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Enhancement of Foley Catheter Assembly Section Quality using Six Sigma (A Case Study of an Indonesian Medical Device Company)

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ABSTRACT: This study aims to enhance the quality of the Foley catheter assembly section at PT XYZ, an Indonesian medical device manufacturer, using Six Sigma methodology. PT XYZ currently faces an 8% defect rate in its Foley catheter assembly section, surpassing the acceptable 3% threshold. The current Sigma level of the Shrink process within the assembly section is 2.36, while the Balloon Vulcanizing and Assembly process stands at 2.68. The Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) framework was used to identify and address root causes of defects. Data collection methods included interviews, questionnaires, and field observations, revealing key issues such as incorrect tray loading, machine calibration errors, operator skill variability, and inadequate handling techniques. Proposed improvements include updating Standard Operating Procedures (SOPs), implementing SCAMPER for calibration, comprehensive training programs, and incentive schemes. Additional measures involve template overlays for precise cutting, vendor maintenance, and control charts for consistency. The Control phase ensures sustainability through documentation, training, and monitoring using control charts and Failure Modes and Effects Analysis (FMEA). Implementing these solutions is expected to reduce the defect rate and elevate the Sigma level of both processes to 3, enhancing process efficiency and product quality. This will improve operational efficiency and customer satisfaction, providing a robust framework for PT XYZ to elevate its quality control and contribute to better healthcare device manufacturing in Indonesia.

KEYWORDS: DMAIC, Foley catheters, Medical Device, Quality Improvement, Six Sigma.

INTRODUCTION

With over 270 million citizens, Indonesia is the fourth most populous country globally and the largest archipelago, characterized by diverse cultures and languages. Addressing the healthcare needs of such a vast population is critical, particularly the use of Foley catheters for urine drainage. These catheters are essential in managing patients undergoing surgery or those with urinary incontinence and retention. Recent research highlights the significant growth of catheterization laboratories (cath labs) in Indonesia, increasing from 181 in 2017 to 310 by the first half of 2022, representing a 71.3% increase.. Java, the most populous island, hosts 208 of these facilities (Muharram et al., 2023). This expansion is crucial in providing accessible and efficient healthcare services across the archipelago. The higher the demand for healthcare services, the more essential it becomes to ensure rigorous quality assurance measures. As the demand for catheterization and other medical procedures continues to rise, maintaining high standards of quality assurance in these facilities becomes increasingly important.

PT. XYZ, an Indonesian company established in 2020, specializes in the production of medical devices within the pharmaceutical industry. The company focuses on manufacturing feeding tubes and catheters, including a variety of Foley catheters made from silicone, a widely used material for such medical devices. PT. XYZ operates offices in both Jakarta and Bandung, positioning itself as a significant player in the medical equipment sector in Indonesia. As demand for high-quality medical devices grows, PT. XYZ's expertise in producing reliable and effective products like Foley catheters becomes increasingly critical to supporting the healthcare infrastructure.

BUSINESS ISSUE

The implementation of quality control across the production process at PT. XYZ is currently suboptimal. In 2023, PT XYZ faces an 8% defect rate in the production of Foley catheters, Ryles, and Levin tubes, which significantly exceeds the company's acceptable threshold of 3%. Among these products, Foley catheters contribute the largest proportion of defects, accounting for 7.24% of the total, compared to 0.34% for Levin and 0.33% for Ryles. This highlights a serious quality control problem specific to Foley catheters.

The production process of Foley catheters at PT. XYZ is divided into three sections: extrusion, injection, and assembly. While the assembly section is the most significant source of defects, with 71,929 defective pieces, followed by the extrusion section with 3,196 defects, and the injection section with 2,619 defects. According to the production manager, the high defect rate in the assembly section is primarily due to its reliance on manual labor and the precise placement required for components like the balloon and inflation port, where human error often results in issues such as leaks or malfunctioning inflation mechanisms.

The primary objective of this research is to enhance the quality of the Foley catheter assembly section at PT. XYZ by identifying key variables responsible for the high volume of defective products. This study aims to analyze the current quality control approaches employed by PT. XYZ, evaluating their effectiveness in addressing the problem. Based on this analysis, the research will provide a feasible approach to improve the quality of the Foley catheter assembly section as well as control plan strategy, with the goal of reducing defects, enhancing process efficiency, and ensuring higher product quality, thereby helping PT. XYZ achieve its acceptable defect rate threshold and improve overall operational performance.

LITERATURE REVIEW

A. Six Sigma

Six Sigma is a strategic approach and methodology used to achieve enhancements in multiple areas of an organization, such as profitability, quality of products/services, productivity, and customer happiness (Montgomery & Woodall, 2008). The fundamental principle of Six Sigma revolves around the sigma level, which measures the ability of a process to do flawless work. A higher sigma level signifies superior process performance and a reduced number of faults (Montgomery & Woodall, 2008). As the sigma value increases, the cost decreases, cycle time decreases, and customer satisfaction increases (Mahajan, 2008).

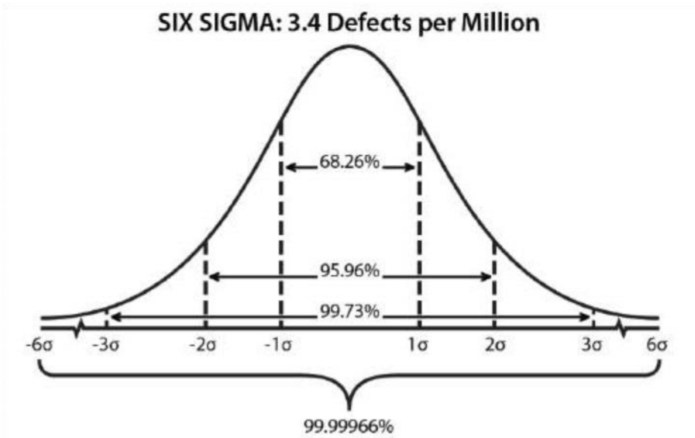

Figure 2.1 The Mathematics of Six Sigma (Kumar & Muthukumaar, 2018)

Figure 2.1 illustrates the mathematical principles of Six-Sigma. The areas under the curve between different standard deviations show the cumulative percentage of data points. For example, 68.26% of data points fall within ±1σ from the mean indicates 68.27% of the process output meets customer requirements, 95.96% fall within ±2σ indicates 95.96% of the process output meets customer requirements, and so on with 99.73% fall within ±3σ. In particular, "Six Sigma" describes a process performance level that strives to reach an exceptionally low defect rate of 3.4 defects per million chances (DPMO). This indicates that the procedure can generate 99.99966% error-free outputs, according to statistics.

