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# Defect Rate Reduction Through the Application of Standard Work, BPM and Poka Yoke in an SME in the Plastics Sector

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## Abstract

The present study addresses the quality problems commonly found in Peruvian SMEs in the plastic sector. These enterprises typically exhibit high levels of process variability, low efficiency, and an average sector defect rate of 6.6%. These challenges are intensified in make-to-order (MTO) environments, where frequent product changes and manual tasks increase operational instability. However, existing studies have not proposed methods specifically aimed at reducing defect rates in MTO SMEs, leaving a gap in approaches that directly target defect generation under high-variability conditions. In order to address this gap, the present research proposes an integrated defect-reduction model based on the application of Standard Work, Poka Yoke and Business Process Management (BPM). The model was implemented and validated through a pilot deployment in a Peruvian MTO plastics SME characterized by limited automation, high manual dependence, and underdeveloped process structures, providing a setting distinct from the more stable and technologically mature firms examined in prior studies. The results indicate a reduction in the total defect rate from 14.91% to 7.84%, accompanied by enhanced stability in critical manual operations. The findings demonstrate that combining Standard Work, Business Process Management, and Poka-Yoke can directly address defect sources in MTO plastics SMEs, offering a practical, low-cost, and replicable approach for improving quality in similar emerging-economy contexts.

## Keywords
Defect Reduction, Plastic SME, BPM, Standard Work and Poka Yoke

## 1. Introduction
Peruvian plastics SMEs face persistent operational challenges that constrain their performance, particularly low efficiency and high waste generation (Allca et al. 2023). These issues stem from unstable processes and limited technical capabilities, mirroring patterns observed internationally, as reported by Jauza et al. (2022) and Loyola et al. (2023), where SMEs commonly struggle with inefficiencies and elevated waste that hinder productivity. Such conditions directly impact quality, leading to increased reprocessing, raw-material consumption, and associated economic losses. In Peru, the average defect rate in plastics SMEs is 6.6% (Sangiacomo-Espinosa et al. 2024), which is a key quality indicator due to its direct impact on usable output, operating costs and competitiveness.

Addressing these issues is essential because these SMEs operate within a rapidly expanding industry. The Peruvian plastics sector demonstrated notable growth, expanding by 5.28% in 2024. This growth outpaced the national manufacturing average (INEI 2024). However, growth within the sector does not necessarily ensure that production systems are efficient or reliable. Given that the majority of firms are SMEs, their operational performance has a significant impact on national productive capacity and the supply of essential packaging and consumer goods. As Hsiao et al. (2023) observes, firms must enhance and optimize their processes to reduce defects, improve efficiency and quality, and control costs to maintain competitiveness. For Peruvian SMEs, this challenge is compounded by limited resources, technical expertise, and the absence of structured improvement methods (Aguilar et al. 2022).

Despite its relevance, research on Peruvian SMEs has centered mainly on efficiency improvements in continuous production systems, overlooking make-to-order plastics SMEs that rely on flexible, highly variable, and predominantly manual operations. Studies such as Quiroz and Vega (2022), Sangiacomo et al. (2024), and Jimenez et al. (2023) apply Lean tools such as standardized work, 5S, TPM, or SMED to reduce downtime, reorganize workflows, and prevent machine failures, all with the aim of increasing overall efficiency. While these interventions can stabilize operations and generate indirect quality improvements, they do not address the underlying causes of defects. Furthermore, the firms analyzed in these studies generally have processes already defined and structurally mature, a condition that contrasts with the context of MTO plastics SMEs, where processes remain informal or underdeveloped. In such cases, Business Process Management (BPM) becomes essential not only as a tool for optimization but as a foundational mechanism to define, formalize, and control processes that do not yet exist.

The present study proposes and evaluates an integrated defect-reduction model adapted to the needs of make-to-order plastics SMEs, where operational variability and manual tasks are predominant. The model integrates standardized work, a BPM-based mold-management process, and a Poka-Yoke alignment device to address the specific sources of defects. When applied to a Peruvian plastics SME, the proposal demonstrates how structured, cost-effective methods can stabilize MTO operations, enhance product quality, and provide a practical framework for other SMEs seeking to enhance their operational performance.

