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Quality Control Analysis to Reduce Rejects in Plastic Seal Manufacturing

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ABSTRACT

Purpose – This study aims to identify the root causes of product rejects and evaluate the effectiveness of quality control improvements at PT Karya Gemilang Indonusa, a plastic seal manufacturing company.
Methodology – The methodology used includes Statistical Process Control (SPC), especially p-chart to monitor defect proportion, and Fishbone Diagram for root cause analysis. Data were collected from production reports between January and December 2024 and after improvements in January–April 2025.
Findings – The study revealed that flashing and short mold are the dominant defects, accounting for more than 55% of total rejects. After corrective actions such as operator training, machine maintenance, and parameter adjustments, the reject rate reduced from 12.91% to 4.48%, and the process capability index (Cpk) improved from 0.333 to 0.667.
Novelty – The integration of SPC and Fishbone Diagram in a real-world manufacturing setting effectively reduced rejects and increased process stability, supporting sustainable production.

INTRODUCTION

Product quality has become a key determinant of competitiveness in the manufacturing sector. In the plastic seal industry, defects (*rejects*) significantly reduce efficiency, increase production costs, and threaten customer satisfaction. Data from PT Karya Gemilang Indonusa show that during 2024, reject levels reached 12.91% of total production, with *flashing* (32.77%) and *short mold* (22.78%) as the dominant defects, accounting for more than 55% of total rejects.

Globally, manufacturing industries are facing demands for zero defect and sustainable production. Customers increasingly require not only functional quality but also compliance with environmental standards (*green manufacturing*). Trends such as *Statistical Process Control (SPC)* and continuous improvement (e.g., *Six Sigma, Lean Manufacturing*) have been widely adopted to minimize variability and improve quality. Previous studies on quality control in the plastic industry mostly focus on general defect analysis or Six Sigma applications. However, integrated approaches combining **SPC (p-chart)** and **Fishbone Diagram** in plastic seal manufacturing are still limited. Moreover, few studies present empirical evidence from Indonesian SMEs regarding process capability improvement after corrective actions.How effective is SPC combined with Fishbone Diagram in detecting, analyzing, and reducing reject rates in plastic manufacturing? How can PT Karya Gemilang Indonusa reduce reject rates to improve cost efficiency and customer satisfaction while enhancing process capability?.To identify dominant types and causes of rejects in plastic seal production. To implement corrective actions based on root cause analysis. To evaluate the effectiveness of SPC and Fishbone integration in reducing reject rates and improving process capability. The novelty of this study lies in the integration of SPC (p-chart), Fishbone Diagram, and 5-Why Analysis supported by empirical production data, evaluated before and after corrective actions. This combination provides a systematic framework not only to detect variations but also to address their root causes. The research also emphasizes sustainability aspects by highlighting waste reduction and efficiency improvements.

LITERATURE REVIEW

Quality

In contemporary manufacturing, quality is understood as the capability of a process to meet specifications consistently while satisfying customer expectations with minimal environmental burden. This broader view positions quality at the nexus of process stability, economic performance, and sustainability. Effective quality decision-making therefore relies on structured, time-based monitoring on the shop floor and timely interpretation of process signals (Zwetsloot et al., 2024). At the same time, the link between variation and its financial or societal consequences underscores that durable quality outcomes require balancing technical performance with cost and environmental goals (Xiong et al., 2022; Siegel et al., 2024).

Quality Control

Quality control comprises systematic practices for detecting, diagnosing, and reducing variation before it manifests as defects. Operationally, robust programmes blend data-driven monitoring (e.g., control charts), root-cause analysis (Pareto and Ishikawa/Fishbone), and structured remedies that are locked in through standard work and mistake-proofing. Industrial case evidence shows that disciplined application of these practices yields meaningful defect reduction and performance gains (Mittal et al., 2023), while recent guidance stresses pragmatic choices about sampling and signal interpretation for real production environments (Zwetsloot et al., 2024). Increasingly, modelling and AI are being integrated to enrich decisions with reliable, near-real-time prediction of part quality (Fernández et al., 2023; Heinish et al., 2021).