B. DMAIC as the Six Sigma Methodology

Drawing from Thomas Pyzdek's (2003) book *The Six Sigma Handbook : A complete Guide for Green Belts, Black Belts, and Managers at All levels* the following concisely summarizes the five phases of DMAIC, a component of the Six Sigma Methodology:

- Define: Identify the goals of the improvement activity, prioritizing customer-derived objectives. At the strategic level, goals include customer loyalty, higher ROI, increased market share, or employee satisfaction. Operational goals might focus on increasing production throughput, while project-level goals could target defect reduction and process efficiency. Gather goals through direct communication with customers, shareholders, and employees.

- Measure: Assess the current system by establishing valid and reliable metrics to monitor progress towards the defined goals.
- Analyze: Examine the system to bridge the gap between current performance and desired goals. Determine the current baseline and utilize exploratory and descriptive data analysis, supported by statistical tools, to understand the data.
- Improve: Enhance the system by innovating to achieve better, cheaper, or faster results. Implement new approaches using project management and planning tools, and validate improvements through statistical methods.
- Control: Institutionalize the improvements by updating compensation, incentives, policies, procedures, MRP, budgets, and operating instructions. Consider standardization, such as ISO 9000, to ensure correct documentation. Use statistical tools to maintain the stability of the new systems.

C. *Competitive Level*

Attaining a Six Sigma level can result in just 3.4 defects per million opportunities (DPMO), reflecting a near-perfect defect elimination rate of 99.9997% in products and services delivered to customers (Nanda and Robinson, 2011). This significant reduction in defects can lower the cost of poor quality to less than 10%, making it a highly desirable goal for many organizations. Higher Sigma levels (5σ and 6σ) signify improved quality, leading to fewer defect rates, higher yields, and lower costs associated with poor quality. 'World Class Manufacturing (WCM)', introduced by Hayes and Wheelwright in 1984, describes how companies can consistently exceed the highest industry standards globally.

Organizations with performance in the range of Six Sigma levels 3σ and 4σ are considered 'industry average', with defect rates of 66807 and 6210 parts per million, respectively. This corresponds to 93.3193% and 99.3790% good products, with the cost of poor quality ranging from 15 to 30 percent of the company's revenue. Firms with lower Sigma levels (1σ and 2σ) experience high defect rates and substantial costs due to poor quality, making them less competitive. As Pyzdek (2009) notes, error rates drop exponentially as the Sigma level increases, correlating well with empirical cost data. It is crucial to adapt Six Sigma methodologies to meet changing customer needs and the increasing complexity of products and processes.

Table 2.1 Sigma Level Performance (Harry, 1998; and Harry Schroeder, 2006)

Sigma Level	*DPMO*	*Cost of Poor Quality (% of sales)*	*Total Cost of Quality (% of sales)*	*Competitive Level*
6σ	3.4	<10%	Less than 1%	World Class
5σ	233	10% - 15%	5% - 15%	
4σ	6,210	15% - 20%	15% - 25%	Industry Average
3σ	66,807	20% - 30%	25% - 40%	
2σ	308,537	30% - 40%	>40%	Non-competitive
1σ	690,000	>40%		

RESEARCH METHODOLOGY

A. *Research Design*

This study focuses on addressing the high defect rate in the production of Foley catheters at PT. XYZ, particularly in the assembly process. The study begins by identifying the core issue and the need for improved quality control methods, supported by a literature

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review that explores various aspects of quality management practices, including Six Sigma methodologies. Data collection involves both primary and secondary sources. Primary data are gathered through questionnaires distributed to workers, interviews with the production manager and supervisor involved in the assembly section and quality control, and field observations of the assembly line help identify potential improvement areas. Secondary data are analyzed using defect repair records and NG product data from PT. XYZ in 2023, as well as inspection records from the same year, to provide insights into defect frequency and types. The data analysis follows the DMAIC framework of Six Sigma, which includes defining the problem, measuring key process aspects, analyzing data to uncover root causes of defects, implementing solutions, and establishing control mechanisms to maintain improvements. The research concludes with recommendations to improve PT. XYZ's quality control methods and reduce defect rates in their Foley catheter production. This methodical approach is based on well-established quality management and Six Sigma methodologies.

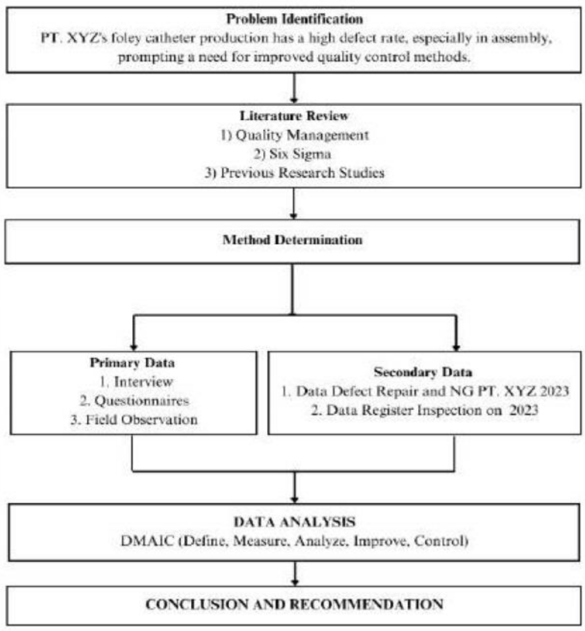

Figure 3.1 Research Design

B. ***Data Analysis Method***

The DMAIC methodology presents a systematic approach to process improvement.