### 1.1 Objectives

The primary objective of this research is to propose and evaluate the effectiveness of an integrated defect-reduction model designed for the operational characteristics of a make-to-order plastic SME. This model integrates Standard Work, a BPM-based mold management process, and a Poka-Yoke alignment mechanism to address the specific sources of defects. To achieve that, the study establishes the following specific objectives:

- Design and implement standardized operational procedures for the dry-blending process to reduce variability and ensure consistent color quality.
- Apply BPM to implement a process that ensures proper storage and maintenance of injection molds, strengthening preventive control and improving operational reliability in the blowing stage.
- Introduce a Poka-Yoke alignment mechanism for the screen-printing process to eliminate human-induced alignment errors and reduce printing-related defects.

## 2. Literature Review

Quality issues in the plastics manufacturing sector are frequently attributable to unstable manual operations, inadequate process control, and limited preventive practices. To address these challenges, the literature proposes three main approaches: Standard Work to reduce operational variability, Business Process Management (BPM) to formalize and control critical processes, and Poka-Yoke to prevent manual errors. The following review examines the contributions and limitations of these approaches in manufacturing environments and identifies the research gaps addressed by this study.

### 2.1. Standard Work in plastics manufacturing

Standard Work is recognized as a foundational method for reducing variability and stabilizing production processes. Almashaqbeh and Hernandez (2024) argue that establishing proper operational management procedures and executing preventive maintenance routines can improve OEE and reduce operational losses and defects in plastic manufacturing. Aguilar et al. (2022) provide quantitative evidence that defining critical operating parameters reduces defect rates associated with process instability. Other research shows that Lean-based standardization improves defect control and facilitates systematic waste reduction in SME environments (Barrientos et al. 2020). Hosseini-Nasab et al. (2013) also note that the standardization of Lean processes across an enterprise strengthens operator performance and supports early detection of irregularities. However, most reported applications are implemented in relatively stable or continuous production systems, where process structures are already formally established. Consequently, limited attention has been given to highly manual make-to-order environments, where variability is intensified by frequent product changes and the absence of formalized workflows. In such contexts, Standard Work alone may be insufficient unless supported by mechanisms that structure and control process execution.

### 2.2. Business Process Management (BPM) in plastics manufacturing
Business Process Management (BPM) has emerged as an effective approach for improving quality and reducing inefficiencies in plastics manufacturing. Research indicates that BPM-based process structuring and control contribute to defect reduction and operational consistency in industrial environments (Hsiao et al. 2023). Additional studies have reported efficiency improvements and waste reduction when BPM is combined with Lean-based interventions (CCopa et al. 2025). Other investigations demonstrate that structured maintenance practices enhance process stability (Lino Moreno et al. 2025). Additionally, studies have indicated that strengthening process control within SMEs can result in significant defect reduction (Loyola et al. 2023). Nevertheless, most BPM applications in manufacturing focus on optimization within already mature operational systems. Less attention has been given to SMEs characterized by informal workflows and limited process governance, where BPM plays a more foundational role by defining, formalizing, and sustaining operational routines. This limitation becomes particularly relevant in make-to-order plastics SMEs, where process instability and manual execution increase exposure to defects.

### 2.3. Poka-Yoke in plastics manufacturing
Poka-Yoke, a core principle of Lean Manufacturing, has been shown to prevent human errors and improve process reliability. Suarez Sasiga et al. (2025) reported that the Poka-Yoke methodology helps minimize human errors and product defects, contributing to quality control and operational efficiency in manufacturing environments. Informational Poka-Yokes have also proven effective in improving calibration accuracy in injection-molding setups (Sangiacomo et al. 2024). However, existing applications are primarily concentrated in semi-automated production environments or rely on sensor-based technologies that may not be economically viable for SMEs with limited automation. Consequently, there remains limited evidence regarding the implementation of low-cost physical Poka-Yoke mechanisms in highly manual MTO environments. This study addresses this gap by incorporating a simple alignment device designed to reduce variability in manual screen-printing operations.

