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Application of Six Sigma and KAIZEN Techniques to Non-Conformities: A Case Study of Pharmaceutical Companies

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ABSTRACT

Every company certainly wants a good product and lots of it in order to get a profit, where at this time the competition is very tight. Therefore, this research is motivated by the many reject problems in the primary packaging product process (filling). This research was carried out at a pharmaceutical company located in Bogor, Wanaherang by taking problems with infusion bottles in January - March 2022, researchers also used 3 comparisons of infusion bottle products in companies, includes: levofloxacin, metronidaol, paracetamol infusion where the number of rejects in January and the most rejects in paracetamol infusion products are 2,303 pcs for 3 months, therefore this study aims to reduce the existing rejects by using the DMAIC, KAIZEN, Six sigma, FMEA and 7tools methods with the results of the study finding 3 critical to quality that covers: fiber, dirt, packaging. The researcher proposes to improve human resources using the KAIZEN 5S method and also scheduling operator training and machine maintenance checks every month so that during the production process minimize all obstacles.

Key Words: filling, DMAIC, KAIZEN, Infused bottle, Seven QC tools, Six sigma

1. INTRODUCTION

The pharmaceutical field is within the scope of the world of health which is closely related to product and service for health. Historically, higher education in pharmacy in Indonesia was formed to produce pharmacists who are in charge of pharmacies. With the rapid development of pharmaceutical science, pharmacists, also known as pharmacists, have been able to occupy a wider field of work. [1-7].

The rapid development of science and technology is due to the current era of globalization which has brought many changes in various aspects. Companies have to change their way of doing business because of the increasing competition in the business world. To stay in business, companies need to develop guidelines and strategies that suit market conditions [8-15].This research was conducted at a pharmaceutical company which is one of several pharmaceutical industries in the Gunung Putri Bogor area which actively produces various forms of pharmaceutical products. The pharmaceutical industry often produces several pharmaceutical dosage forms, include tablets, capsules, syrups, suspensions, creams and some sterile products. One is the preparation of infusion bottles.The problems that often arise in the production of infusion bottles in the manufacturing department is reject quality at the filling process stage. Where the amount of Reject impurities or unwanted substances enters the infusion bottle. To identify one product that will be used as a research subject, a calculation is made of three products that are processed usingsimilar filling machines and the results obtained are shown in the figure below

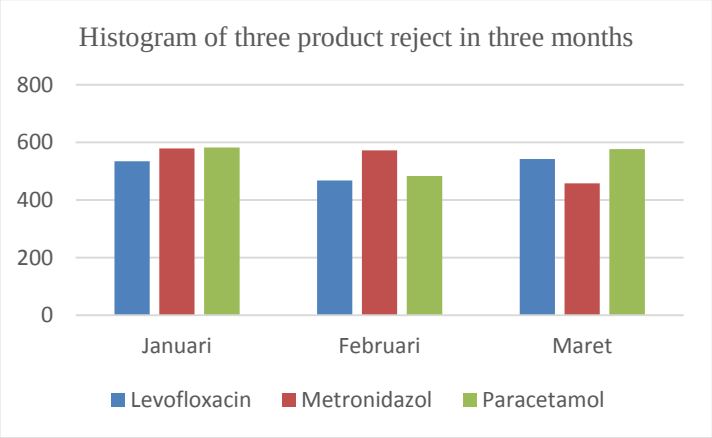

Figure 1 Reject Data for January - March 2022

The data above shows defective products in the filling process with the highest number of Levofloxacin Infusion products in the production process each producing 4800 pcs. And it can be concluded that production rejects are divided into 3 parts, namely rejects: fiber, black dots (dirt), average packaging The rejects produced are mostly fiber rejects. The following is a picture of a fiber reject product in the production of infusion bottles: This problem, of course, causes losses to the company and it is urgent that repairs be made immediately in order to reduce rejects and reduce losses. In addition, the quality of the product can decrease and the public (consumers) will have less trust in the company's products.

The number of factors that can cause product rejects can be from human factors and also space, so in this study using the DMAIC and KAIZEN methods in writing the DMAIC method related to Six sigma which calculates the analysis of reject measurements every month. DMAIC is a structured problem-solving method, often used for quality and process improvement. DMAIC is an implementation of the Six Sigma philosophy. The DMAIC method consists of five main stages, namely defining, measuring, analyzing, improving, and controlling [15-22].