- **Define Phase:** The primary goal is to identify the objectives of the improvement activity, understand customer needs, and align them with organizational goals. This includes creating a Project Charter to outline the business case, problem statements, scope, goals, project plan, and team selection. Business Process Mapping helps visualize existing processes and identify areas for improvement.
- **Measure Phase:** Focuses on quantifying current performance by performing Sigma Level Calculation to analyze defect levels and using a Pareto Chart to identify the most influential factors contributing to defects.
- **Analyze Phase:** Utilizes the Current Reality Tree (CRT) to map out cause-and-effect relationships, identifying root causes of problems within the assembly section. It links undesirable effects (UDEs) to their root causes, providing a thorough understanding of the issues.
- **Improve Phase:** Focuses on developing and implementing solutions to address the fundamental problems identified in the Analyze phase. This includes implementing enhancements in the Assembly Section and using Poka-Yoke techniques to prevent errors.
- **Control Phase:** Ensures long-term maintenance of improvements. This involves creating a thorough Documentation Plan to keep procedures updated, implementing a comprehensive Training Plan to equip employees with necessary knowledge and skills, and establishing a Monitoring Plan to regularly assess performance and make necessary adjustments.

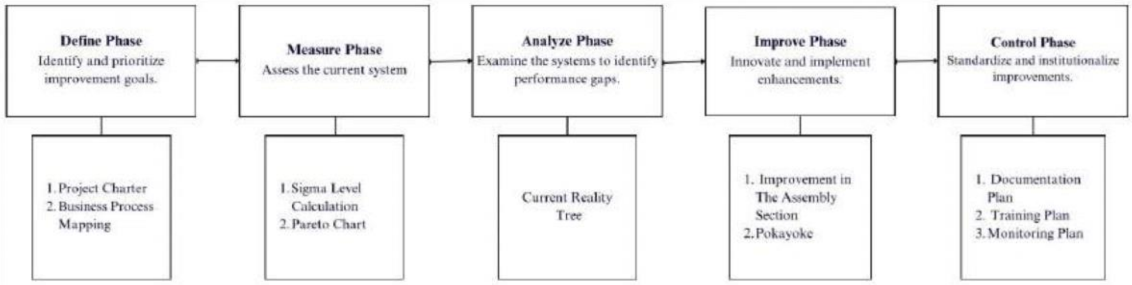

Figure 3.2 Data Analysis using DMAIC

RESULT AND DISCUSSION

A. Define Phase

The initial phase of the DMAIC (Define, Measure, Analyze, Improve, Control) approach is referred to as "Define". The primary tasks in the Define phase often involve formulating the problem statement, establishing project objectives, discerning customer requirements, and developing a broad project outline. This phase is elaborated by researcher using two methods: (1) Project Charter and (2) Process Mapping.

Project Charter

- **Business Case:** PT. XYZ faces challenges with high defect rates in Foley catheters, Ryles, and Levin tubes, reaching 8% in 2023. This includes 3% NG (Not Good) products, totaling 30,672 units, and 5% requiring repair, totaling 54,515 units, exceeding the acceptable 3% threshold.
- **Problem Statement:** Foley catheters have the highest defect rate at 7.24%, with most defects occurring in the assembly section (71,929 pieces), compared to extrusion (3,196 defects) and injection (2,619 defects). • **Goal Statement:** Reduce the defect rate to within the optimum range of 3% in 2024 • **Project Scope:** Focus on the assembly section, including:
  - o Balloon Vulcanizing and Assembly: From material mixing to finished cutting and cleaning.

  o Shrink: From preparation of shrink packaging to quality standard examination. o Tip: From tip insertion and alignment to quality compliance inspection.
  - o Hole Punch: From punching drainage holes to functionality examination.
- **Project Plan:** Outlined in **Table 4.1**, starting with discussions and problem analysis in February-March, data collection in March, data analysis in April-May, process modifications and training programs in May-June, and detailed implementation planning in July.

Table 4.1 Project Plan

No	Activity	Feb	March	April	May	June	July
1	Initial discussion and problem examination with PT XYZ	■					
2	Select project team members	■					
3	Conduct direct observation and gather primary data		■				
4	Gather secondary data		■	■			
3	Analyze the gathered data			■	■		
4	Generate feasible solutions				■	■	
5	Implementation planning with PT XYZ						■

Process Mapping

The assembly process begins with Balloon Vulcanizing & Assembly, where materials are mixed, formed using a vulcanizer, cut into balloons, installed, glued, and cleaned. Next is the Shrink Process, where silicone balloons are assembled on the tube, glued, packaged, and processed in a conveyor machine set to 150°C for 15 minutes. The automation tank process involves evaporating the product at 150°C for 15 hours. The Tip Process involves inserting silicone adhesive into the tip cup, heat treatment, inspection, and

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defect handling. In the Hole Punch Process, holes are punched for urine discharge, followed by inspection, printing, and color coding. Balloon Testing ensures the integrity of the balloons, with defective products either repaired or discarded. Compliant products proceed to final storage. This rigorous process checks products at various stages to minimize defects and ensure high quality, ensuring that only products meeting all criteria are delivered for medical use.