Statistical Process Control (SPC)

SPC provides a time-series framework to monitor process stability and detect small or gradual shifts early. Beyond classical Shewhart charts, enhanced EWMA schemes with variable sampling intervals improve sensitivity to subtle changes (Bai et al., 2024), while distribution-free (nonparametric) charts offer robustness when normality assumptions do not hold (Abid et al., 2024). Evidence across domains demonstrates SPC's tangible benefits for early detection and sustained stability, reinforcing its generalizability beyond traditional manufacturing contexts (Waqas et al., 2024). In practice, the effectiveness of SPC hinges on well-designed sampling and consistent, informed interpretation by line personnel (Zwetsloot et al., 2024). Statistical Process Control (SPC) is an action to monitor the production process of goods or services, make measurements, and take corrective actions involving methods. Statistical Process Control (SPC) is a methodology aimed at improving the quality of production output and meeting customer needs and wants by collecting and analyzing data related to quality, and conducting measurements regarding processes within an industrial system. The basis of Statistical Process Control is to detect process variations and immediately take anticipatory action against them. Process variations can be identified by plotting data from the existing process, and if there is data that falls outside/deviates from the established control limits, it can be concluded that a process variation has occurred. Control charts are statistical methods that distinguish between variations or deviations due to common causes and special causes at the control limits. If deviations or errors exceed the control limits, it indicates that special causes have entered the process, and the process must be examined to identify the cause of the excessive deviations or errors; common causes usually fall within the control limits. A control chart consists of three lines: the center line is the target value in some cases; the other two lines are the Upper Control Limit (UCL) and the Lower Control Limit (LCL), and the characteristics of the values in the chart depict the state of a process. Based on the above description, a control chart is a graph used to evaluate a production process over time. The control chart shows changes in data over time but does not show the cause. Control charts also serve as good decision-makers because the patterns formed by the points on the control chart will determine whether the activity is good, bad, or has no impact on the process. A control chart is a tool for monitoring an ongoing process and helps detect deviations that occur. Walter A. Shewart was the first to introduce the theory of control charts; therefore, control charts are sometimes called Shewart control charts. Based on the definitions of several experts, it can be concluded that a control chart is a technique in the form of a map/graph that has upper and lower control limits to monitor the activity of an ongoing process using a number of samples or subgroups plotted according to the time order or the order in which the samples were taken.

Definition of Plastic Seal

A plastic seal is a device made from plastic material used to ensure the security, authenticity, and integrity of a product or package. These seals are designed to be tamper-evident, meaning they cannot be opened or replaced without leaving visible traces or causing damage to the seal itself. Plastic seals are commonly used across various industries, including food, pharmaceuticals, logistics, and valuable goods.

Zero Waste

Zero-waste and circular-economy perspectives advocate closed material loops, design-for-recovery, and minimisation of losses across the product life cycle. Frameworks and reviews synthesise strategies that align operational excellence with circularity principles (Kerdlap et al., 2019; Awogbemi et al., 2022). Case-based evidence in manufacturing shows that zero-waste strategies operationalised through structured quality initiatives can lower raw-material consumption and disposal volumes while improving line efficiency (Iqbal et al., 2020). Conceptually, defects are a salient form of waste; thus, statistical reduction of variation through SPC and follow-on improvements directly advances circular-economy objectives (Farrukh et al., 2023; Siegel et al., 2024). Zero waste is defined as "the conservation of all resources through responsible production, consumption, reuse, and recovery of products, packaging, and materials without burning and with no discharges to land, water, or air that threaten the environment or human health." Zero waste is not merely about waste management, but also encompasses the comprehensive management of a product's entire life cycle. Zero waste plays a significant role in Green Supply Chain Management (GSCM), which integrates sustainability principles into the entire supply chain process. Effective GSCM can help companies reduce the environmental impact of their operations while improving efficiency. In this context, the application of zero waste includes better waste management, material reuse, and recycling of products that are no longer in use.

Six Sigma

Six Sigma—particularly the DMAIC roadmap—structures improvement from problem definition through control and has repeatedly delivered defect reduction and operational gains in manufacturing (Mittal et al., 2023). Many organisations combine Lean and Six Sigma to eliminate waste and reduce variability in tandem; integrated frameworks have achieved measurable variability reductions in process industries and can be tailored across contexts (Alarcón et al., 2024; Trubetskaya et al., 2023). Sustainability-aware variants (e.g., Green or Sustainable Lean Six Sigma) explicitly link improvement projects to environmental metrics and governance, aligning quality, cost, delivery, and sustainability outcomes (Utama & Abirfatin, 2023; Siegel et al., 2024). Six Sigma is a structured, project-based approach that is data-driven, customer-focused, and aimed at improving the performance of products, processes, and services.

