work is not from scratch; there is already progress. The idea is to organize, guide, and possibly improve.

5.2 Control Charts approach

Control charts are more a means of continuous improvement than a way to correlate data. This implementation suggestion is aimed at continuous improvement. It would not be entirely useful to find the correlation between the data and the final outputs without establishing control parameters for these optimal parameters. It is fundamental to understand that an improvement action is not truly an improvement if it is not maintained over time. The control charts methodology not only refers to increasing quality but also to standardizing it and making it a routine.

The need for control charts can be questioned by simple visual procedures, as in manufacturing, it could be defined that if it looks correctly visual, there

are no major problems. However, the idea is to create procedures so that both Sulapac and the subcontractor facilitate decision-making between them. Ultimately, the need is to generate historical records and propose improvements in a well-monitored and understandable process.

6 Conclusions and Future research

6.1 Conclusions

By taking the opportunity to re-verify the current processes with the subcontractor, it was possible to understand the connection between the behaviours of the final product and the key manufacturing parameters for both jars and lids of the 50 ml Premium model. Additionally, recognizing the independence of each piece in terms of design and manufacturing, yet their joint mechanical function, is essential. By prioritizing, adjusting, and calculating the RPN for defects, the FMEA has contributed to the understanding of the current defect situation, provided important insights into the production process, and acted as a tool to identify the most valuable parameters to be further analysed in a DoE. The application of occurrence, severity, and detection metrics has allowed for a comprehensive understanding of the current situation. More importantly, the FMEA can be applied to each different model by the Sulapac quality team. With a clear FMEA, the DoE is easier to apply, serving as a guide to analyse factor studies.

Sulapac's familiarity with the DoE approach benefits the current study by supporting product quality and aiding future research for products in development. By addressing key parameters for different product models, DoE can be applied to both preventive and corrective actions, serving as a reference for similar models with comparable mechanical characteristics. The execution plan for DoE was developed based on Sulapac's timelines and needs, proposing an initial replication of the 17 different runs. However, to narrow the range further, additional replications of the various 17 settings at different levels are necessary. This will allow for a more segmented and beneficial study, which Sulapac may choose to develop further in the future.

Implementing control charts will be crucial for maintaining long-term quality with the subcontractor. By establishing these charts as standard procedures and coordinating with the subcontractor, it is possible to maintain a narrow range of optimal parameters. This process can be refined over time through proper analysis, ensuring consistent quality and minimizing control gaps.

It is crucial to comprehend how processing parameters relate to the product's functional performance or visual appeal. Sulapac can guarantee that the product continuously satisfies high requirements by employing control charts to keep these characteristics within specified ranges. This approach significantly reduces the need for frequent, batch-specific, destructive performance testing. Instead, the focus shifts to real-time monitoring and adjustments, which allows for a more efficient and streamlined manufacturing process. This guarantees a high-quality product, reduces waste, and improves overall production efficiency.

Control chart implementation also offers a proactive way to ensure quality. Potential flaws can be found and fixed before they have an impact on the finished product by regularly checking and modifying the processing parameters. Because of its exceptional predictive power, one may immediately take appropriate action to preserve process integrity if any of the predetermined criteria are departed from. It turns out that sustainable production processes are just as important as product quality.

On the other hand, procedures and roles are extremely important in business partnerships, especially concerning outsourcing, as in the case of Sulapac with their subcontractor. For such a proposal to work, it depends on both stakeholders. There must be a clear and well-communicated coexistence to address problems or disruptions that may occur. This will allow for improvements, decision-making, and less downtime in solutions. Implementing in processes or work methods is possible, but the ideal is to maintain them over time and for these methodologies to bring benefits, as well as the flexibility to adapt to current work methods without creating friction in the roles performed or the efficiency of functions.