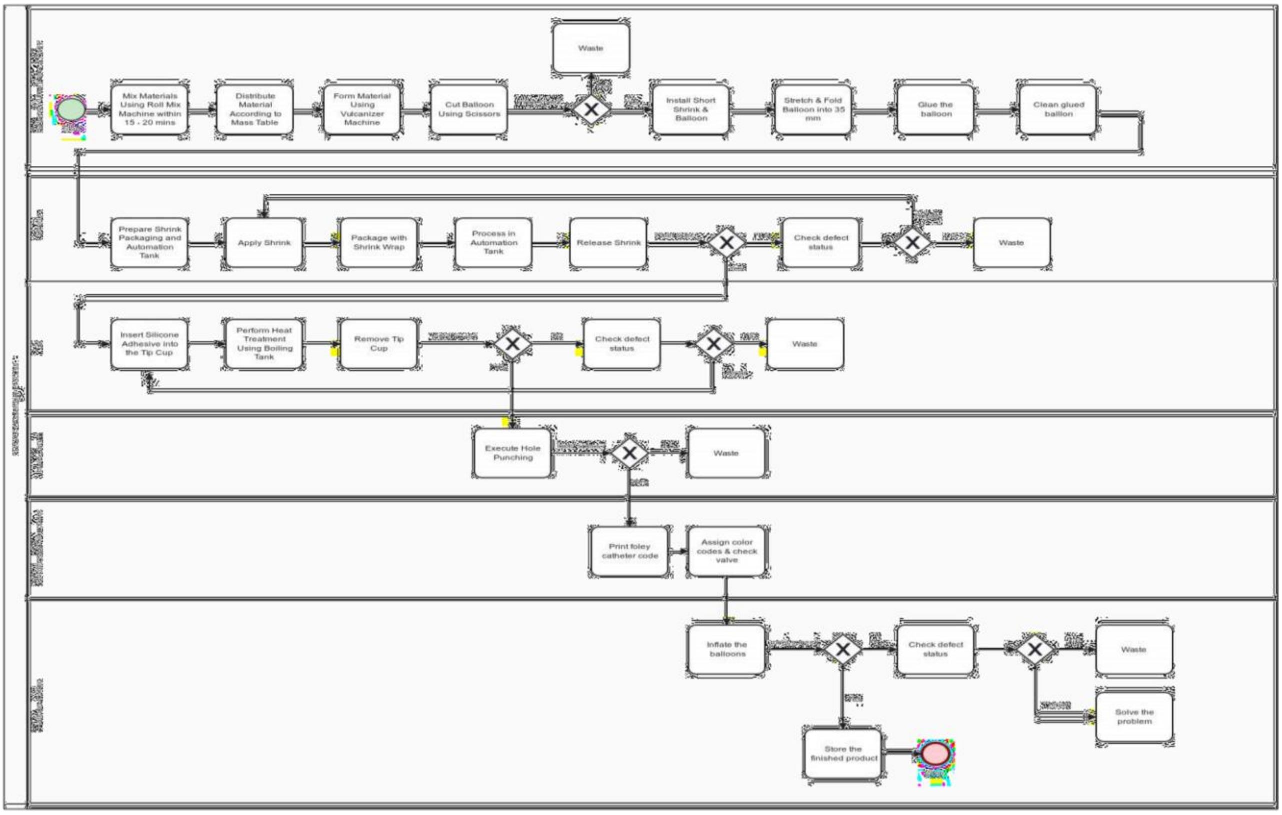

Figure 4.1 BPMN Assembly Section

***B. Measure Phase* Sigma**
Level Calculation

Table 4.2 presents the sigma level calculations for the assembly section of PT. XYZ from 2023-2024. It provides information on the defect rates and sigma levels of four different processes. There are significant quality and performance disparities in the sigma level calculations for PT. XYZ's various processes. According to the data in **Table 4.2,** the Tip and Hole Punch process has achieved sigma values of 3.23 and 4.22, which exceed the industry standard of 3 to 4 sigma. On the other hand, the Shrink and Balloon Vulcanizing and Assembly processes have sigma levels of 2.36 and 2.68, respectively, which is below the industry competitive level generally considered acceptable (3 Sigma). Below is a brief overview and assessment of each:

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Table 4.2 Sigma Level Calculation

No	***Sigma Level***	***Explanation***
1	Defects: 18,619 Number of Opportunities: 156,353 DPMO: 119083 Sigma Level: 2.68	Balloon Vulcanizing and Assembly Current defects: $\frac{\mathbf{18619}}{\mathbf{156353}}$ **=11.9% of Total Production in Balloon Vulcanizing and Assembly Process** The Balloon Vulcanizing and Assembly process in PT. XYZ in 20232024 has a sigma level of 2.68
2	Defects: 45,731 Number of Opportunities: 233,320 DPMO: 196001 Sigma Level: 2.36	Shrink Current defects: $\frac{\mathbf{45731}}{\mathbf{233320}}$ **=19.6% of Total Production in Shrink Process** The Shrink process in PT. XYZ in 2023-2024 has a sigma level of 2.36
3	Defects: 7,337 Number of Opportunities: 173,616 DPMO: 42260 Sigma Level: 3.23	Tip Current defects: $\frac{\mathbf{7337}}{\mathbf{173616}}$ **=4.2% of Total Production in Tip Process** The Tip process in PT. XYZ in 2023-2024 has a sigma level of 3.23
4	Defects: 242 Number of Opportunities: 73,249 DPMO: 3304 Sigma Level: 4.22	Hole Punch Current defects: $\frac{\mathbf{242}}{\mathbf{73249}}$ **=0.3% of Total Production in Tip Process** The Hole Punch process in PT. XYZ in 2023-2024 has a sigma level of 4.22

Pareto Chart

The Pareto Chart provides a visual representation of how defects are distributed among different processes in the production line, emphasising the key factors that contribute the most to the overall defect rate. Based on **Figure 4.2**, it is evident that the Shrink process is responsible for the majority of defects, with a frequency of 45,731 defects, resulting in 63.6% of the total defects. The need for the Shrink process to be improved immediately is highlighted by this significant contribution. The Balloon Vulcanizing and Assembly process has a total of 18,619 defects, which accounts for approximately 25.9% of all defects. Since these two processes account for over 80% of all defects (cumulative proportion of 89.5%), resolving problems in these areas has the potential to significantly lower overall defect rates. While not as significant as Shrink and Balloon Vulcanizing and Assembly, the Tip process accounts for 7.2% of all defects, or 7,337 defects, making up a significant fraction of the problems.

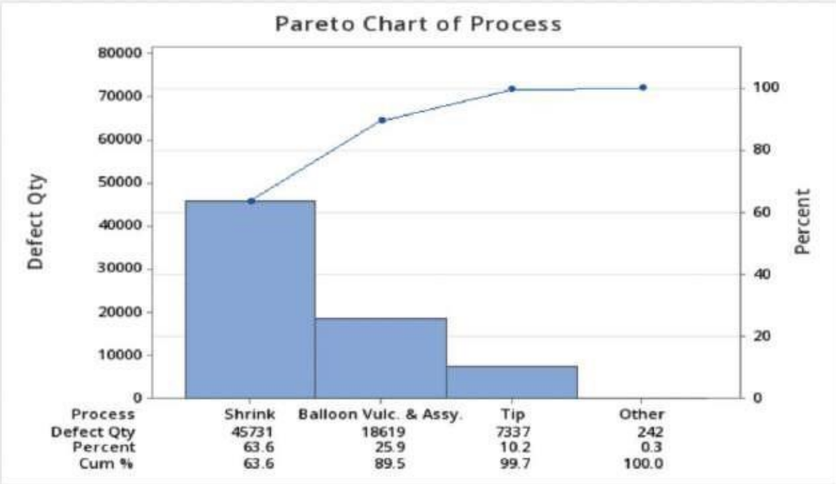

Figure 4.2 Pareto Chart of Assembly Section

In conclusion, this research focusing on improving the Shrink and Balloon Vulcanizing and Assembly processes which the sigma level have not met the industry standard. With a strategic focus on these areas, PT. XYZ can work towards enhancing the sigma levels of these processes, resulting in a decrease in defects and an overall improvement in product quality and customer satisfaction.