Six Sigma is implemented through a systematic series of steps known as DMAIC, which consists of:

1. Define: Identifying the problem, improvement goals, and customer requirements.
2. Measure: Collecting data to understand the current condition of the process.
3. Analyze: Identifying the root causes of the problem based on data.

4. Improve: Developing and implementing solutions to address the problem.
5. Control: Sustaining the improvements to ensure consistent results

Process Capability

Process capability analysis complements SPC by benchmarking the “voice of the process” against specification limits and expressing quality in customer-risk and economic terms. Recent work addresses common departures from normality in plant data and proposes capability procedures suitable for non-normal or heavy-tailed characteristics (Borucka et al., 2023). Beyond Cp/Cpk, indices with zero-loss economic meaning strengthen the connection between dispersion and financial consequences (Xiong et al., 2022). Robust formulations of CpmC_{pm}Cpm and CpmkC_{pmk}Cpmk under Weibull assumptions extend applicability to skewed quality metrics typical of plastics processing, while practical guidance helps practitioners select and interpret indices appropriately within SPC programmes (Yang et al., 2023; Benková et al., 2024).

METHOD

This research applies a quantitative descriptive approach.

Type of Research: Quantitative–descriptive, aimed at identifying, analyzing, and improving quality control in production.

Population and Sampling: The population is all rejected products of PT Karya Gemilang Indonusa during January–December 2024. The sampling technique is saturated sampling, where all population data are analyzed since the dataset is limited and accessible.

Data Collection Method and Location:

- Location: PT Karya Gemilang Indonusa, Tangerang, Banten.
- Data: Secondary data from production and reject reports (2024–2025).
- Primary data: Focus Group Discussion (FGD) and brainstorming with 6 production personnel (technicians, operators, warehouse staff).

Data Testing Method:

- Check Sheet: for production and defect data tabulation.
- Pareto Chart: to identify dominant defects.
- p-chart (SPC tool): to monitor defect proportion over time.
- Fishbone Diagram & 5-Why Analysis: to identify and verify root causes.

Software Used:

Data analysis was conducted using POM-QM for Windows V5, which was utilized to generate p-charts and calculate process capability indices (Cpk).

This methodology ensures objectivity in identifying variations, systematic analysis of root causes, and reliable evaluation of corrective actions.

RESULT AND DISCUSSION

Table 1. Distribution of Defect Types, January–December 2024

Defect Type	Frequency (pcs)	Percentage (%)
Bending	460,225	6.98%
Gas mark	477,369	7.24%
Silver mark	432,045	6.55%
Flashing	2,162,044	32.77%

Under cut	352,848	5.35%
Crack	394,576	5.98%
Flow mark	363,172	5.51%
Scratches	242,413	3.67%
Burn mark	209,561	3.18%
Short mold	1,502,795	22.78%
Total	6,597,049	100.00%

source: company records

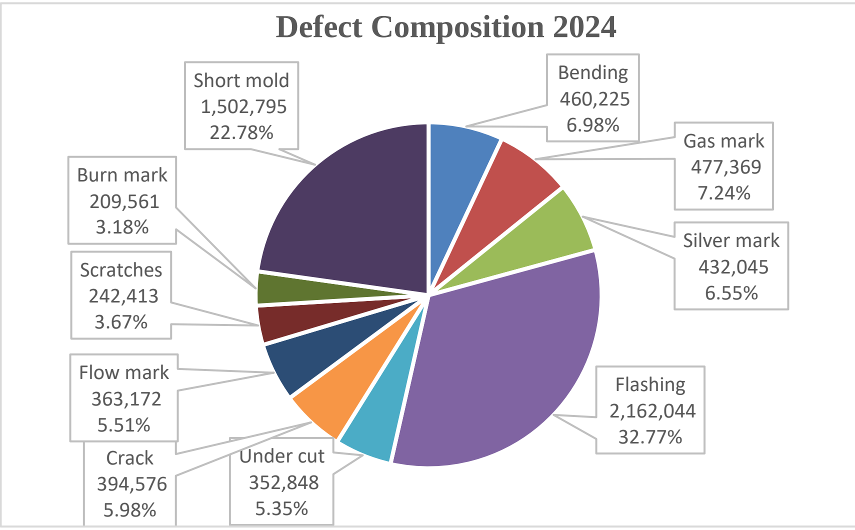


figure 1. Defect Composition 2024 (Flash & Short Mold dominate >55%)

The table above shows that two defect categories, the reject rate averaged 12.91% with dominant defects: flashing (32.77%) and short mold (22.78%). The Flashing and Short Mold together represent 55.55% of all defects in 2024. Given this concentration, the company prioritized corrective measures addressing these two failure modes.