Across the literature, Standard Work, BPM, and Poka-Yoke have independently demonstrated positive effects on quality improvement, variability reduction, and process reliability. However, current research largely evaluates these approaches in isolation and within operationally mature or semi-automated production systems. As a result, limited evidence exists regarding integrated improvement frameworks capable of simultaneously addressing process informality, manual variability, and operator-dependent defects in make-to-order plastics SMEs. This gap is particularly relevant in emerging-economy manufacturing contexts, where SMEs often lack formal process structures and rely heavily on manual execution. Therefore, this study contributes to the literature by proposing and validating an integrated Lean–BPM framework capable of simultaneously addressing operational variability, process informality, and operator-dependent defects within highly manual MTO plastics SMEs.

## 3. Methods
This study proposes an integrated defect-reduction model for make-to-order (MTO) plastics SMEs, following the conceptual structure of Allca et al. (2023) and Sangiacomo-Espinosa et al. (2024), structured around a sequential *input–intervention–output* approach that organizes Lean tools into functional modules. The model was evaluated through an As-Is versus To-Be comparison of operational performance under comparable production conditions through sequential pilot implementation. As illustrated in **Figure 1**, the model is composed of three components designed to address the root causes contributing to the SME's high defect rate (12.10%): an inadequate working method in the dry-blend stage (30.57%), the absence of a standardized process for mold storage and maintenance (12.34%), and alignment deviations between printing layers (38.24%). When implemented as an integrated model, these components are designed to reduce defects by targeting their sources at each production stage, making the approach particularly suitable for SMEs with limited resources and high manual involvement.

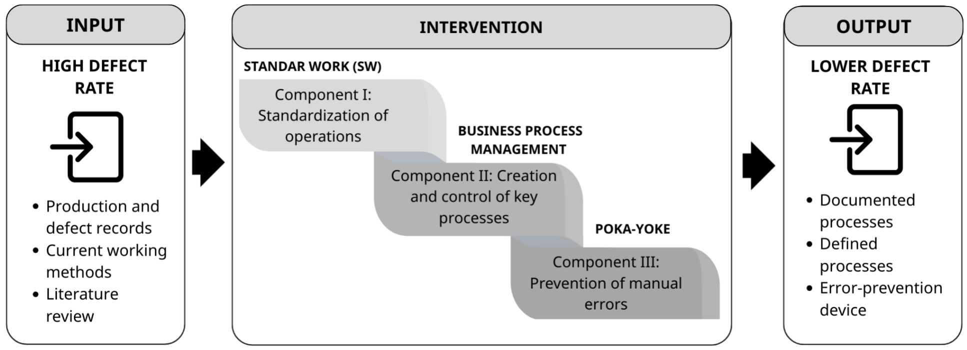


Figure 1. Proposed Model

The three components were validated through four-week pilot implementations under normal operating conditions. Week 0 represented the As-Is scenario using existing operating practices, while Weeks 1–3 corresponded to the To-Be stage after implementation of the proposed interventions. During the pilot, production conditions, workforce composition, and operational demand remained stable to ensure comparability between stages. Performance was evaluated using operational variability and defect-related indicators specific to each process.

## Component I: Standardization of operations

The first component focuses on reducing variability in the dry-blending stage through the combined application of BPM and Standard Work. The intervention established a standardized workflow including parameter definition, SOP deployment, and controlled execution routines aimed at improving operational consistency during pigment preparation. Performance was evaluated through blending-time variability and color-related defect rate.

## Component II: Creation and control of key processes

The second component applies BPM to formalize the mold-conditioning process during the injection stage. The intervention incorporated standardized cleaning, lubrication, inspection, and storage routines supported by control points and traceability records to improve process discipline and mold readiness.