C. Analyze Phase

Current Reality Tree of Shrink Process

Shrink process aimed to assemble silicone balloon on the tube. According to Current Reality Tree in **Figure 4.3** the analysis concluded with the identification of three main root causes:

RC 1: Incorrect Tray Loading Practices.

After the shrink gluing process, Foley catheters are packaged and placed into a conveyor machine using trays that hold 10 Foley catheters per tray for 15 minutes. Incorrect tray loading practices occur when the number of catheters per tray causing prolonged waiting times and premature glue exposure. This results in uneven glue surfaces, compromising the bond between the shrink and the tube, and increasing defect rates.

RC 2: Calibration Error in Machine Temperature Settings.

The conveyor machine or Heat Shrink Machine, used to smooth the balloon after shrink application, must maintain precise temperature settings as per SOP (150°C for 15 minutes). Calibration errors occur when the machine's actual temperature deviates from the displayed settings, leading to under-curing or over-curing of the adhesive. This discrepancy creates gaps or holes in the adhesive layer, directly contributing to high defect rates.

RC 3: Variability in Operator Skill and Technique.

Shrink gluing for Foley catheters is a critical, manually performed stage, introducing variability due to differences in operator skill and technique. Inconsistent glue application leads to uneven adhesive layers and attachment issues. Human error in spreading glue results in some areas having too much or too little glue, causing defects like uneven glue surfaces when the shrink is applied, as the bond may not be strong enough.

RC 4: Inadequate Handling Techniques During Shrink Insertion Process.

Inadequate handling during the shrink insertion process involves improper expansion and insufficient pressing of the shrink before insertion. This can cause the shrink to touch the glued surface of the tube, disturbing the adhesive layer and leading to defects such as uneven bonding or gaps, thereby increasing defect rates.

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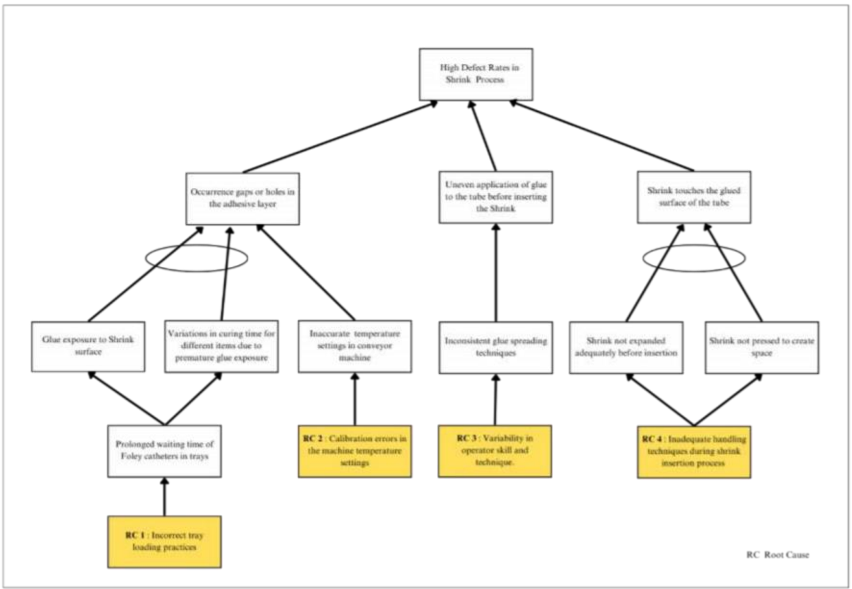

Figure 4.3 Current Reality Tree (CRT) of Shrink process.

Current Reality Tree of Balloon Vulcanizing and Assembly Process

The main issue identified at the top of the tree is "High Defect Rates in Balloon Vulcanizing and Assembly Process”. This process involves several critical steps where root causes of defects may occur. The analysis concluded with the identification of 2 root causes:

RC 1: Worker Misalignment During Cutting After Molding Process.

The process starts with mixing materials using a roll mix machine for 15-20 minutes, followed by distributing the material according to a mass table and forming it with a vulcanizer machine. After forming, employees remove and cut the balloons with scissors. Worker misalignment during this manual cutting process can lead to uneven or improperly cut balloons, affecting their symmetry and elasticity. This root cause is critical as the small diameter of the balloons (4.62 mm to 7.92 mm) requires precision. Misalignment results in asymmetrical shapes, poor elasticity, and increased defect rates.

RC 2: Inconsistent Mold Configuration Due to Machine Malfunction.

The process involves mixing materials with a roll mix, distributing them, and forming balloons using a press vulcanizer. Inconsistent mold configurations arise due to machine malfunctions, particularly with temperature settings. Often, balloons stick to the mold after curing, indicating improper mold temperature. This sticking issue affects the balloons' elasticity and symmetry, leading to defects such as leaks and asymmetry. Poor mold configuration is a significant contributor to the high defect rates.

