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Quality Improvement of X Brand Tube Packaging PT XYZ Using the Six Sigma Method and Failure Mode and Effect Analysis (FMEA)

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Abstract. PT XYZ is a manufacturing company producing cosmetic products, including 180 ml lotion packaged in tubes. Production data from January to July 2024 indicate an average defect rate of 0.82%, exceeding the company's maximum tolerance limit of 0.8%. This study aims to evaluate process performance using the sigma level, identify the root causes of packaging defects, and propose effective quality improvement measures. The research employs the Six Sigma methodology integrated with Failure Mode and Effect Analysis (FMEA) through the DMAIC (Define, Measure, Analyze, Improve, and Control) framework. The results identify four dominant defect types: unsealed sealing, damaged caps, damaged batches, and dented containers. The initial process performance shows an average sigma level of 3.27, indicating suboptimal quality conditions. FMEA results reveal that the primary causes of defects are worn machine components, imprecise dosing and sealing mechanisms, and the absence of standardized work instructions. Improvement actions include replacing critical machine components, optimizing machine parameters, implementing bulk material viscosity control, and installing a leakage tester. Post-implementation evaluation demonstrates a significant improvement in quality performance, with the sigma level increasing to 4.30 and the average defect rate decreasing by 96.65%. These findings confirm that the integration of Six Sigma and FMEA is effective in reducing packaging defects and enhancing process stability in cosmetic manufacturing.

Keywords: Failure Mode and Effect Analysis (FMEA); Quality Improvement; Sigma Level; Six Sigma; Tube Packaging

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1. Introduction

Industry can be defined as a group of companies that produce and market similar goods or services, which are generally classified into service industries and manufacturing industries. The manufacturing industry focuses on transforming raw materials into value-added products through structured processes, ranging from production planning to quality control, to ensure that products meet established standards and are competitive in the market (Hutabarat, 2022). Amid increasing global competition, the manufacturing sector in Indonesia plays a crucial role in supporting national economic growth by generating added value through innovation and consistent product quality.

Product quality is a critical factor influencing consumer purchasing decisions and brand trust. Therefore, maintaining quality is essential for companies to sustain competitiveness and long-term viability. However, in practice, manufacturing processes frequently encounter quality issues in the form of defective products that fail to meet specifications in terms of functionality, physical appearance, or packaging integrity. The presence of defects not only reduces production efficiency and customer satisfaction but also increases quality-related costs, including inspection, rework, and corrective actions (Yusuf & Supriyadi, 2020).

PT XYZ is a manufacturing company operating in the Fast Moving Consumer Goods (FMCG) sector, producing skin care and adhesive products. As an FMCG manufacturer, the company is required to maintain high and consistent product quality to meet large-scale market demand. Nevertheless, quality problems have been identified in Brand X cosmetic products packaged in tubes, as evidenced by complaints from both consumers and distributors. These complaints indicate that the current quality control system has not yet operated optimally and requires further evaluation and improvement.

Several types of defects have been observed in the tube-packaged products, including improper sealing, dented tubes, damaged batches, and defective caps. To control product quality, PT XYZ has established a maximum defect tolerance of 0.8% of total production output. Exceeding this threshold is considered a sign of process deviation that requires immediate corrective action. However, production data from January to July 2024 show that the defect rate of the 180 ml lotion product frequently exceeded the allowable limit, as presented in Table 1.

Table 1. Total Production of 180 ml Tube-Packaged Lotion (Brand X)

Month	Total Production (Pcs)	Total Product Reject (Pcs)	Reject Percentage (%)
Januaty	1.198.512	6.422	0,55%
February	1.048.320	6.500	0,62%
March	1.895.040	12.576	0,66%
April	2.096.640	17.284	0,82%
May	1.290.240	14.136	1,10%
June	1.411.200	12.861	0,91%
July	1.209.600	12.822	1,06%
Total	**10.149.552**	**82.601**	**0,82%**

Based on the data, the defect rate fluctuated throughout the observed period, with four out of seven months exceeding the company's tolerance limit of 0.8%. The overall rejection rate during this period reached 0.82%, indicating that the production process has not yet achieved a stable and consistent level of quality. This condition highlights the need for systematic identification of defect causes and structured improvement efforts to prevent recurring quality issues.