6.2 Future Research

Implementing and tailoring FMEA and DoE in other product models can bring additional benefits to Sulapac. It is possible to enhance both FMEA and DoE, from increasing DoE levels to employing factorial designs for product improvement. Techniques like control charts for real-time monitoring could assist in providing live tracking of production performance, thereby allowing for tighter control and better preventive measures.

The use of DoE in this research guarantees an improvement in product quality and facilitates the work of another relevant future research. Determining key parameters for different product models aids in both prevention and correction. This method will serve as a benchmark for models with the same mechanical behavior. By collaborating with the subcontractor, Sulapac can optimize all these processes, resulting in increased customer satisfaction and expanded business opportunities. This method also helps in the effective utilization of materials by Sulapac, ensuring optimal performance and enhancing customer satisfaction.

7 Appendices

Nordic Collection Jars

Premium Material Properties

MECHANICAL PROPERTIES		
MATERIAL	SULAPAC PREMIUM	POLYPROPYLENE
PHYSICAL PROPERTIES		
Hardness (Shore D)	70 – 80	55 – 75
Material density (g/cm^3)	1.27	0.90
TENSILE PROPERTIES (ISO 527-1)		
Tensile strength (MPa)	45 – 50	20
Tensile modulus (GPa)	5 – 6	1.20
Tensile strain (%)	1.2 – 1.4	100 – 600 (typical)
FLEXURAL PROPERTIES (ISO 178)		
Flexural strength (MPa)	70 – 80	25
Flexural modulus (GPa)	4 – 5	1.25
Flexural strain (%)	2.0 – 2.4	-
IMPACT PROPERTIES (Unnotched, ISO 179-1)		
Charpy impact strength (kJ/m^2)	6 – 7	165

BARRIER PROPERTIES			
MATERIAL	**SULAPAC PREMIUM**	**POLYPROPYLENE**	**POLYETHYLENE (HD)**
WVTR (g/m²/day)	2.6	0.5	0.7
OTR (cm3/m²/day)	<0,1	19	12
OIL (% area)	0	0	0

PROCESSING CONDITIONS – SULAPAC PREMIUM		
	TEMPERATURE	**GENERAL INSTRUCTIONS**
Throat	40 – 60 °C	• Typical settings may require optimization. • Both cold and hot runner systems are suitable for this material. • Valve gate systems can be used. • Avoid using temperatures above 200°C in order to lower the risk of material degradation. • The dwell time of the material inside the machine shall be reduced to a minimum in order to lower the risk of thermal degradation.
Feed zone	150 – 160 °C	
Compression zone	170 – 190 °C	
Homogenizing zone	175 – 190 °C	
Machine nozzle	175 – 190 °C	
Back pressure	5 – 10 bar	
Screw speed, max	< 0,20 m/s	
Hot runner nozzle and bushing	180 – 200 °C	
Tooling temperature T_{mold}	20 – 40 °C	

Barrier Material Properties

MECHANICAL PROPERTIES	
MATERIAL	SULAPAC BARRIER
PHYSICAL PROPERTIES	
Hardness (Shore D)	85
Material density (g/cm^3)	1.49
Shrinkage (%)	1.0
TENSILE PROPERTIES (ISO 527-1)	
Tensile strength (MPa)	44
Tensile modulus (GPa)	8.7
Tensile strain (%)	1.1
FLEXURAL PROPERTIES (ISO 178)	
Flexural strength (MPa)	65
Flexural modulus (GPa)	8.2
Flexural strain (%)	1.1
IMPACT PROPERTIES (Unnotched, ISO 179-1)	
Charpy impact strength (kJ/m^2)	8.7
RHEOLOGICAL PROPERTIES (ISO 1133)	
MFI (190°C/2.16 kg)	8,0 – 13,0 (g/10 min)

BARRIER PROPERTIES		
MATERIAL	**SULAPAC BARRIER**	**POLYPROPYLENE**
WVTR (g/m²/day) ASTM F1249 (23 C/85%)	0.01	0.01
OTR (cm3/m²/day) ASTM D3985 (23 C/0%)	2.3	35-377*