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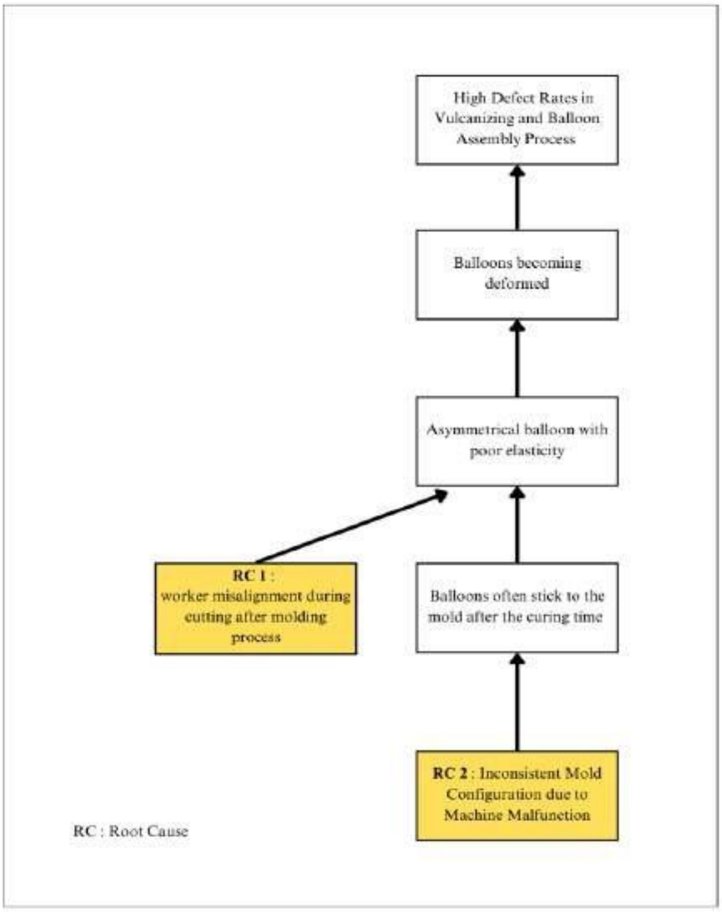

Figure 4.4 Current Reality Tree (CRT) of Balloon Vulcanizing and Assembly process

D. Improve Phase

Proposed Solution for Shrink Process

Develop and Document Standardized Procedures for Tray Loading

To address the RC 1: incorrect tray loading practices, PT. XYZ should update the Standard Operating Procedures (SOPs) to include specific limits on the number of items per tray and establish a maximum waiting time for Foley catheters in trays before they enter the conveyor. The revised SOPs should adjust the quantity based on the size of the catheters, as noted in the practice of changing the tray load from 10-15 items to a more appropriate number based on the size of the catheters. The smaller the diameter of the catheter, the longer it takes to apply the glue, so that smaller sizes have fewer items per tray and larger sizes are adjusted accordingly to ensure it does not exceed the optimal duration for glue exposure.

Implement SCAMPER Technique

The SCAMPER technique, specifically focusing on Substitute, Combine, and Adapt (SCA), was selected to address RC 2: calibration error in machine temperature settings. The choice to use only SCA from the SCAMPER framework is based on the insights from our discussions with the manager. The manager highlighted that the current conveyor machine used in the shrink process can be maintained and repaired rather than replaced, emphasizing cost efficiency. The conveyor machine requires a general inspection every two weeks and comprehensive maintenance every month to ensure it operates effectively. This approach focuses more on maintenance solutions than on purchasing new equipment, aligning well with the SCAMPER technique's principles of substitution, combination, and adaptation.

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Table 4.3 SCAMPER Solution Explanation

SCAMPER Category	***Solution***	***Implementation***
Substitute	Thermometer Gun	Use a reliable thermometer gun to cross-check the temperature settings manually, ensuring accuracy.
Combine	Combine daily calibration with regular maintenance	• Implement a daily calibration schedule to be done every morning before production begins. • Maintain general inspection every two weeks and comprehensive maintenance every month
Adapt	Upgrade Sensors	Improve calibration accuracy with advanced sensors such as Infrared Temperature Sensors for non-contact measurement, high accuracy, fast response, easy to integrate with existing systems

The use of BPMN facilitated the application of the SCAMPER technique. By mapping out the process, it became evident where specific interventions were needed. Based on the findings from the root cause analysis, conducting a daily calibration check using a thermometer gun is necessary to ensure the machine maintains the correct temperature, leading to accurate machine temperature and reducing the likelihood of defects. Consequently, there is a need to include this new step in the SOP and improve the BPMN to systematically incorporate it into the workflow, preventing temperature-related inconsistencies. The key improvement in the revised BPMN focuses on the element of Substitute, leading to the addition of the new step: "Conduct daily calibration check using thermometer gun," (color code green) as seen in **Figure 4.5**.

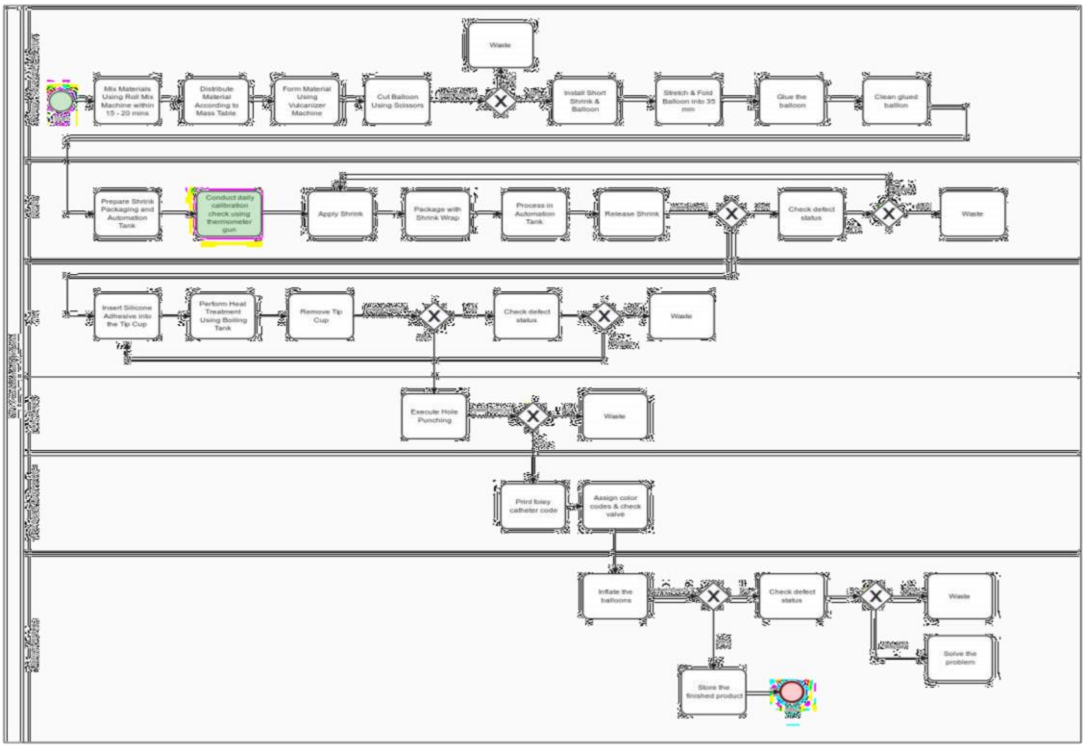

Figure 4.5 Proposed New Business (BPMN) of PT XYZ in Shrink Process

To address RC 3: Variability in Operator Skill and Technique and RC 4: Inadequate Handling Techniques During Shrink Insertion Process, several proposed solutions are made:

- *Create new KPIs to track production quality and defect rates*
  To enhance focus on quality, PT. XYZ will develop new Key Performance Indicators (KPIs) alongside existing ones that measure daily production quantity. The new KPI will track the number of defects produced by each worker, aiming for 'zero defects' to encourage quality as well as quantity. For example, currently every worker has a standard to produce 500 - 700 units a day, then the KPI will not only count these units but also monitor how many of these units are defect-free. A system will be implemented to record and report these KPIs daily, providing operators with regular feedback on their performance. The expected outcome is an enhanced focus on quality, leading to reduced defects and improved overall performance.
- *Develop Training Programs*
  Collaborating with expert workers, PT. XYZ will develop detailed training programs covering all aspects of the shrink and balloon vulcanizing and assembly processes. These programs will include practical hands-on training sessions, theoretical lessons, and visual aids. Regular training sessions will be scheduled for all workers regularly to ensure everyone is trained to the same high standard. Additionally, refresher courses will be provided periodically to keep skills sharp and up to date.
- *Utilizing visual aids and guided tools for standardized procedures*
  To reduce human error PT. XYZ will create posters, diagrams, and instructional videos that clearly show the correct handling techniques and place these visual aids at strategic locations within the workspace for easy reference. The visual aids can be in the form of a diagram illustrating the steps for applying glue evenly or an instructional video so that workers might be able to rewatch and learn remotely. The implementation of visual is supported by relevant research. According to the study "Interactive Visual Aids for Training and Knowledge Testing" by Magdić,et al. visual aids are proven to be effective in enhancing the learning, training, and testing processes, particularly when integrated into web collaboration systems. Brown's article, "Visual Aids Increase Training Impact and Value," further supports the use of visual aids in reducing defects and improving risk communication in various industrial applications.
- *Create incentive programs to encourage high-quality performance*
  According to Philip Crosby in his fourteen-step of improvement, one of the steps is by creating Incentive Programs for Employees. Thus, PT. XYZ will design incentive programs that reward operators for achieving quality targets and maintaining low defect rates. Regular performance appraisals will be conducted to evaluate both production quantity and quality, and operators who achieve 'zero defects' or significantly improve their performance will receive incentives such as bonuses, recognition, and other rewards. The expected outcome is increased motivation among employees to maintain high-quality standards and continuously improve their performance. Regarding incentive programs, research indicates significant benefits. The study "Employee Productivity Spillovers Generated by Incentive Schemes" by Gerhardus van Zyl and Mpho Dennis Magau, published in the SA Journal of Human Resource Management, highlights that incentive schemes can substantially boost productivity. Similarly, Ibrahim and Abiddin's article, "The Impact of Incentives on Employee Productivity: Review of Past Literatures," published in the Journal of Business Administration Research, emphasizes that incentives, such as cash payments, bonuses, accolades, and non-cash benefits, have a substantial positive impact on employee productivity and organizational performance.

Proposed Solution for Balloon Vulcanizing and Assembly Process

Pokayoke Template Overlay

One potential solution to address worker misalignment during cutting is a template overlay. A simple Poka-Yoke technique used to ensure accurate cutting or placement of a material based on a predefined design. This method is simple to implement and requires minimal investment. Workers can utilize a transparent sheet material, such as an overhead projector sheet or a thin acrylic sheet.

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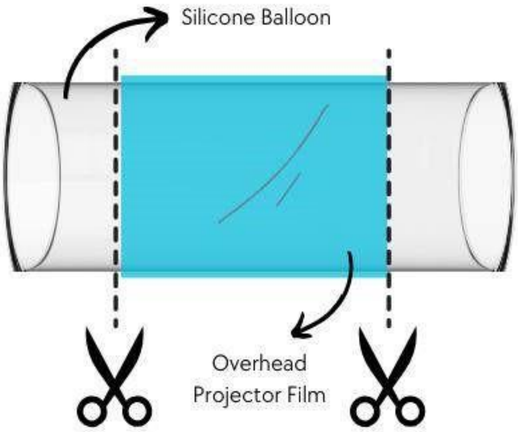

Figure 4.6 Poka Yoke: Template Overlay

The visualization of the template provided in **Figure 4.6** The silicone balloon must be cut precisely on both the 3 sections on top and 3 sections in bottom sections. By using the template's outline as a visual guide, workers have less effort by only measuring in one section and can achieve accurate cutting and minimize the risk of misalignment. This approach offers a low-cost and userfriendly way to improve cutting precision. *Vendor Reparation and Create Control Charts*

The malfunction of the machine, particularly the temperature control system, requires specialized tools and expertise beyond PT XYZ's current capabilities, necessitating vendor intervention. The vendor, equipped with the necessary tools and technical knowledge, will effectively diagnose and fix these complex issues. The process begins by sending the malfunctioning machine to the vendor's facility, accompanied by detailed information about the temperature issues and mold configuration problems. The vendor will then conduct a comprehensive diagnosis to identify faults in the temperature control system, heating elements, and mold mechanisms. Following this, they will repair faulty components and recalibrate the machine, adjusting the heating elements and sensors to optimal settings. Test runs will be performed to ensure the machine operates correctly, maintaining accurate mold temperatures and preventing balloons from sticking.

To achieve consistent mold configurations and prevent future malfunctions, PT XYZ will implement control charts as a monitoring tool. These charts will track temperature readings over time, with defined control limits based on the optimal temperature range for the balloon molding process. Operators will review the charts daily to identify any deviations from acceptable temperature ranges and take immediate action if readings fall outside these limits. Additionally, the data collected from the control charts will be used to implement preventive maintenance and necessary adjustments, ensuring that issues are promptly addressed and future malfunctions are prevented.