One widely used approach for quality improvement is the Six Sigma method, which emphasizes process control and defect reduction through a structured, data-driven framework known as DMAIC (Define, Measure, Analyze, Improve, and Control) (Rifaldi & Sudarwati, 2024). In addition, Failure Mode and Effect Analysis (FMEA) can be applied to identify potential failure

modes by evaluating their severity, occurrence, and detection, thereby enabling the prioritization of corrective actions based on risk levels (Backtiar et al., 2021).

Previous studies have demonstrated the effectiveness of the Six Sigma method in reducing defects in packaging processes. Hartono et al. (2024) applied DMAIC and FMEA to analyze tube packaging defects at PT Arisu and reported significant quality improvements. Similarly, Muhtadin (2022) and Anbiya (2021) showed that the Six Sigma DMAIC approach effectively reduced defects in rice seed packaging processes at PT Agri Makmur Pertiwi. However, many previous studies focused primarily on defect reduction without emphasizing risk prioritization as a basis for improvement planning. Therefore, this study integrates the Six Sigma DMAIC framework with FMEA to systematically identify dominant defect causes, prioritize failure risks, and formulate more targeted and effective improvement strategies for tube-packaged cosmetic products at PT XYZ.

2. Methods

This study adopts a quantitative–descriptive approach using the Six Sigma methodology integrated with Failure Mode and Effect Analysis (FMEA) to analyze and reduce packaging defects at PT XYZ. The research stages consist of a preliminary study, data collection, data processing using the DMAIC framework, and analysis of results followed by conclusions and recommendations. The overall research procedure is illustrated in Figure 1.