	TEMPERATURE
Throat	40 – 60°C
Feed zone	165°C
Compression zone	175°C
Homogenizing zone	180°C
Machine nozzle	180°C
Back pressure	5 – 10 bar
Hot runner nozzle and bushing	180-183°C
$T_{mold, Front}$	60 – 70°C
$T_{mold, Back}$	60 – 70°C

Sulapac's Subcontractor Quality Checklist

START OF THE PRODUCTION RUN			
	Inspection item / activity	**YES/NO**	**Notes**
1	Sulapac material name and material code are correct and match the production order.		
2	Material package is intact and tightly closed: no opportunity for contamination.		
3	Visual inspection of the material: material appears clean and intact, no contamination or excessive moisture inside the bag.		
4	Use correct drying time and temperature. Information is available on Sulapac TDS.		
5	Injection moulding parameters – Separate document.		

VISUAL INSPECTION OF READY-MADE LIDS AND BOTTOMS			
	Item does not have any of the following defects	**YES/NO**	**Notes**
	<u>Injection moulding defects</u>		
1	Flashing		
2	Short shots – items are complete		
3	Burning		
4	Sink marks		
5	Shiny areas		
6	Matt areas		
7	Streaks		
8	Knit lines / joint marks		
9	Flow lines		
	Mechanical defects		
10	Scratches		
11	Deformations		
12	Distortion		
13	Ejector impressions		
14	Stress whitening		
15	Scrapings		
16	Cracks		
	Contamination		
17	Dark spots / other colour defects		
18	Dust, oil, fat or other contaminants		
	Other		
19	Even and defect free colour		
20	Date clock correct		

FUNCTIONALITY OF READY-MADE JARS			
	Item does not have any of the following defects	**YES/NO**	**Notes**
	Injection moulding defects		
1	Dimensions are within tolerances		
2	Jar and lid, and fit together – no rattling or movement, no excessive tightness		
3	Threads are complete and smooth		

8 References

Advance Innovation Group. (2024). *Failure Mode and Effects Analysis, Innovation Quality*. Lean Six Sigma How to Reduce the Risks in FMEA?

Al-Jadaa, A., Attin, T., Peltomäki, T., & Schmidlin, P. R. (2015). Comparison of three in vitro implant leakage testing methods. *Clinical Oral Implants Research*, *26*(4), e1–e7. https://doi.org/10.1111/clr.12314

Bouzouita, A. (n.d.). *Elaboration of polylactide-based materials for automotive application : study of structure-process-properties interactions*. https://www.researchgate.net/publication/311707402

Byun, S. (2019). Managing tolerance stack-up through process integration team in steel industry. *Annals of Business Administrative Science*, *18*(6), 223–236. https://doi.org/10.7880/abas.0191002a

Cardozo, D. (2009). A brief history of the filling simulation of injection moulding. *Proceedings of the Institution of Mechanical Engineers, Part C: Journal of Mechanical Engineering Science*, *223*(3), 711–722. https://doi.org/10.1243/09544062JMES986

Chaabene, A., Chatti, S., & Slama, M. Ben. (n.d.). *OPTIMIZATION OF THE COOLING OF A THERMOPLASTIC INJECTION MOULD*. https://doi.org/10.2021/15.12.2021

Chiozza, M. L., & Ponzetti, C. (2009). FMEA: A model for reducing medical errors. *Clinica Chimica Acta*, *404*(1), 75–78. https://doi.org/10.1016/j.cca.2009.03.015

Cong Lin. (2009). Establishing an Effective Standardization System in Production Department. *Business Engineering, Logistics Sci-Tech*.

Dhafr, N., Ahmad, M., Burgess, B., & Canagassababady, S. (2006). Improvement of quality performance in manufacturing organizations by minimization of production defects. *Robotics and Computer-Integrated Manufacturing*, *22*(5–6), 536–542. https://doi.org/10.1016/j.rcim.2005.11.009

Edward Deming. (1986). 6-out-crisis-edwards-deming. *MIT* .