Flashing: Observed Patterns and Root Causes

Flashing appeared as a thin, unwanted film of plastic along parting lines and ejection interfaces. Visual inspection records and FGD notes indicate that flashing occurrences tended to cluster on particular mold cavities and during high-volume production months (notably October–December).
Root cause analysis revealed a mix of contributing factors:

1. Mechanical wear on mold edges and parting surfaces,
2. Excessive injection pressure and hold time settings that pushed molten plastic into clearance gaps,
3. Nadequate clamp force or imprecise alignment due to worn guide pins, and
4. Operator interventions that occasionally bypassed standard pre-start checks during peak shifts.

Corrective actions implemented included scheduled mold refurbishment (polishing and re-machining of critical edges), re-evaluation and lowering of nominal injection pressure in sensitive part families, verification and calibration of clamp force, and reinforcement of pre-shift inspection checklists. Operator training emphasized detection cues for early flashing onset and immediate shutdown procedures to prevent volume growth of scrapped parts.

Short Mold (Short Shot): Observed Patterns and Root Causes

Short mold defects, where injected parts are incompletely filled, were the second largest contributor to rejects. Inspectors recorded frequent short shots when producing thicker or slender geometries that require higher melt flow or adjusted packing strategies.

Contributory causes included: inconsistent material drying (excess moisture reduces melt flow), intermittent hopper feeding issues causing air entrapment, incorrectly set injection speed profiles, and occasionally blocked gate channels due to degraded nozzle tips. Root cause analysis via 5-Why sessions highlighted maintenance gaps in the material handling system and lapses in process parameter documentation.

Actions taken included implementation of stricter material drying protocols, replacement of vulnerable nozzle tips and check valves, preventive maintenance on feed and hopper systems, and standardization of recipe parameters per family of parts. The engineering team also introduced a low-cost trial using modified venting techniques for cavities prone to air entrapment.

SPC analysis and p-chart interpretation

The p-chart constructed for the 12 months of 2024 plotted monthly defective proportions and visually highlighted multiple observations beyond control limits and non-random patterns (runs and trends) that indicate special-cause events. These special-cause signals corresponded temporally with known events such as extended production runs with minimal mold maintenance and material lot changes.

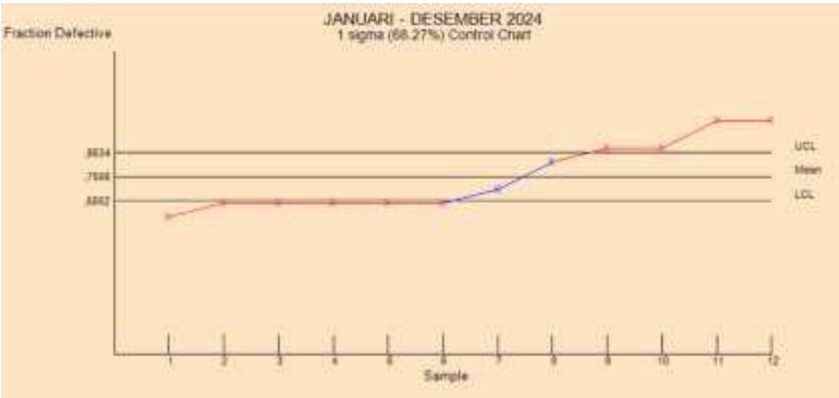
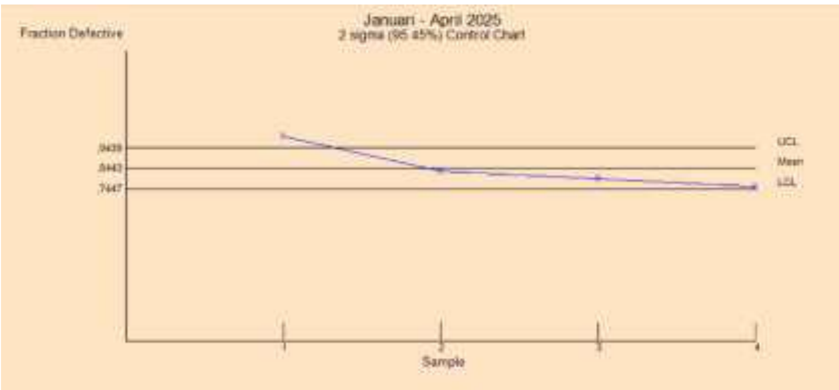


figure 2. P-Chart Rejects Production January - December 2024

While an ideal p-chart analysis requires consistent sample sizes, the production context used monthly aggregates (varying n). The interpretive approach therefore focused on pattern detection