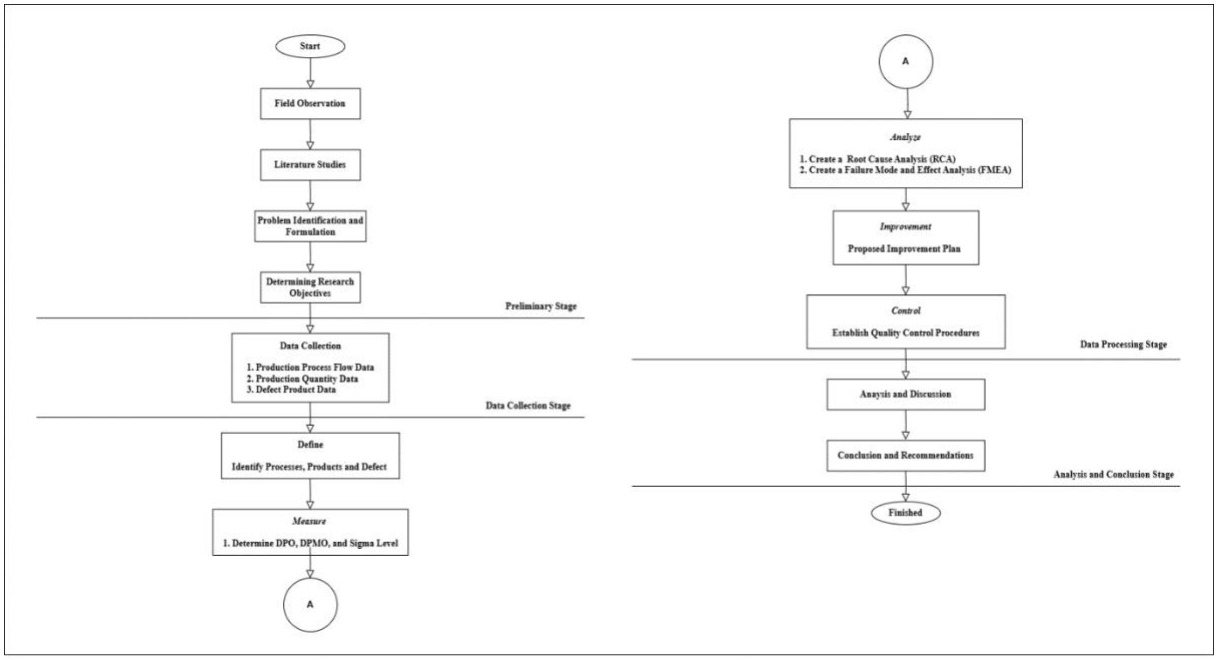


Figure 1. Flowchart

Preliminary Study

The preliminary study represents the initial stage of the research and aims to identify and formulate quality-related problems in the tube packaging process at PT XYZ. Activities conducted at this stage included direct observations in the production area to obtain an in-depth understanding of the packaging process and to identify types of defects occurring on the production line. These observations were complemented by semi-structured interviews with operators, line leaders, and quality control personnel to capture practical insights regarding operational constraints and quality issues.

In addition, a literature review was conducted to strengthen the theoretical foundation related to quality improvement, particularly the application of the Six Sigma and FMEA methods (Alfarizi et al., 2023). Based on field observations, interview results, and relevant literature, the dominant quality problems and potential defect causes were identified, and the research problem

was formulated to define the focus of improvement. The primary objective of this study is to reduce packaging defect rates by prioritizing defect risks using FMEA and by proposing improvement solutions that are feasible for implementation at PT XYZ (Andriana & Noya, 2016; Bachtiar et al., 2021).

Data Collection

Data collection was carried out to obtain a comprehensive and realistic representation of the production process and packaging quality performance. Two types of data were used in this study, namely primary data and secondary data.

Primary data were obtained through direct observations and interviews with operators and production personnel to understand process flows, identify potential defect causes, and support the development of root cause analysis (RCA) and FMEA. Secondary data were collected from internal company documents, including machine specifications, packaging material characteristics, production volumes, and historical defect data over a defined observation period. These secondary data served as the basis for quantitative performance measurement and comparative analysis.

Data Processing Using the DMAIC Approach

Data processing was conducted using the Six Sigma method through the DMAIC (Define, Measure, Analyze, Improve, and Control) cycle to systematically evaluate process performance and identify improvement opportunities.

In the **Define** stage, the types of defects occurring in the tube packaging process were identified and classified based on production records and field observations. The **Measure** stage focused on evaluating process performance by calculating Defects per Opportunity (DPO), Defects per Million Opportunities (DPMO), and the sigma level using the following equations:

$$\text{DPO} = \frac{\text{Total defects}}{\text{Total production quantity x defect opportunity}} \quad (1)$$

$$\text{DPMO} = \left(\frac{\text{D}}{\text{U x O}}\right) \text{x } 1.000.000 \quad (2)$$

$$Sigma\ level = \text{NORMSINV}\left(1 - \frac{\text{DPMO}}{1.000.000}\right) + 1{,}5 \quad (3)$$

In the **Analyze** stage, root cause analysis was performed using a fishbone diagram to identify potential causes of defects. Subsequently, FMEA was applied to assess each failure mode based on severity (S), occurrence (O), and detection (D). The Risk Priority Number (RPN) was calculated to determine improvement priorities (Tang, 2021; Bhagwati, 2023; Gazpers, 2007), as shown in Equation (4):

$$\text{RPN} = \text{Severity (S) x Occurrence (O)x Detection (D)} \quad (4)$$

The **Improve** stage focused on developing and proposing corrective actions aimed at reducing defect levels, lowering DPMO values, and improving the sigma level. Improvement proposals were formulated based on the highest RPN values to ensure that corrective actions targeted the most critical failure modes. Finally, the **Control** stage aimed to sustain improvement results through the implementation of standard operating procedures (SOPs), control checklists, and continuous monitoring of quality performance indicators to ensure process consistency.

Analysis of Results and Conclusion

The final stage of the research involved analysis and discussion of the results obtained from each phase of the DMAIC cycle. This stage evaluated the effectiveness of the proposed improvements by comparing process performance before and after implementation. The study concludes with the formulation of conclusions aligned with the research objectives and the development of practical recommendations as strategic guidance for PT XYZ to maintain product quality and support continuous improvement initiatives.