Feng, B., Wu, J., Tu, H., Tang, J., & Kang, Y. (2022). A Review of Magnetic Flux Leakage Nondestructive Testing. In *Materials* (Vol. 15, Issue 20). MDPI. https://doi.org/10.3390/ma15207362

Garavand, F., Rouhi, M., Razavi, S. H., Cacciotti, I., & Mohammadi, R. (2017). Improving the integrity of natural biopolymer films used in food packaging by crosslinking approach: A review. In *International Journal of Biological Macromolecules* (Vol. 104, pp. 687–707). Elsevier B.V. https://doi.org/10.1016/j.ijbiomac.2017.06.093

Gopal, M., & Dessalegn Dejene, N. (n.d.). *The Hybrid Pareto Chart and FMEA methodology to Reduce Various Defects in Injection Moulding Process*. https://www.researchgate.net/publication/350105300

Gu Yuanxian, S. C. (2003). OPTIMIZATION ON INJECTION RATE OF FILLING PHASE IN INJECTION MOULDING. *Engineering, Materials Science, Acta Polymerica Sinica*.

Hassan, H., Regnier, N., Lebot, C., Pujos, C., & Defaye, G. (2009). Effect of cooling system on the polymer temperature and solidification during injection moulding. *Applied Thermal Engineering*, *29*(8–9), 1786–1791. https://doi.org/10.1016/j.applthermaleng.2008.08.011

He, Y., Song, K., Meng, Q., & Yan, Y. (2020). An End-to-End Steel Surface Defect Detection Approach via Fusing Multiple Hierarchical Features. *IEEE Transactions on Instrumentation and Measurement*, *69*(4), 1493–1504. https://doi.org/10.1109/TIM.2019.2915404

Hill, D. (n.d.). *Further studies of the injection moulding process*.

Hong Lin Li, Z. X. J. (2012). *Applied Mechanics and Materials (Volumes 201-202)*.

HVS - Technical moulded parts. (2023). *The injection moulding cycle of plastic products*. The Injection Moulding Cycle of Plastic Products.

Ibrahim, I. D., Hamam, Y., Sadiku, E. R., Ndambuki, J. M., Kupolati, W. K., Jamiru, T., Eze, A. A., & Snyman, J. (2022). Need for Sustainable Packaging: An Overview. In *Polymers* (Vol. 14, Issue 20). MDPI. https://doi.org/10.3390/polym14204430

Ivar Do Sul, J. A., & Costa, M. F. (2014). The present and future of microplastic pollution in the marine environment. In *Environmental Pollution* (Vol. 185, pp. 352–364). https://doi.org/10.1016/j.envpol.2013.10.036

J. Enright, H. L. & A. R. (n.d.). *Advanced Manufacturing Systems.* https://doi.org/10.1007/978-3-319-00557-7

J.E. Hunt, C. J. P. M. H. L. (1993). Automating the FMEA process. *Department of Computer Science*, *2*.

John S. Oakland. (2014). *Total Quality Management and Operational Excellence*. www.routledge.com/cw/oakland

Jung, J., Park, K., Cho, B., Park, J., & Ryu, S. (2023). Optimization of injection moulding process using multi-objective bayesian optimization and constrained generative inverse design networks. *Journal of Intelligent Manufacturing*, *34*(8), 3623–3636. https://doi.org/10.1007/s10845-022-02018-8

Karagöz, İ. (2021). An effect of mould surface temperature on final product properties in the injection moulding of high-density polyethylene materials. *Polymer Bulletin*, *78*(5), 2627–2644. https://doi.org/10.1007/s00289-020-03231-2

Kim, D. B., Denno, P. O., & Jones, A. T. (2015). A model-based approach to refine process parameters in smart manufacturing. *Concurrent Engineering Research and Applications*, *23*(4), 365–376. https://doi.org/10.1177/1063293X15591038

Kryachek, V. M. (2004). INJECTION MOULDING (REVIEW). In *Powder Metallurgy and Metal Ceramics* (Vol. 43).