## Component III: Prevention of manual errors

The third component implements a Poka-Yoke alignment mechanism to reduce positioning variability during manual screen printing. The intervention introduced a physical alignment device designed to ensure repeatable bottle placement and minimize operator-dependent deviations. Performance was evaluated through the percentage of misalignment defects during screen-printing operations.

## Model indicators

The effectiveness of the proposed model was evaluated using the indicators presented in Table 1.

Table 1. Performance Indicators for Model Evaluation

| Component | Key Indicator |
|---|---|
| C1: Standardization of Dry-Blending | Std. deviation of blending time (s) |
| | % of color-related defects |
| C2: BPM in Mold Management | % of mold-related defects |
| | % of molds cleaned before production |

| | |
|---|---|
| C3: Screen-Printing Poka-Yoke | % of misalignment defects |
| Global Defect Rate | % of total defects |

These indicators enabled systematic comparison between baseline and improved operational conditions across the three intervention components.

## 4. Data Collection

This section presents the baseline diagnostic conducted prior to implementation of the proposed model. Data collection combined historical production records and direct observation under normal operating conditions to identify the principal defect sources and characterize process variability across the three critical production stages.

### Historical Data Collection

The company exhibited persistent quality issues, as evidenced by a high number of units rejected at inspection points and returned by customers. On-site observational studies revealed that over 80% of defects originated from three sources, all illustrated in **Figure 2**: misalignment in screen printing (38.24%), improper pigment dry-blending (30.50%), and mold-related issues in injection (12.34%). Following the identification of the three primary defect categories and the analysis of their respective occurrence processes, a comprehensive analysis was conducted to ascertain the underlying causes of the identified defects.


Figure 2. Principal defects type

### Root Cause 1 in Dry-blending process

In order to ascertain whether the dry-blend operation had a significant impact on process instability, mixing time was measured at the batch level over a period of two weeks. The weekly production population consisted of ten batches of 10 kilograms each, and the required sample size was calculated using the finite population formula ($Z = 1.95$; $p = q = 0.5$; $e = 5\%$), resulting in a target of nine batches. Measurements were collected as batches became available during the study period, and total blending time was recorded manually using a stopwatch.

The analysis yielded a mean dry-blending time of 109.88 seconds and a standard deviation of 20.37 seconds, indicating a very high level of dispersion relative to the average duration of the activity. This significant deviation indicates that the operation lacks stability and repeatability, as execution relies heavily on each operator's judgment rather than on defined criteria. As a result, the dry-blending stage is a key source of process variability, meaning it is necessary to intervene through the structured workflow definition and Standard Work procedures established in Component I to reduce variability in the color of the bottles.

### Root Cause 2 in Cap injection molding

A comprehensive census of all molds utilized in the production orders was conducted to evaluate their condition prior to the injection process. To ensure the collection of objective evidence, operators were provided with a simple technical checklist to verify cleanliness, lubrication, and general condition at the start of each run. Over the course of two weeks of observation, covering ten production cycles, the records indicated that eight out of ten molds exhibited adhered residues or lacked recent lubrication. This suggests that molds were frequently returned to operation without adequate post-use conditioning.

The evaluation's comprehensive scope, encompassing the entire population of molds utilized during the observation period, provides statistically robust confirmation that mold preparation does not adhere to defined routines. The high proportion of molds in suboptimal condition reflects a structurally inconsistent process that heightens the likelihood of dimensional and surface-quality issues during injection. This evidence underscores the necessity of implementing a formalized and preventive mold-handling process within the improvement model.

### Root Cause 3 in Manual screen printing process

To evaluate alignment consistency in the manual screen-printing stage, a full inspection was conducted on a production order of 50 two-color bottles, allowing the analysis to cover 100% of the population. For each bottle, alignment deviation between printed layers was measured using a vernier caliper, recording displacement in millimeters relative to the nominal reference line.