3. Results and Discussion

Production Process Overview

The production process in the cosmetics department at PT XYZ operates continuously, utilizing IWK automatic machines for filling and sealing products into tube packaging. These machines are designed to ensure filling volume accuracy, maintain hygienic conditions, and guarantee sealing quality so that packaging remains intact during handling and distribution.

The production process of Product X on the IWK machine begins at the **Tube Feeding Station**, where empty tubes are temporarily stored in a buffer tube (TZF) to maintain a stable supply and prevent production interruptions. Tubes are then automatically directed to a prism component that transfers them into the holder. The presscone subsequently pushes the tube into position with precision. Prior to filling, a **dedusting process** using a vacuum system is conducted to remove dust and contaminants from the tube interior.

At the **Print Registration Stage**, an eyemark sensor reads the orientation mark on the tube to ensure alignment between the printed design and the nozzle direction. The process then continues to the **Dosing and Filling Station**, where the product is filled automatically with high accuracy to meet volume specifications. Following filling, the tube tip is heated at the **Hot Air Station** to soften the material and prepare it for sealing without damaging the tube structure.

Sealing and coding occur simultaneously at the **Pressing and Embossing Station**, where batch numbers and expiration dates are printed. The sealed tubes then pass through a **chiller** to stabilize the seal. Subsequently, at the **Trimming Station**, excess material from the pressed end is cut to ensure neat and symmetrical packaging in accordance with aesthetic standards. The final stage is **Ejection**, an automated sorting process that separates acceptable products (good bin) from defective ones (reject bin) based on sensor detection. Products that pass all inspection stages are transferred to the conveyor and sent to the packaging area as finished goods (FG). The integration of these stages ensures process efficiency, cleanliness, and consistent quality.

Defect Data Analysis

Production and defect data for Product X were obtained from the Quality Control (QC) department of PT XYZ, specifically from the cosmetics production line. The dataset consists of daily records of total production output and defective products, compiled from routine in-process inspections. The data analyzed include production volumes and defect types observed in 180 ml tube-packaged products during the period April–July 2024, as presented in **Table 2**.

Table 2 Product Defect Data for The Period April-July 2024

Month	Week	Production Quantity (Pcs)	Number of Defective Products (Pcs)				Total Defective Products
			Unsealed Sealing	Damaged Caps	Damaged Batch	Dented Containers	
April 2024	Week-1	524.536	3.000	201	463	622	17.284
	Week-2	523.992	3.067	217	449	688	
	Week-3	524.726	3.084	224	432	631	
	Week-4	523.386	2.933	216	409	648	
May 2024	Week-1	322.561	2.487	169	329	495	14.136
	Week-2	323.139	2.505	154	334	565	
	Week-3	322.306	2.523	167	348	552	
	Week-4	322.234	2.425	181	364	538	
June 2024	Week-1	353.917	2.226	165	326	516	12.861
	Week-2	352.165	2.239	151	309	526	
	Week-3	352.075	2.215	141	325	465	
	Week-4	353.043	2.241	173	337	506	
July 2024	Week-1	301.906	2.197	157	330	501	12.822
	Week-2	302.412	2.145	154	349	525	

Week-3	303.148	2.248	153	312	497	
Week-4	302.134	2.281	174	310	489	
Total	**6.007.680**	**39.816**	**2.797**	**5.726**	**8.764**	**57.103**

Table 2 shows that total production during the observation period reached 6,007,680 units, with 57,103 defective products identified. Defects were classified into four main categories: unsealed sealing, damaged caps, damaged batches, and dented containers. Across all months and weeks, **unsealed sealing defects consistently represented the highest proportion**, indicating that sealing performance is the most critical quality issue in the tube packaging process.

Measure Stage: DPO, DPMO, and Sigma Level

In the **Measure** stage, defect data were used to calculate Defects per Opportunity (DPO), Defects per Million Opportunities (DPMO), and sigma level as indicators of process capability. These metrics provide quantitative insight into process performance and the likelihood of defects occurring relative to available defect opportunities. The calculation results are presented in **Table 3**.