Kuang, T., Wang, J., Liu, H., & Yuan, Z. (2023). Effects of Processing Method and Parameters on the Wall Thickness of Gas-Projectile-Assisted Injection Moulding Pipes. *Polymers*, *15*(9). https://doi.org/10.3390/polym15091985

Kumar, S., Park, H. S., & Lee, C. M. (2020). Data-driven smart control of injection moulding process. *CIRP Journal of Manufacturing Science and Technology*, *31*, 439–449. https://doi.org/10.1016/j.cirpj.2020.07.006

Liparoti, S., Hunag, T. M., Sorrentino, A., Titomanlio, G., & Cakmak, M. (2015). Rapid control of mould temperature during injection moulding proceb. *AIP Conference Proceedings*, *1664*. https://doi.org/10.1063/1.4918490

M. Juran Joseph, & A. De Feo Joseph. (2010). *Juran's Quality Handbook*.

Mansur, A., Mu'Alim, & Sunaryo. (2016). Plastic Injection Quality Controlling Using the Lean Six Sigma and FMEA Method. *IOP Conference Series: Materials Science and Engineering*, *105*(1). https://doi.org/10.1088/1757-899X/105/1/012006

Mesa, G. S. (2006). *Variables in Bottle Cap Torque Testing*. www.mesalabs.com

Moghimi, N., Kim, S. J., & Park, S. Il. (2016). Assessing of Flexible Packaging Integrity: Using the Aerosolization Bacteria. *Packaging Technology and Science*, *29*(3), 135–143. https://doi.org/10.1002/pts.2191

Mukras, S. M. S. (2020). Experimental-based optimization of injection moulding process parameters for short product cycle time. *Advances in Polymer Technology*, *2020*. https://doi.org/10.1155/2020/1309209

Nadarajah, S., & Kotz, S. (2008). Technical Note: The Cycle Time Distribution. *International Journal of Production Research*, *46*(11). https://doi.org/10.1080/00207540601186071ï

Pouzada, A. S., Ferreira, E. C., & Pontes, A. J. (2006). Friction properties of moulding thermoplastics. *Polymer Testing*, *25*(8), 1017–1023. https://doi.org/10.1016/j.polymertesting.2006.06.009

Psarommatis, F., Sousa, J., Mendonça, J. P., & Kiritsis, D. (2022). Zero-defect manufacturing the approach for higher manufacturing sustainability in the era of industry 4.0: a position paper. *International Journal of Production Research*, *60*(1), 73–91. https://doi.org/10.1080/00207543.2021.1987551

R, R., Philip, E., Madhavan, A., Sindhu, R., Pugazhendhi, A., Binod, P., Sirohi, R., Awasthi, M. K., Tarafdar, A., & Pandey, A. (2021). Advanced biomaterials for sustainable applications in the food industry: Updates and challenges. *Environmental Pollution*, *283*. https://doi.org/10.1016/j.envpol.2021.117071

Rapid MFG. (2020, May 12). *What is the cooling system in injection moulding?*

Reichert, C. L., Bugnicourt, E., Coltelli, M. B., Cinelli, P., Lazzeri, A., Canesi, I., Braca, F., Martínez, B. M., Alonso, R., Agostinis, L., Verstichel, S., Six, L., De Mets, S., Gómez, E. C., Ißbrücker, C., Geerinck, R., Nettleton, D. F., Campos, I., Sauter, E., … Schmid, M. (2020). Bio-based packaging: Materials, modifications, industrial applications and sustainability. In *Polymers* (Vol. 12, Issue 7). MDPI AG. https://doi.org/10.3390/polym12071558

Sharad Chaturvedi, D. C. (2017). Operational efficiency in manufacturing process using design of experiments. *International Journal Process Management and Benchmarking*, *249–261*.