(points outside limits, runs, and shifts) rather than relying solely on pointwise statistical decision-making.

figure 3. P-Chart Rejects Production January - April 2025

After corrective actions were implemented (end of 2024 into early 2025), the p-chart for January–April 2025 showed substantially fewer signals and more points within limits, consistent with observed reductions in reject proportions. However, because process capability remained below industrial benchmarks (Cpk = 0.667), the process still required continuous monitoring and additional optimization.

Process Capability (Cpk) and Interpretation

Measured process capability (Cpk) improved from 0.333 (pre-intervention) to 0.667 (post-intervention). Although this improvement is meaningful, it indicates a reduction in process spread relative to the specification limits, the Cpk still suggests that the process produces a non-negligible fraction of nonconforming parts if left uncontrolled.

Two practical implications follow: first, short-term controls and robust inspection are still necessary to avoid shipments with unacceptable defect levels; second, medium-term investments in tooling accuracy, automated process control (closed-loop control on temperature and pressure), and material quality assurance are recommended to reach Cpk ≥ 1.33.

The company could adopt staged investments:

1. Further reduce process variability through preventive maintenance and tighter material controls,
2. Implement statistical monitoring at a finer granularity (shift-level or cavity-level sampling) to detect localized problems earlier, and
3. Evaluate automation options for critical steps that currently rely on manual operator settings.

Table 2. Summary of Key Metrics Before and After Corrective Actions

Metric	Before (2024)	After (Jan–Apr 2025)
Average reject rate	12.91%	4.48%
Process capability (Cpk)	0.333	0.667
Dominant defect share (Flashing + Short Mold)	55.55%	reduced (post-action)

The table above summarizes the primary quantitative outcomes: the overall defect proportion declined markedly and Cpk doubled. The dominant-defect concentration also decreased, though full elimination requires continuing interventions.

Management Implications, Cost Estimates and Sustainability

Reducing rejects by the observed magnitude (from 12.91% to 4.48%) has immediate cost implications. Direct savings include fewer raw materials consumed for scrapped parts, lower handling and rework labor, and reduced disposal costs. Indirect benefits include improved on-time delivery and product reputation, which can affect customer retention and sales growth.

From a managerial perspective, the following practices were recommended and partially implemented:

1. Formalized preventive maintenance schedules tied to production volume thresholds;
2. A standardized shift handover checklist documenting key parameters and recent deviations;
3. A structured training curriculum for operators emphasizing parameter setup and defect recognition;
4. Introduction of a small, dedicated engineering response team for fast-tracking mold repairs.

Sustainability implications are also significant. Fewer rejects lower the material throughput destined for downcycling or waste management. The company explored reuse pathways for some grades of scrap via in-house regrinding and reincorporation subject to quality constraints. The findings align with circular-economy thinking and may support future eco-labeling efforts.

Root-cause: Method and Results

A facilitated root-cause workshop assembled production supervisors, quality staff, a maintenance engineer, and two senior operators. Using structured Fishbone facilitation, participants listed contributing factors for flashing and short shots under the 4M1E (Man, Machine, Material, Method, Measurement, Environment).

The group then applied the 5-Why method to the most plausible causes. For example, a short-shot event traced to moist pellets

1. Why 1: short shot? because melt viscosity too high;
2. Why 2: why viscosity high? because pellets had high moisture;
3. Why 3: why moisture high? because dryer setpoint was lower than specified and dryer cycling was inconsistent;
4. Why 4: why dryer cycling inconsistent? because scheduled checks were omitted during busy periods;
5. Why 5: why omitted? because there was no shift-level accountability process). This chain revealed actionable interventions (drying SOP, shift accountability checklist).

The workshop documented clear owners, deadlines, and verification steps for each corrective action. Follow-up audits validated that most actions were completed within two months, and several were effective in reducing recurrence.

Pareto Analysis and Seasonal Patterns

Pareto analysis confirmed that Flashing and Short Mold were the 'vital few'. The remaining eight defect types collectively accounted for less than half of rejects but still represented meaningful opportunities for incremental improvements.