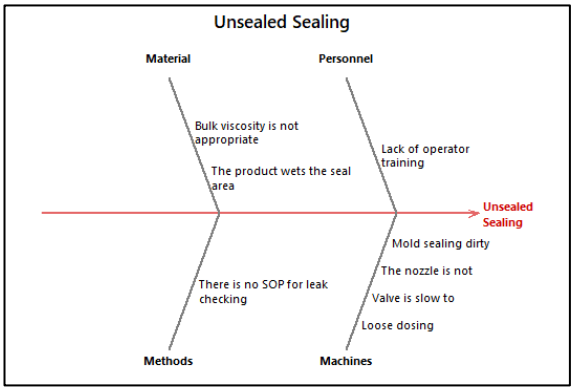
Tabel 3 DPMO and Sigma Values of Products April-July 2024

Month	Production Quantity (Pcs)	Total Defective (Pcs)	DPO	DPMO	*Level Sigma*
April 2024	2.096.640	17.284	0,032974664	32974,66422	3,34
May 2024	1.290.240	14.136	0,043824405	43824,40476	3,21
June 2024	1.411.200	12.861	0,036454082	36454,08163	3,29
July 2024	1.209.600	12.822	0,042400794	42400,79365	3,22
Average	**6.007.680**	**57.103**	**0,038913486**	**38913,48607**	**3,27**

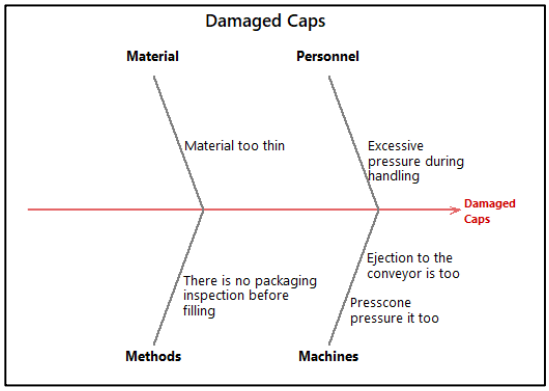
Based on **Table 3**, process performance fluctuated between April and July 2024. The best performance occurred in April, with the lowest DPO value (0.0329) and the highest sigma level (3.34), while the worst performance was recorded in May, with the highest DPO (0.0438) and the lowest sigma level (3.21). The average sigma level during the four-month period was 3.27, which falls within the *industry average* category. Although acceptable, this level indicates that the production process still incurs substantial quality costs—estimated at 20–30% of total production costs—and therefore has considerable potential for improvement.

Analyze Stage: Root Cause Analysis and FMEA

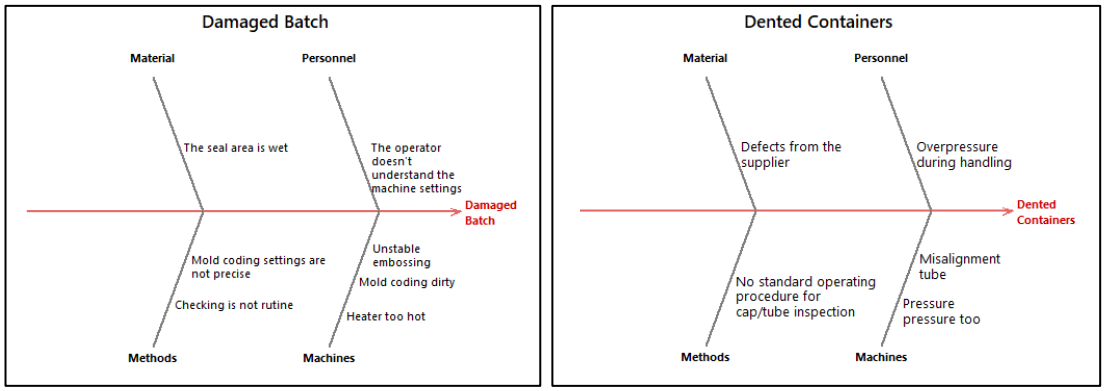
Following performance measurement, the **Analyze** stage was conducted to identify the root causes of defects using Root Cause Analysis (RCA). Defect causes were analyzed based on five main factors: people, methods, machines, materials, and the environment. The results of the RCA for each defect type are illustrated in **Figure 3**, covering (a) unsealed sealing, (b) damaged caps, (c) damaged batches, and (d) dented containers.



a



b



c d

Figure 3 a. unsealed sealing defect, b. damaged caps, c. damaged batch, d. dented containers

The RCA results served as the foundation for developing the **Failure Mode and Effect Analysis (FMEA)**. FMEA was applied to evaluate each potential failure mode by assessing severity, occurrence, and detection, followed by calculating the Risk Priority Number (RPN). The detailed FMEA results are presented in **Table 4**.

