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Implementing Six Sigma in Filling Process of Injection Medicine: A Case Studies in Healthcare Industry

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ABSTRACT

The research focuses on a pharmaceutical company operating in the pharmaceutical and health-related products industry. The filling process for injection medicines has experienced a higher average rate of rejects, reaching 3.2% between September 2022 and February 2023, which exceeds the company's set limit of 2.0%. This study aims to identify the factors contributing to the problem and provide recommendations for reducing rejects using the DMAIC method. During the Define stage, SIPOC diagrams and CTQ identification are utilized. Three CTQ categories are identified: volume defects, imperfect sealing defects, and empty defects. The Measure phase, employing a Pareto diagram, highlights volume defects as the most prevalent. DPMO calculation using the rejected injection medicine preparation data results in a value of 10630, with a sigma level of 3.80. The Analyze stage involves identifying the factors causing the problem through the use of a Fishbone Diagram. Furthermore, the highest RPN value of 112, indicating potential failure, is determined to be due to insufficient supervision during the production process according to FMEA. In the Improve stage, the 5W+1H tools are employed to generate appropriate improvement proposals. These proposals are documented, disseminated, and adopted as standard work guidelines.

Key Words: Six Sigma, Healthcare industry, Defects.

1. INTRODUCTION

The rapid advancement of technology has led to a highly competitive business environment. According to the 2019 KBLI report, the Chemical, Pharmaceutical, and Traditional Medicine Industry experienced significant growth, particularly in the Chemicals and Chemical Goods sector, which transitioned from a negative growth of 4.18% in 2018 to a positive growth of 8.2% in 2019. Additionally, the Pharmaceutical Industry, Chemical Medicinal Products, and Traditional Medicines sector saw an increase from a positive growth of 4.46% in 2018 to a positive growth of 9.03% in 2019.

The current pharmaceutical industry competition can be observed through the proliferation of various types of medicinal products available in the market. The rise in advertisements for over-the-counter (OTC) medicines in print and electronic media indicates intense competition to capture and maintain market share in Indonesia's health care market. This competition directly influences companies' strategies, particularly in marketing. The pharmaceutical sector competition is not only evident through the availability of diverse products with different brands but is also fueled by growing public awareness in the healthcare sector. The research subject is currently facing a challenge related to a high number of rejects in the filling process for injectable medicine preparations, surpassing the company's tolerance limit of 2.0%. These ongoing issues can have negative consequences for the company, necessitating a solution to reduce or eliminate the root cause of the problem. The attached graphical data illustrates the percentage of rejects from the injection medicine production process between September 2022 and February 2023.

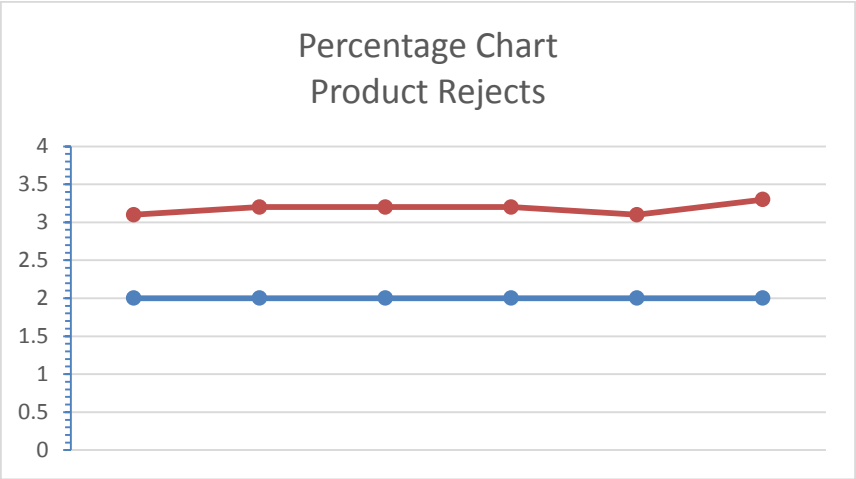

Figure 1. Graph of Product Reject Percentage

Based on the gathered data, it is evident that the defect percentage for September was 3.1%, October was 3.2%, November was 3.2%, December was 3.2%, January was 3.1%, and February was 3.1%. These defect rates exceed the predetermined limit of 2.0% set by the company. The defects in the filling process of injectable medicine preparations can be categorized into three types: volume not meeting specifications, imperfect sealing, and empty ampoules. Creating a Pareto diagram aims to identify the primary factors causing the issues by highlighting the most significant defect type from the available categories of defects.