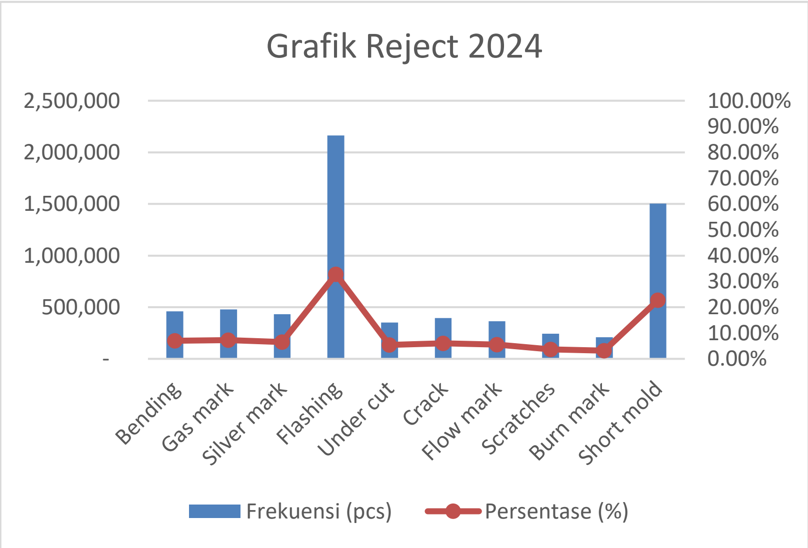


figure 4. Pareto Diagram Reject 2024

Seasonal patterns emerged: the final quarter (Oct–Dec) showed elevated reject volumes associated with higher production throughput and occasional overtime use. The combined effect of extended runtime and deferred maintenance appeared to increase the probability of mold wear-induced flashing and material handling lapses that contributed to short shots.

A seasonal production plan that locks in maintenance windows before high-volume runs and assigns experienced operators during those periods was proposed as a tactical mitigation.

Limitations and Future Research Directions

This research relies on company-provided operational data which, while comprehensive, varied in granularity. Monthly aggregation concealed some cavity-level or shift-level signals; as a result, finer-grained SPC at the cavity or shift level could reveal additional, localized special causes.

The Cpk calculations were constrained by the availability of continuous measurement data for certain dimensions. Future work could integrate in-process measurement sensors providing cycle-by-cycle metrics to compute capability on a rolling basis.

Finally, while actions produced measurable short-term gains, longitudinal studies spanning multiple years would be beneficial to confirm sustainability of improvements and to quantify lifetime cost savings and environmental benefits from reject reduction.

CONCLUSION

The findings of this study demonstrate that the systematic application of Statistical Process Control (SPC) and Fishbone Diagram can effectively identify and reduce major types of rejects in plastic seal manufacturing. The results answered the research objectives by showing that the dominant factors causing rejects were *flashing* and *short mold*, which together accounted for more than 55% of all defects. Corrective actions, including operator training, machine maintenance, and parameter adjustment, successfully reduced the reject rate from an average of 12.91% in 2024 to 4.48% in the January–April 2025 period. These improvements were further supported by an increase in the process capability index (Cpk) from 0.333 to 0.667, indicating enhanced process stability, although the process had not yet achieved full capability. The results also provide empirical evidence that strengthens previous findings in the literature. For instance, studies by Elyas et al. (2020) and Chen et al. (2023) confirmed the effectiveness of SPC tools, particularly control charts, in monitoring process stability, while Aristriyana and Fauzi (2022) highlighted the usefulness of Fishbone Analysis for identifying root causes of production defects. The present study supports these findings and extends them by demonstrating the effectiveness of integrating SPC and Fishbone approaches in the context of plastic seal manufacturing in Indonesia. However, not all hypotheses were fully supported. While significant improvements were observed after corrective actions, certain external factors such as fluctuations in raw material quality and environmental conditions still posed challenges, limiting the achievement of a process capability index above 1. This suggests that additional interventions are necessary to move towards world-class quality standards. For further research, it is recommended to expand the scope of analysis by incorporating advanced quality management methods such as Failure Mode and Effect Analysis (FMEA), Six Sigma, or Lean Manufacturing tools. Future studies could also explore the integration of sustainability aspects, such as energy efficiency and waste reduction strategies, in line with the Sustainable Development Goals (SDGs). Moreover, comparative studies across different manufacturing industries would provide broader insights into the generalizability of SPC and Fishbone applications in various production contexts.

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