Shen, C., Wang, L., Cao, W., & Qian, L. (2007). Investigation of the effect of moulding variables on sink marks of plastic injection moulded parts using Taguchi DOE technique. *Polymer - Plastics Technology and Engineering*, *46*(3), 219–225. https://doi.org/10.1080/03602550601152887

Singh, G., & Verma, A. (2017). A Brief Review on injection moulding manufacturing process. In *Materials Today: Proceedings* (Vol. 4). www.sciencedirect.comwww.materialstoday.com/proceedings

Song, M. C., Liu, Z., Wang, M. J., Yu, T. M., & Zhao, D. Y. (2007). Research on effects of injection process parameters on the moulding process for ultra-thin wall plastic parts. *Journal of Materials Processing Technology*, *187–188*, 668–671. https://doi.org/10.1016/j.jmatprotec.2006.11.103

Statistical Manufacturing Journal. (2002). *Fundamentals of Design of Experiments*.

Strasser, S., Tripathi, S., & Kerschbaumer, R. (2018). An Approach for Adaptive Parameter Setting in Manufacturing Processes. *DATA 2018 - Proceedings of the 7th International Conference on Data Science, Technology and Applications*, 24–32. https://doi.org/10.5220/0006894600240032

Sulapac Ltd. (n.d.). *Sulapac Materials*. Https://Www.Sulapac.Com/Materials/.

Tambare, P., Meshram, C., Lee, C. C., Ramteke, R. J., & Imoize, A. L. (2022). Performance measurement system and quality management in data-driven industry 4.0: A review. In *Sensors* (Vol. 22, Issue 1). MDPI. https://doi.org/10.3390/s22010224

Tsai, S. B., Zhou, J., Gao, Y., Wang, J., Li, G., Zheng, Y., Ren, P., & Xu, W. (2017). Combining FMEA with DEMATEL models to solve production process problems. *PLoS ONE*, *12*(8). https://doi.org/10.1371/journal.pone.0183634

Ulaga, W., & Eggert, A. (2006). Relationship value and relationship quality: Broadening the nomological network of business-to-business relationships. *European Journal of Marketing*, *40*(3–4), 311–327. https://doi.org/10.1108/03090560610648075

Uy, M., & Telford, J. K. (n.d.). *Optimization by Design of Experiment Techniques*.

Vo, B., Kongar, E., & Suarez-Barraza, M. F. (2020a). Root-Cause Problem Solving in an Industry 4.0 Con. *IEEE Engineering Management Review*, *48*(1), 48–56. https://doi.org/10.1109/EMR.2020.2966980

Vo, B., Kongar, E., & Suarez-Barraza, M. F. (2020b). Root-Cause Problem Solving in an Industry 4.0 Con. *IEEE Engineering Management Review*, *48*(1), 48–56. https://doi.org/10.1109/EMR.2020.2966980

Xu Chun-long. (2010). Design of optional cooling time for injection moulding. *Machinery Design and Manufacture.*

Yang, Y., & Gao, F. (1999). *Adaptive control of the "lling velocity of thermoplastics injection moulding*.

YIElgady, I. (2022). DERIVATION OF NEW MODEL FOR INJECTION MOULDING COOLING TIME. In *International Journal of Engineering Applied Sciences and Technology* (Vol. 7). http://www.ijeast.com

Youssef, A. M., & El-Sayed, S. M. (2018). Bionanocomposites materials for food packaging applications: Concepts and future outlook. In *Carbohydrate Polymers* (Vol. 193, pp. 19–27). Elsevier Ltd. https://doi.org/10.1016/j.carbpol.2018.03.088

Zink, B., Szabó, F., Hatos, I., Suplicz, A., Kovács, N. K., Hargitai, H., Tábi, T., & Kovács, J. G. (2017). Enhanced injection moulding simulation of advanced injection moulds. *Polymers*, *9*(2). https://doi.org/10.3390/polym9020077