The Pareto diagram reveals that the highest type of defect is volume not meeting specifications, accounting for 45.70%, followed by imperfect sealing at 30.20%, and the least common defect being empty ampoules at 24.10%. The number of defects exceeds the company's target, necessitating improvements and controls to reduce defects and increase the number of produced products. To achieve this, a comprehensive study is required to identify and evaluate the factors influencing the process of filling injectable medicine preparations in order to find optimal solutions for meeting production expectations. In quality control, various methods can be utilized, and for this study, the Six Sigma method will be employed. Six Sigma is a quality control methodology focused on reducing variability in production or service processes to enhance quality and efficiency. Statistical techniques such as data collection, regression analysis, and hypothesis testing are employed to ensure consistency and accuracy in production or services (1-15). The DMAIC (Define, Measure, Analyze, Improve, and Control) approach is used to identify problems, measure process performance, analyze root causes of problems, implement improvements, and establish process controls (16-23)

In the Define stage, Critical to Quality (CTQ) factors will be determined, and SIPOC Diagrams will be created to trace and assess the level of existing problems. The Measure stage involves calculating the sigma level and constructing P control charts. The Analyze stage focuses on tracing problems to their root causes through techniques such as Fishbone Diagrams and Failure Mode and Effects Analysis (FMEA)(23-27). The Improvement stage involves identifying problems, optimizing the production process, and providing improvement suggestions using the 5W+1H analysis. Finally, in the Control stage, an evaluation of the improvement plan will be conducted, and processes will be standardized to sustain the implemented efforts (27-30).

Previous researchers have successfully applied the DMAIC method in various studies (30-32). Their improvements included developing work instructions for machine operators, determining optimal settings for conveyor machine speeds, conducting thorough checks on cartons to be used, creating clear work instructions for carton folding, procuring measuring instruments to aid machine setup, and providing guidance and supervision to ensure proper machine adjustment. Similarly, (33-34) implemented the DMAIC method to reduce the rejection rate in the Plastic Painting Department. Their improvements involved manufacturing paint mixer machines and vacuum cleaners, performing maintenance at all stations, and implementing quality control measures for production paint materials (34-48). Drawing from the previous research, this study employs the DMAIC method to identify the factors influencing

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defects and provide quality improvements for the resulting products. The ultimate goal is to support the company in achieving its production targets.

2. RESEARCH METHOD

This research follows the DMAIC method, which consists of several stages and utilizes various tools. The stages in the DMAIC method are Define, Measure, Analyze, Improve, and Control. Throughout these stages, several tools are employed, including SIPOC Diagrams (Supplier, Input, Process, Output, Customer), Process Flow Diagrams, Pareto Charts, Fishbone Diagrams, and Failure Modes and Effect Analysis (FMEA). The DMAIC method is employed to achieve continuous improvement towards the six sigma target and aims to enhance the quality of a process or product by identifying and rectifying associated problems.

1. Define: In the Define stage, the focus is on identifying the specific product or process to be improved and determining the necessary resources for the research. This stage involves using SIPOC Diagrams to outline the overall workflow or business process and creating process flow maps to visualize the sequence of inputs and outputs. By doing so, potential problems and improvement opportunities can be identified. The research aims to identify the total number of product defects based on Critical to Quality (CTQ) factors related to product quality.
2. Measure: The Measure stage involves assessing the sigma level, which indicates the quality level of the company's products. A higher sigma level corresponds to a lower number of defects per one million opportunities (DPMO). In this stage, the dominant defect (CTQ) is determined using a Pareto diagram, and measurements are taken to calculate the DPMO and sigma level.
3. Analyze: During the Analyze stage, efforts are made to understand the root causes of the identified problems. This stage involves using cause and effect diagrams, such as Fishbone diagrams, to visualize the relationships between various factors and determine the root causes of the problems. Statistical process control techniques are employed to analyze and understand the factors influencing the product or process.
4. Improve: In the Improve stage, FMEA (Failure Mode and Effect Analysis) is utilized to prioritize improvement plans. FMEA is a systematic approach that identifies and evaluates potential failure modes in a system, product, or process, particularly related to the root functions and factors affecting them. FMEA assists in estimating the likelihood of errors or failures occurring and determining corrective actions to mitigate risks. Additionally, the 5W + 1H Technique is used to identify and address the root causes of problems and implement necessary actions to improve processes or products.
5. Control: The Control stage is the final stage in the Six Sigma process, focusing on maintaining and monitoring the implemented improvements to ensure long-term effectiveness and efficiency. This stage involves conducting periodic evaluations, adhering to the control plan, and documenting the control process and evaluation results. It aims to monitor and control the process to consistently achieve satisfactory results.