The results showed a standard deviation of 0.96 mm, nearly as close to the margin of ±1.0 mm, indicating high process variability. While the majority of units met the acceptable limit, the inspection also revealed a maximum deviation of 3.4 mm, indicating substantial variability in manual positioning even under identical printing conditions. As the entire lot was measured, these findings provide statistically complete evidence of instability in the process.

The combination of an average deviation above tolerance, a significant number of nonconforming units, and the presence of large misalignments demonstrates that the current operation lacks a mechanism to ensure repeatable bottle placement. This confirms that the screen-printing stage is highly sensitive to operator technique and requires an error-prevention solution that standardizes alignment and reduces positional variation.

The baseline diagnosis confirmed that the principal defect sources were associated with process variability, absence of standardized routines, and operator-dependent execution across the evaluated production stages. These findings supported the design and implementation of the proposed integrated improvement model.

## 5. Results and Discussion

### 5.1 Proposed Improvements

The proposed improvement model was developed to address the three principal sources of defects identified during the diagnostic phase: dry-blending variability, mold contamination during injection, and bottle misalignment during screen printing. The model integrates Standard Work, Business Process Management (BPM), and Poka-Yoke techniques to reduce operational variability, standardize critical activities, and minimize operator dependent errors within the make-to-order production system.

### Standardized Dry-Blending Procedure with BPM-Based Control

The first intervention focused on the dry-blending stage, where inconsistent execution methods generated color deviations and instability in the material preparation process. To address this issue, a standardized operating procedure (SOP) supported by BPM structuring was designed to establish a defined sequence of activities, operational parameters, and execution controls for each batch. The proposal included definition of standardized mixing times, sequence-based execution flow, visual process controls and operator guidance through standardized work instructions. The BPM structure enabled the formalization of the workflow and the establishment of process checkpoints to ensure consistent execution. **Figure 3** illustrates the situation before and after the implementation.


Figure 3. Dry-Blending stage improvement

### BPM-Based Standardization of Mold Cleaning and Lubrication

The second intervention addressed mold contamination problems during the injection process. The diagnostic phase revealed that mold cleaning and lubrication activities lacked standardization, resulting in inconsistent maintenance practices and contamination-related defects. To reduce variability in mold preparation, a BPM-based process flow was developed to standardize cleaning activities, lubrication routines, inspection procedures, and verification checkpoints before production startup. The intervention incorporated checklist-based verification mechanisms to ensure mold readiness before each production cycle. **Figure 4** illustrates the situation before and after the implementation.


Figure 4. Mold-conditioning process

### Poka-Yoke Alignment Device In Screen-Printing Process

The third intervention focused on reducing bottle misalignment during the screen-printing operation. Since alignment was previously performed manually, the process was highly dependent on operator skill and visual judgment, generating frequent positioning errors. To address this problem, a low-cost physical Poka-Yoke alignment mechanism was designed and installed in the printing station. The device restricted incorrect bottle positioning and ensured repeatable alignment during each printing cycle. **Figure 5** presents the implemented alignment device.