E. Control Phase

As the final step of the DMAIC framework, the "Control" phase is crucial for maintaining improvements and ensuring consistent process performance at PT XYZ. The control plan includes a documentation plan to standardize processes and ensure continuous quality improvement, with key documents like SOPs for tray loading and temperature calibration, production quality KPIs, visual aids, incentive programs, training programs, cutting precision SOPs, and vendor reparation and control charts. The training plan details modules for new SOPs, SCAMPER technique, production quality KPIs, operator training, Poka-Yoke techniques, and control charts, ensuring high-standard training and regular refreshers for all employees. The monitoring plan uses control charts, such as the Shewhart control chart and P-chart, to monitor solution efficiency and identify out-of-control processes for immediate remediation. Process Capability Analysis evaluates if the process meets specifications, while FMEA identifies and prioritizes potential failure points, emphasizing ongoing training, performance tracking, and preventive maintenance to ensure long-term reliability and effectiveness of improvements.

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The Risk Priority Number (RPN) shows the failure risk levels that need prioritization in the **Table 4.4**. The highest RPN score of 336, related to operator skill and method variability during shrinking, implies the need for ongoing training and performance tracking. Workers misaligned during cutting, with an RPN of 320, need skill assessments and refresher sessions. Tray loading errors and mold designs with RPNs of 180 require ongoing training and preventive maintenance. Prioritising these activities by RPN scores improves process reliability and product quality by addressing the most pressing concerns.

Table 4.4 FMEA Monitoring Plan

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Causes	OCCURRENCE (1 - 10)	Current Controls	DETECTION (1 - 10)	RPN	Action Recommended	Resp.	Actions Taken
What is the process step, change or feature under investigation?	In what ways could the step, change or feature go wrong?	What is the impact on the customer if this failure is not prevented or corrected?		What causes the step, change or feature to go wrong? (how could it occur?)		What controls exist that either prevent or detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving detection?	Who is responsible for making sure the actions are completed?	What actions were completed (and when) with respect to the RPN?
Shrink Process	Incorrect tray loading practices	Defects in catheters	6	Operators' forget of SOP	5	SOP review when briefing sessions	6	180	Regular refresher training sessions	Assembly Supervisor	Conduct quarterly training sessions and SOP audits
	Calibration error in machine temperature settings	Incorrect temperature settings	7	Digital sensor calibration drift	3	Regular calibration checks using digital thermometer sensors	6	126	Implement a digital calibration system and regular calibration audits	Assembly Supervisor	Upgrade to digital calibration system and conduct monthly calibration audits
	Variability in operator skill and technique	High defect rates	7	Inconsistent training methods	6	Regular training and performance monitoring	8	336	Develop a continuous training program and performance tracking system	Assembly Supervisor & Production Manager	Establish continuous training program and implement performance tracking system
Balloon Vulcanizing and Assembly Process	Worker misalignment during cutting	Misaligned balloons	7	Human error in cutting process	4	cutting overlays	4	112	conduct training for workers on the correct use of the template	Assembly Supervisor & Production Manager	regularly review the use of the template & provide feedback to workers
	Inconsistent mold configuration	Defects in molded balloons	6	Machine malfunction	5	control chart measurements	6	180	Schedule regular preventive maintenance and vendor inspections	Production & Quality Manager	Implement quarterly preventive maintenance and vendor inspections

CONCLUSION

The Foley catheter production assembly section at PT XYZ faces several key issues in balloon vulcanizing and assembly and shrink processes. These issues include incorrect tray loading, machine temperature calibration mistakes, operator competence and technique variations, inadequate shrink insertion handling, worker misalignment during cutting, and machine malfunctions causing mold designs to change.

Currently, PT XYZ's approach involves placing about 10-15 Foley catheters on a single tray for all catheter sizes, adjusting machine settings to higher temperatures to compensate for discrepancies between displayed and actual temperatures, and conducting training only when new employees join the company. Additionally, PT XYZ establishes KPIs based on the number of products assembled by workers each day, reminds operators regularly, and prepares for vendor intervention.

To enhance quality, several solutions are proposed: updating the Tray Loading SOP, implementing SCAMPER for calibration, updating performance appraisals, providing comprehensive operator training, utilizing visual aids and guided tools, developing performance and incentive programs, using Poka-Yoke cutting overlays, and employing control charts to monitor temperature. These measures are estimated to reduce defects in balloon vulcanizing from 18,619 to 10,000 items and in the shrink process from 45,731 to 15,000 items, achieving an industry average of a 3-sigma level.

RECOMMENDATION

To enhance the quality and efficiency of PT XYZ's Foley catheter production, several targeted solutions should be systematically implemented:

1. **Updated Tray Loading SOP:** Standardize tray loading procedures and conduct regular training to minimize errors.
2. **Implement SCAMPER:** Use reliable thermometer guns for manual checks, implement a daily calibration schedule, update SOPs, and upgrade to advanced infrared sensors for accurate temperature measurement.

3. **Updated Performance Appraisal:** Introduce new KPIs to track production quality and defect rates, emphasizing the importance of maintaining high standards.
4. **Comprehensive Operator Training:** Provide extensive training on all aspects of the shrink and balloon vulcanizing and assembly processes to ensure adherence to best practices.
5. **Visual Aids and Guided Tools:** Implement posters, diagrams, and instructional videos to standardize procedures and reduce human error.
6. **Performance and Incentive Programs:** Develop incentive programs to motivate operators to achieve quality targets, including regular appraisals and rewards for low defect rates.
7. **Poka-Yoke Cutting Overlay:** Use template overlays and precision techniques to improve balloon cutting accuracy, with regular reviews and maintenance.
8. **Control Charts:** Monitor temperature readings and other essential data with control charts, ensuring consistent mold configurations and preventing malfunctions, with immediate action for deviations.\

For future research, explore additional methods to reduce defects and improve Foley catheter production is recommended, considering new technologies and process innovations for continuous improvement. Investigating advanced manufacturing techniques, such as automation and robotics, could significantly minimize human error and enhance precision in the production process. Additionally, exploring the integration of real-time data analytics and machine learning algorithms can provide predictive insights and proactive solutions for quality control. Implementing Industry 4.0 technologies, like IoT sensors and smart manufacturing systems, can further optimize the production line by continuously monitoring and adjusting processes to maintain optimal performance.

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