Overall, by following the DMAIC method and utilizing the aforementioned tools, this research aims to identify the root causes of defects, provide quality improvement recommendations, and establish effective control measures to achieve the desired production targets.

3. RESULT

3.1 Reject Data

The data collection for this study involved gathering historical data from September 2022 to February 2023. The data was obtained through the recapitulation of the company's records, as well as direct observations of the production process. Information was also gathered from various employees involved in the process, including production operators, supervisors, and managers.

Table 1. Data the quantity of injection medicine production

No	Period	Years	Quantity	Total Productions
1	September	2022	Pieces	374775
2	October		Pieces	374482
3	November		Pieces	375154
4	December		Pieces	377432

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No	Period	Years	Quantity	Total Productions
5	January	2023	Pieces	379759
6	February		Pieces	377459
	Total			2259061
	Average			376510

Based on the table, the production of injectable medicine preparations from September 2022 to February 2023 resulted in an average production quantity of 376,510 pieces. However, during the production process, there were rejects encountered in the filling process.

Table 2. Reject Data

No	Period	Years	Quantity	Reject/pcs	Percentrage (%)
1	September	2022	Pieces	11585	3.1
2	October		Pieces	11878	3.2
3	November		Pieces	12060	3.2
4	December		Pieces	12125	3.2
5	January	2023	Pieces	11890	3.1
6	February		Pieces	12501	3.3
	Total			72039	19.1
	Average			12007	3.18

Based on the provided data, the highest percentage of rejects occurred in February 2023 with 3.3%, while the lowest percentages were observed in September 2022 and January 2023 with 3.1% each. The average reject rate for the filling process of injection preparations from September 2022 to February 2023 is 3.18%. It is important to note that this average exceeds the company's tolerance limit of 2.0%. The following image illustrates the distribution of product defects during the filling process of injection preparations:

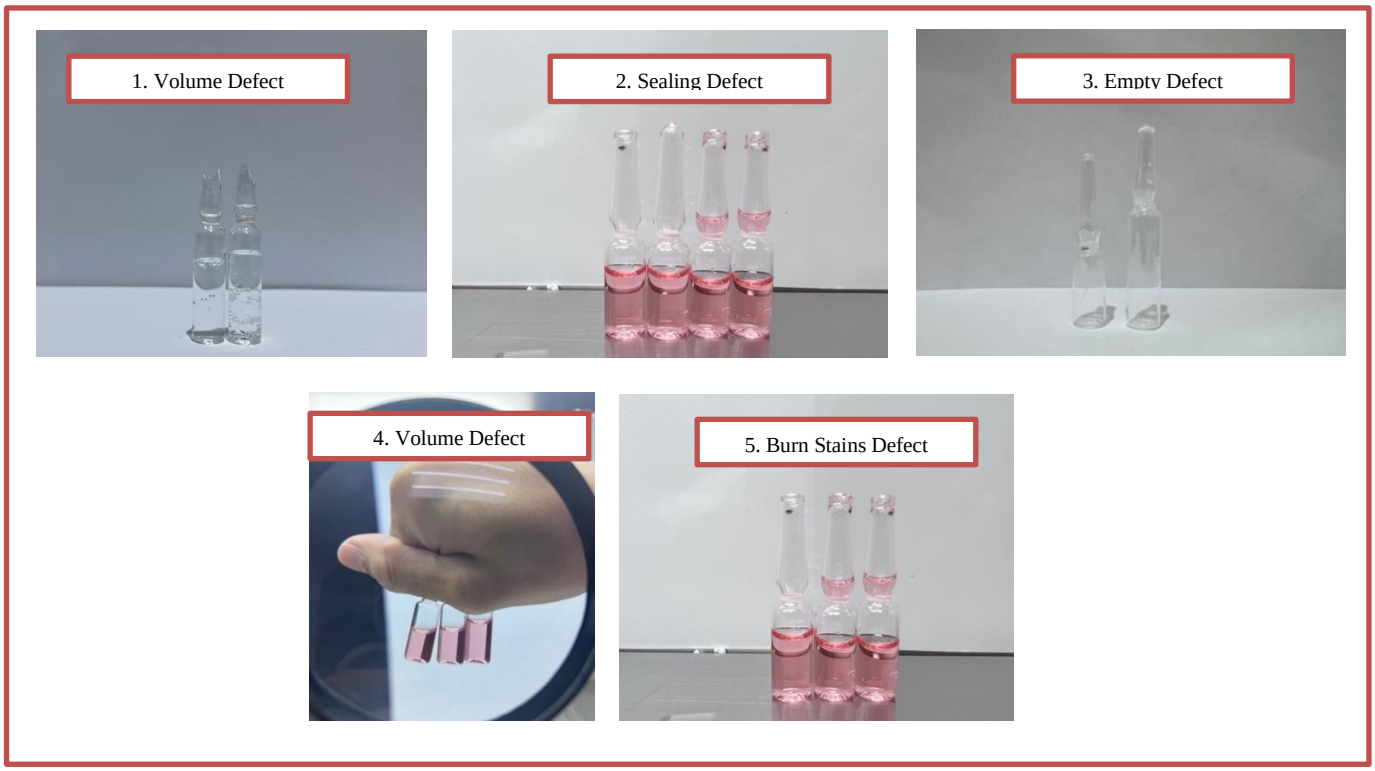

Fig 2. Defect Product

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3.2 DMAIC

1. **Define Stage:** During the Define stage, the SIPOC diagram is used to understand the overall process flow of producing injectable medicine preparations, while the Critical to Quality (CTQ) characteristics are identified to determine the key quality parameters of the filling process. The following are the outcomes of the SIPOC and CTQ analyses:

   a. SIPOC Diagram (Supplier, Input, Process, Output, Customer):

   - Suppliers: The pharmaceutical company collaborates with various suppliers to obtain the necessary raw materials for the production of injectable medicine preparations.
   - Inputs: The inputs for the manufacturing process include excipients, active ingredients, Water For Injection (WFI), and ampoules.
   - Process: The manufacturing process of injectable medicine preparations involves several stages:
     1. Preparation: This stage involves preparing the tools, materials, and production areas in accordance with Good Manufacturing Practice (GMP) standards.
     2. Weighing: Raw materials and additives are accurately weighed based on the Batch Processing Records (BPR).
     3. Mixing: The weighed raw materials and additives are mixed using a Mixing Tank machine.
     4. Filling: The solution obtained from the mixing process is filled into ampoule containers to create the final product.
     5. Inspection: Filled ampoules undergo a selection process in a dedicated room to separate those that meet quality standards from those that do not.
     6. Quarantine in Process: The produced injectable medicines are labeled and stored according to the batch processing records.
   - Outputs: The output of the process is the injection medicine preparations.
   - Customers: The customers of the pharmaceutical company are clinics and hospitals that use these medicine preparations.

   b. Critical To Quality (CTQ): Based on the analysis conducted, the Critical to Quality (CTQ) characteristics for injection preparations consist of three types, namely:

   1. Volume defects: Ensuring the accurate volume of the medicine solution is filled into each ampoule.
   2. Imperfect sealing defects: Ensuring the proper sealing of the ampoules to prevent leakage or contamination.
   3. Empty ampoules: Minimizing the occurrence of ampoules that are not filled with the medicine solution.

      These CTQ characteristics are crucial in meeting the quality requirements and reducing the number of defects during the filling process of injection medicine preparations.

      a). Volume Defect:

      The volume defect refers to variations in the amount of medicine solution filled into the ampoules, exceeding the specified standard. This could lead to inconsistent dosages and potential issues in the efficacy and safety of the medicine.

      b) Imperfect Sealing Defects:

      Imperfect sealing defects occur when the sealing process of the ampoules is not executed properly, resulting in inadequate closure. This can lead to potential damage, leakage, or contamination of the medicine inside the ampoules, compromising its quality and integrity.

      c). Empty Ampoule Defects:

      Defects in empty ampoules occur when the ampoules pass through a sensor but do not get filled with the medicine during the filling process. This can happen due to malfunctions in the sensor or

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issues with the filling mechanism, resulting in the production of unusable ampoules without any medicine content.

2. **Measure Stage:** In the measure stage, two key measurement techniques were employed: Pareto charts and DPMO calculations.

   a. Pareto Charts: The Pareto diagram was constructed to identify the main sources of defects based on their dominance within the defect categories. According to the Pareto chart, the volume defect was found to be the most significant, accounting for 45.7% of the total defects, with 32,922 rejected units.

   b. DPMO Calculations and Sigma Levels: The DPMO was calculated based on the rejected injection medicine preparations, resulting in a value of 10,630. The corresponding sigma level was determined to be 3.80. These results indicate that the filling process for injection preparations needs improvement, as it has not yet achieved the Six Sigma quality target of a Sigma Level of 6σ.