Tabel 4 FMEA Analysis

Process Function	***Potential Failure Mode***	***Potential Failure Effect***	***Seve...***	***Possible Cause of Failure***	***Occu...***	***Current Control***	***Dete...***	**RPN**
Filling	unsealed sealing	Reject	8	**Material (bulk)** Bulk viscosity is not appropriate	5	Bulk viscosity check after mixing (1300-3000 mPas)	5	**200**
				Material (bulk) The product wets the seal area	5	Setting machine seal parameters	5	**200**
				Man Lack of operator training	5	Regular training and performance evaluation of operators by supervisors	4	**160**
				Machine Mold sealing dirty	6	Cleaning of mold seals after each batch change and visual inspection before start-up	6	**288**
				Machine The nozzle is not precise	8	Regular calibration and adjustment of nozzles by maintenance technicians	6	**384**
				Machine Valve is slow to respond	8	Weekly preventive maintenance	7	**448**
				Machine Loose dosing	8	Calibration and dosing adjustment are performed regularly by maintenance technicians	7	**448**
				Method There is no SOP for leak checking	7	Leak checks in the control process	6	**336**
Tube Feeding	dented containers	Not Good product (NG)	5	**Material (tube)** Material too thin	5	Sampling by the QC team	4	**100**
				Man Overpressure during handling	6	SOP for handling tubes under the supervision of the operator leader	6	**180**

					and the use of handling aids		
				Machine Ejection to the conveyor is too hard	7	Adjustment of ejection piston pressure	6	**210**
				Machine Presscone pressure it too hard	5	Presscone pressure validation for each batch and recording of machine parameters	5	**125**
				Method There is no packaging inspection before filling	6	Sampling of packaging before entering the filling machine (QC Line Check)	5	**150**
Pressing and Embossing	damaged batch	Reject	7	**Material (tube)** The seal area is wet	7	Visual inspection of the seal area before the coding process	7	**343**
				Man The operator doesn't understand the machine settings	6	Training on embossing settings and embossing coding SOPs is provided, and operator performance is evaluated periodically	5	**210**
				Machine Unstable embossing pressure	7	Digital monitoring of coding pressure and temperature and recording of parameters by the leader of each batch.	4	**196**
				Machine Mold coding dirty	6	Cleaning of the coding mold for each batch and at start-up.	6	**252**
				Machine Heater too hot	5	Checking the heater temperature and routine calibration of the machine.	4	**140**
				Method Mold coding settings are not precise	7	Validation of embossing results by the operator after start-up and batch change.	6	**294**
				Method Checking is not rutine	5	Checking by the packing operator.	5	**175**
Tube Feeding	damaged caps	not good product (NG)	5	**Material (tube)** Defects from the supplier	7	Inspection of incoming materials by QC	5	**175**
				Man Overpressure during handling	6	SOP for handling tubes under the supervision of the operator leader and using handling tools	6	**180**
				Machine Misalignment tube	7	Checking by the operator leader	5	**175**
				Machine Pressure pressure too high	5	Validation of presscone pressure for each batch and recording of machine parameters	5	**125**
				Method	6	Sampling of packaging before entering the	5	**150**

		No standard operating procedure for cap inspection	filling machine (QC Line Check)

The FMEA results indicate that many failure causes have RPN values ≥ 200, placing them in the **high-risk category**. The most critical failure causes include slow valve response and loose dosing (RPN 448), as well as imprecise nozzles (RPN 384). These failure modes reflect a combination of high severity, frequent occurrence, and low detectability. Furthermore, Action Priority Level (APL) analysis shows that most high-RPN causes fall into the **red (high)** APL category, requiring immediate corrective actions, while medium (yellow) and low (green) APL categories can be controlled through procedural improvements and supervision.