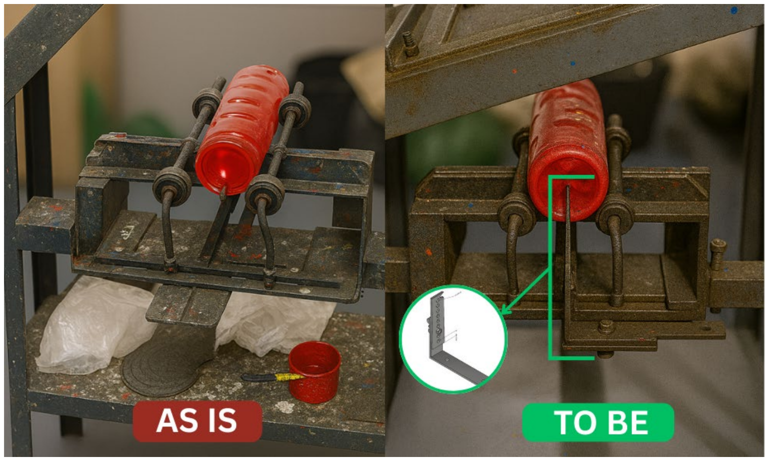


Figure 5. Installed prototype of the alignment mechanism

## 5.2 Validation

The Lean–BPM model was validated through a controlled pilot implementation conducted under normal operating conditions within the SME. Validation followed an As-Is versus To-Be comparative approach designed to evaluate the operational performance before and after implementation of the proposed interventions. The pilot was executed over four consecutive weeks. Week 0 represented the baseline operating condition using the company's existing procedures, while Weeks 1–3 corresponded to the implementation and evaluation of the proposed model. To ensure comparability between stages, the same product family, production volume, operators, production schedule, and operational resources were evaluated throughout the validation period. Prior to running the pilot, the required number of observations for each variable was defined based on the production characteristics of the process.

For the dry-blend process, blending time was measured at the batch level, where the weekly population consisted of 10 kilogram batches. Applying the finite population formula ($Z = 1.95$; $p = q = 0.5$; $e = 5\%$) resulted in a sample of nine batches. Additionally, defects related to color deviation and compliance with the blending procedure were recorded through census-type observations, since all produced units were fully inspected during the pilot. The complete sampling structure is provided in Table 2.

Table 2. Sampling Structure for Dry-Blending Related Variables

| Variable | Unit of Analysis | Type of Variable | Population (N) | Sample (n) |
|---|---|---|---|---|
| Blending time (s) | 10-kg dry-blending batch | Continuous | 10 batches/week | 9 batches |
| % defective bottles due to incorrect color | Blown bottle | Discrete (conforming/non-conforming) | ≈1,800 bottles/week | 100% inspected |

In the mold-conditioning stage of the injection process, all caps produced during the shift were fully inspected. As a result, both the percentage of mold-related defective caps and the percentage of clean molds before production were recorded through complete census observation. Mold cleanliness was evaluated across five production cycles per week, corresponding to the number of mold starts performed by operators. The complete sampling structure is shown in Table 3.

Table 3. Sampling Structure for Injection-Process Variables

| Variable | Unit of Analysis | Type of Variable | Population (N) | Sample (n) |
|---|---|---|---|---|
| % defective caps due to mold contamination | Injected cap | Discrete (conforming/non-conforming) | ≈1,800 caps/week) | 100% inspected |
| % clean molds before production | Production start (cycle) | Discrete (clean/not clean) | 5 weekly cycles | 5 observations/week |

For the screen-printing process, inspection was carried out under a census scheme due to the relatively small batch size (≈1,800 bottles/week). To ensure comprehensive data collection for the assessment of this component, misalignment defects were documented on a daily basis, as illustrated in **Table 4**.

Table 4. Sampling Structure for Screen-Printing Variables

| Variable | Unit of Analysis | Type of Variable | Population (N) | Sample (n) |
|---|---|---|---|---|
| % defective bottles due to misalignment | Screen-printed bottle | Discrete (conforming/non-conforming) | ≈1,800 bottles/week | 100% inspected |

These sampling schemes were implemented to ensure consistent, complete, and statistically sound data collection across the three components. This allowed for a reliable comparison of As Is and To Be performance.

### 5.3 Numerical Results

The pilot's numerical results offer a clear overview of the impact achieved by each component of the defect-reduction model. As shown in **Table 5**, the comparison between the As-Is and To-Be conditions highlights the improvements obtained through the BPM-based process structuring, the application of Standardized Work, and the Poka-Yoke mechanism, evidencing reductions in variability and defect rates across the system.