3. **Analyze Stage:** After the measurement stage, the analysis phase focused on identifying the factors causing the volume defect using Fishbone Diagrams and Failure Mode and Effect Analysis (FMEA).

   a. Fishbone Diagrams: The cause-and-effect diagram, or Fishbone diagram, revealed several factors contributing to volume defects in the filling process, including:

   - Machine-related issues, such as sensor errors, off-centered needles, frequent breakdowns, and mismatched conveyor speeds.
   - Material-related problems, such as inadequate storage leading to ampoule breakage or leakage, and weak ampoule strength affecting volume accuracy.
   - Method-related issues, such as the absence of periodic check sheets during the filling process.
   - Human-related factors, including errors in machine setup and insufficient operator skills due to inadequate training, rotation, or lack of attention to detail while pursuing production targets.

   b. FMEA (Failure Mode and Effect Analysis): FMEA was conducted to identify and evaluate potential failure modes. The analysis revealed that the lack of product supervision during the production process had the highest Risk Priority Number (RPN) score of 112, indicating its significance as a cause of volume defects. The second cause was the lack of operator and machine skills, which often resulted in breakdowns (RPN score of 96). Other potential failures included improper machine settings (RPN score of 84), inadequate product storage (RPN score of 70), and subpar materials (RPN score of 48).

4. **Improve Stage:** Having identified the factors causing volume defects in injectable medicine preparations, it is essential to propose improvements to reduce the number of rejects. The 5W + 1H technique was utilized to determine these improvements. The following are the proposed improvements:

   1. Conduct regular training sessions to enhance operator skills and competence.
   2. Implement preventive maintenance practices on the machines to ensure their optimal condition and prevent major breakdowns.
   3. Establish a machine downtime log to document any minor or major disturbances or damages that occur during machine operations.
   4. Perform machine calibration prior to the scheduled due date to maintain accuracy and precision.
   5. Create a log sheet for periodic volume checks during the production process to monitor and control ampoule volumes.

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These improvement proposals were formulated based on observations of existing conditions and through discussions involving operators, supervisors, and relevant departments.

5. **Control Stage:** In the control stage, the proposed improvements are documented, disseminated, and utilized as standard work guidelines. Several forms of documentation are suggested to ensure effective control and monitoring:

   a. Machine operation documentation: Record and document all machine operations, including setups, operations, stops, breakdowns, maintenance, and cleaning activities. This documentation helps identify any significant issues with the machines.

   b. Operator assessment documentation: Regularly assess and evaluate operator performance to understand their work capabilities and identify areas for improvement. The assessment results will aid in enhancing operator skills and competence.

   c. Training documentation: Document the data and information obtained from implemented training programs. This documentation allows for a review of the training process and an assessment of its impact on employee performance.

   d. Periodic volume check documentation: Implement in-process control checks on filled ampoules at 60-minute intervals. Sample one ampoule from each of the four filled needles during the production process. If the volume specifications do not meet the requirements, promptly conduct mechanical adjustments to achieve the desired volume. Any ampoules that fail to meet the volume requirements during the filling process should be rejected.

By implementing these control measures and documentation practices, the company can effectively monitor and maintain the improvements made during the improvement stage.

4. CONCLUSION

1. The volume defects in the injection medicine filling process can be attributed to various factors, including lack of supervision during the production process, insufficient operator skills, frequent machine breakdowns, incorrect machine settings, inadequate product storage, and subpar material quality. After analyzing these factors using the FMEA (Failure Mode and Effect Analysis) method, it was found that the lack of supervision during the production process has the highest RPN (Risk Priority Number) value of 112, while unfavorable materials have the lowest RPN value of 48.

2. To reduce the number of defects in the injectable medicine filling process, several improvement suggestions have been identified using the DMAIC (Define, Measure, Analyze, Improve, Control) method. These suggestions include:

   - Conducting regular training programs for operators to enhance their knowledge and skills, ensuring that the filling results comply with the established standards.
   - Implementing preventive maintenance practices to properly maintain and optimize machine performance, reducing the likelihood of breakdowns.
   - Creating machine downtime sheets to track and document any instances of machine downtime during the production process, aiding in identifying patterns or potential issues.
   - Performing machine calibration on schedule to verify the proper functioning of the machines, ensuring accuracy and precision.
   - Establishing periodic volume check log sheets during the production process to monitor and control the filling volume. Any deviations from the required volume can be promptly addressed by adjusting the filling machine, ensuring compliance with standards.

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By implementing these improvement suggestions, the company can work towards reducing defects in the injection medicine filling process and improving overall product quality.

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