Improve Stage: Recommendation and Implementation

Based on the FMEA results, improvement recommendations were formulated and prioritized according to RPN and APL categories. The proposed corrective actions for each failure mode are presented in **Table 5**. Priority was given to addressing high-risk failure causes, while preventive actions were also defined for moderate- and low-risk issues to ensure sustainable quality improvement.

Tabel 5 Recommendation Action

Potential Failure Mode	Potential Failure Effect	Possible Cause of Failure	Recommendation Action
unsealed sealing	Reject	**Material (bulk)** Bulk viscosity is not appropriate	Regularly check viscosity and maintain bulk temperature parameters before tapping into IBC.
		Material (bulk) The product wets the seal area	Optimize sealing parameters and conduct routine inspections and cleaning of the seal area to prevent bulk contamination on the seal surface.
		Man Lack of operator training	Improve training effectiveness with hands-on methods, defect simulations, and regular work performance evaluations.
		Machine Mold sealing dirty	Adding deep cleaning with a special solution and detailed inspection using visual aids (flashlight/loupe).
		Machine The nozzle is not precise	Replacing the nozzle with a higher precision type and adding daily alignment inspections before startup.
		Machine Valve is slow to respond	Performing periodic valve overhauls and replacing worn components after a certain cycle limit.
		Machine Loose dosing	Replace the dosing unit and ensure installation according to torque standards.
		Method There is no SOP for leak checking	Add a Tube Leakage Tester and implement an SOP leak test before the product enters packaging.
dented containers	Not Good product (NG)	**Material (tube)** Material too thin	Evaluate tube specifications with the supplier and conduct incoming material testing.
		Man Overpressure during handling	Provide retraining on proper handling techniques and conduct regular evaluations.
		Machine Ejection to the conveyor is too hard	Replace the ejection piston with a low-speed type or add a pressure damper.

		Machine Presscone pressure it too hard	Validate presscone pressure at the start of the batch according to parameters
		Method There is no packaging inspection before filling	The operator leader conducts a visual inspection before handling the packaging to the buffer tube
Pressing and Embossing	damaged batch	**Material (tube)** The seal area is wet	Optimize sealing parameters and conduct routine inspections and cleaning of the seal area to prevent bulk contamination on the seal surface
		Man The operator doesn't understand the machine settings	Conduct on-the-job training on production machines and periodic operator competency tests.
		Machine Unstable embossing pressure	Periodic maintenance
		Machine Mold coding dirty	Add deep cleaning with a special solution and detailed inspection using visual aids (flashlight/loupe)
		Machine Heater too hot	Cleaning & periodic maintenance on the heater, install a temperature alarm
		Method Mold coding settings are not precise	Add visual guides (guide jigs) on the mold and precision checklists before startup
		Method Checking is not rutine	Schedule regular inspections with daily checklists that must be filled out by the packing operator.
Tube Feeding	damaged caps	**Material (tube)** Defects from the supplier	Incoming QC must perform tensile and visual cap tests, and send feedback to the supplier every month.
		Man Overpressure during handling	Provide retraining on proper handling techniques and conduct regular evaluations.
		Machine Misalignment tube	Add cap position detection sensors.
		Machine Pressure pressure too high	Validate presscone pressure at the start of the batch according to parameters.
		Method No standard operating procedure for cap inspection	Develop and implement SOPs for cap inspections and train operators on their implementation.

Implementation focused primarily on failure causes classified under the red APL category. Key corrective actions included replacing critical IWK machine components, particularly in the dosing piston unit and its drive system, and strengthening preventive maintenance activities. Critical spare parts such as lip seals, O-rings, and rotary valves were identified and stocked to prevent unplanned downtime. Viscosity checks of bulk materials prior to filling were implemented to ensure product stability, and IWK machine parameters were adjusted to improve dosing accuracy and sealing quality.

In addition, a **Leakage Tester** and **Vacuum Desiccator** were installed to enhance leak detection capability. Moderate- and low-risk failure causes were managed through the development and enforcement of SOPs and work instructions to maintain overall process control.