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Table 5. Validation results

| Component | Key Indicator | As-Is Value | To-Be Value | Improvement Achieved |
|---|---|---|---|---|
| C1: Standardization of Dry-Blending | Std. deviation of blending time (s) | 19.81 | 5.06 | −14.75 |
| | % of color-related defects | 5.69% | 1.69% | −4.00% |
| C2: BPM in Mold Management | % of mold-related defects | 10.62% | 4.13% | −6.49% |
| | % of molds cleaned before production | 25% | 82.33% | 57.33% |
| C3: Screen-Printing Poka-Yoke | % of misalignment defects | 12% | 3.03% | −8.97% |
| **Global Defect Rate** | **% of total defects** | **14.91%** | **7.84%** | **−7.07%** |

The results suggest that the combined implementation of BPM, Standard Work, and Poka-Yoke generated complementary effects across the production system. While Standard Work reduced execution variability during dry blending, BPM strengthened process discipline and consistency in mold-conditioning activities, and the Poka-Yoke mechanism minimized alignment deviations during screen printing. The simultaneous reduction of process variability, operational informality, and operator-dependent errors explains the substantial decrease in the global defect rate observed during the pilot implementation.

## 5.4 Discussion

The results demonstrate that defect generation in highly manual MTO plastics SMEs is strongly associated with operational variability and process informality. The reduction observed after implementation confirms that structured operational routines can significantly improve process stability even in low-automation environments. The findings are consistent with the previous studies of Almashaqbeh and Hernandez (2024) and Hsiao et al. (2023) that reported the positive effects of Standard Work and BPM on operational stability. However, unlike previous investigations conducted in mature or semi-automated manufacturing systems, the present study validates these approaches within a highly manual make-to-order SME characterized by informal workflows and limited technological resources. Similarly, while prior studies frequently rely on sensor-based or automated Poka-Yoke systems, the present study demonstrates that low-cost physical alignment mechanisms can also effectively reduce variability in manual screen-printing operations.

The principal contribution of this research lies in the integration of Standard Work, BPM, and Poka-Yoke within a unified operational framework specifically adapted for highly manual MTO plastics SMEs. While previous studies generally evaluate these approaches independently, this research demonstrates how their coordinated implementation can simultaneously address process instability, operational informality, and operator-dependent defects. Additionally, from a managerial perspective, the proposed model offers SMEs a practical and low-investment alternative for improving product quality without requiring advanced automation technologies. The interventions can be progressively implemented using existing operational resources, making the framework accessible for small manufacturing firms operating in emerging economies.

## 5.5 Limitations

This study presents certain limitations. Validation was conducted in a single SME and focused on one product family under controlled pilot conditions. Therefore, the generalizability of the results may be limited. Additionally, the pilot implementation was evaluated over a relatively short period, which restricts assessment of long-term sustainability and organizational adaptation. Future research could evaluate the proposed framework in larger production systems, different plastics applications, or longer implementation periods to analyze scalability and long-term operational performance.

## 6. Conclusion

The implementation of the integrated Lean–BPM model significantly reduced the defect rate within the studied SME, demonstrating the effectiveness of combining Standard Work, BPM, and Poka-Yoke to address operational variability in highly manual MTO environments. Standard Work reduced variability in the dry-blending activity, ensuring color consistency. Additionally, the Poka-Yoke alignment mechanism effectively minimized operator-dependent misalignments during screen printing. Collectively, these measures led to a significant reduction in the overall defect rate, from 14.91% to 7.84%. While this value did not reach the sector benchmark of 6.6%, it signifies notable progress, validating the positive impact of the integrated model and establishing a robust foundation for future enhancements and that quality improvement in plastics SMEs does not necessarily require advanced automation technologies. Instead, structured operational control and low-cost preventive mechanisms can substantially improve process stability and product conformity.

To improve the model even further and move closer to the sector benchmark, it would be necessary to strengthen the sustainability of the improvements, as the components did not incorporate long-term control routines. The dry-blending stage requires supportive mechanisms that prevent operators from reverting to inconsistent practices; mold management needs preventive-maintenance routines, audits, and traceability to ensure stable mold conditions over time; and for the screen-printing process, it is necessary to establish a standardized method for operating the Poka-Yoke device so that its use remains consistent and reliable. Incorporating these sustainability elements would help preserve process stability and enable deeper defect reduction in future iterations of the model.

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