Post-Improvement Evaluation

After the implementation of improvements, production quality was monitored during January–March 2025. Defect data were collected and analyzed to recalculate DPO, DPMO, and sigma levels. The post-improvement defect data are presented in **Table 6**, while the corresponding DPMO and sigma values are shown in **Table 7**.

Tabel 6 Product Defect Data for The Period January-March 2024

Month	Week	Production Quantity (Pcs)	Number of Defective Products (Pcs)				Month
			Unsealed Sealing	Damaged Caps	Damaged Batch	Dented Containers	
Jan 2025	Week-1	322.560	-	43	41	92	**702**
	Week-2	524.160	-	34	42	100	
	Week-3	323.064	-	28	41	106	
	Week-4	121.056	-	40	33	102	
Feb 2025	Week-1	120.960	-	38	39	64	**563**
	Week-2	282.480	-	34	35	72	
	Week-3	287.424	-	25	30	86	
	Week-4	282.288	-	42	32	66	
Mar 2025	Week-1	320.232	-	37	39	140	**647**
	Week-2	235.944	-	33	35	148	
	Week-3	247.704	-	40	60	115	
Total		**3.067.872**	**-**	**394**	**427**	**1.091**	**1.912**

Tabel 7 DPMO and Sigma Values of Products April-July 2024

Month	Production Quantity (Pcs)	Total Defective (Pcs)	DPO	DPMO	*Level Sigma*
Jan-25	1.290.840	702	0,00217533	2175,328	4,35
Feb-25	973.152	563	0,00231413	2314,13	4,33
Mar-25	803.880	647	0,00321939	3219,386	4,22
Average	**3.067.872**	**1.912**	**0,00256961**	**2569,614**	**4,30**

The results demonstrate a substantial improvement in process performance. The average DPMO decreased significantly from 38,913 to 2,569, indicating a drastic reduction in defect occurrences. Simultaneously, the average sigma level increased from 3.27 to 4.30, reflecting a more stable and capable production process approaching world-class performance standards. These improvements confirm the effectiveness of the integrated Six Sigma DMAIC and FMEA approach in addressing critical quality issues related to people, machines, methods, and materials.

Control Stage

Quality improvement efforts were sustained through the **Control** stage of the DMAIC cycle. Control mechanisms included the implementation of SOPs, Work Instructions (WIs), and daily check sheets used by operators to monitor quality and productivity. To enhance operational understanding, **One Point Lessons (OPLs)** were developed for IWK machine settings and leakage tester operation. Additionally, a dedicated **In-Process Control (IPC)** checklist was introduced for leak inspection. These control tools were systematically documented and implemented to ensure long-term consistency and sustainability of quality improvements in the production process.

4. Conclusions

This study identified several critical quality issues in the tube packaging process at PT XYZ, including unsealed sealing, dented containers, damaged batches, and damaged caps. Through the integrated application of the Six Sigma DMAIC framework and Failure Mode and Effect Analysis (FMEA), unsealed sealing was identified as the most dominant defect type and classified as a high-risk failure mode with the highest Risk Priority Number (RPN) and Action Priority Level (APL high). The analysis revealed that key contributing factors included loose dosing, slow valve response, imprecise nozzle performance, and wet seal areas.

Based on these findings, targeted improvement actions were implemented, including the replacement and recalibration of critical IWK machine components, optimization of process parameters, routine bulk material viscosity control, and the installation of a leakage tester to

enhance defect detection. These technical improvements were reinforced through the implementation of control mechanisms, such as In-Process Control (IPC) checklists, standard operating procedures, and One Point Lessons (OPLs), to ensure consistency and sustainability of the improvement outcomes.

The effectiveness of the proposed improvements was demonstrated by a substantial reduction in defects of 96.65% and a significant increase in the sigma level from 3.27 to 4.30. These results indicate a marked improvement in process stability and quality performance, bringing the tube packaging process closer to world-class manufacturing standards. Overall, this study confirms that the integration of Six Sigma DMAIC and FMEA provides an effective and systematic approach for reducing packaging defects and supporting continuous quality improvement in FMCG manufacturing environments.

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