Six Sigma focuses on increasing customer satisfaction, which has an obsession with perfect results. Six Sigma is called a discipline because it follows a formal model namely; DMAIC (Definite, Measure, Analyze, Improve, Control). Six Sigma is widely proven in practice and research shows high success in its application in corporate organizations, hospitals, schools, factories, airlines and universities. Thus, in this research, it is necessary to study literature and field studies in which the results of reject infusion bottles get analysis results [23-27]

The definition of Gemba Kaizen is the Japanese culture of continuous improvement in the workplace. However, it is a complete and well-tested “management”. It can be interpreted that the kaizen method requires human resources to make repairs and control periodically with the thought that a good production process can be maintained due to kaizen focuses on human resource management trained to have a 5S attitude. A bad work environment causes low productivity so that it will have an impact on the quality of the product produced. Production targets and plans cannot be realized, if the productivity elements (which include quality, efficiency, and effectiveness) are low, the company's productivity will also get low [28-34].

2. RESEARCH METHOD

2.1 Types of Research

This study uses a qualitative method with descriptive research, and uses analysis in each section so that the subjects studied are authentic (real). This study aims to identify the factors that cause and influence the occurrence of production process rejects, with the aim of reducing rejects in production process.

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In completing this research, using the Logbook of company documents related to production and rejects and conducting interviews with production operators in the field. The data used is data taken from the results of the sterile preparation production process. This is to ensure that the research data used is valid data.

2.2 Types of Data and Information

The data used is data taken from the results of the infusion bottle production process. The type of primary data is production results in the form of physical and secondary data in the form of supporting document logbooks. After determining the topics and objects to be discussed, the formulation of the problem is carried out by identifying through the inspection data analysis process at the production (packing) stage of the product after so that it can formulate the problem correctly and precisely based on the facts in the field.

2.3 Method of collecting data

Data collection by the author is:

a. Perform company data collection.

Retrieving production process data for 3 months starting from January – March 2022

b. Field study

Data collection is carried out in the manufacture section in order to get direct results in the form of physical form

c. Interview

Questions and answers were carried out to obtain reject data and what problems are usually faced by employees in the production process, starting from January - March 2022.

Table 1Interviewee

No	Person	Experience
1	Supervisor Production	5 years
2	Infusion bottle filling operator	12 years
3	inspection operator	7 years

2.4 Data Processing and Analysis Methods

Data processing uses the DMAIC and KAIZEN methods through several stages, include:

DMAIC Method:

1. Define (definition)

Identify reject problems with Critical to Quality (CTQ)

2. Measure (measurement)

The research measurement uses a pareto chart diagram and six sigma company calculations for 3 months.

3. Analyze (analysis)

Analyzing the production process from the reject diagram cause & effect diagram.

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4. Improvement (improvement)

Proposed improvements based on the highest RPN value in FMEA provide improvement proposals using 5W+1H and Kaizen 5S.

5. Control (control)

A good results analysis controller after carrying out improvement results and making a monthly improvement report check sheet.

2.5 Research Steps

The research steps are the process flow of the description of this research so that the structure of this research will start from problem identification by utilizing literature studies such as DMAIC, KAIZEN, six sigma, FMEA combined with field observations and production processes. After collecting all the data which is total data and production/reject data, the author will identify product reject problems with CTQ, then calculate the DPMO, sigma and Pareto chart values, so as to be able to find the cause of the problem of product rejects with Fishbone diagrams and FMEA. After that, the author will determine the corrective action based on the largest RPN value and the 5S & 5W + IH kaizen proposal so that the subject can carry out a machine & HR maintenance check sheet. Finally, there will be conclusions and suggestions.

3. RESULT

3.1 Research results and discussion

In the previous chapter, we discussed the analysis and calculations of research on infusion bottles where the cause of many rejects of infusion bottles was due to operators not understanding the flow of the production process so that many made mistakes or procedures that were not good and the results were poor. Efforts made to describe the results of the discussion analysis will be carried out using 5 stages through the DMAIC method (Define, Measure, Analyze, Improve and Control). As follows:

3.1.1 Define

Define is the step to summarize what happened in research in order to facilitate data processing and the following types of rejects that are present at the stage of the production process (filling) are:

a. Fiber

One of the most common production processes rejects because all production processes use a lot of fiber samples from operator clothing or rooms where humidity is not maintained.

b. Packaging

Rejects usually enter into the production process where there are many broken bottles and it is likely that only 40% of the rejects will occur

c. Dirt

One of the rejects that becomes a lot of rejects because dirt generally occurs on attached machines or tools used

Where the number of rejects in the production process (filling) is fiber rejects. And the most rejects were Paracetamol infusion products in January 2022

3.1.2 Measures

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In the calculation stage where six sigma tools are used to get a dpmo defect per million opportunities of 40486 and a sigma value of 3.24 for the largest reject product, namely paracetamol infusion in January, so that the company has received a loss of 10-15% every month.

3.1.3 Analyze

From the analysis carried out using fishbone tools which focus on the most rejects, include fiber rejects and getting references from employees who work directly at the company and FMEA analysis with the calculation of RPN (Risk Priority Number), the biggest failure mode for humans is operator 576. The following is fishbone diagram analysis results.

1. Man

a. Lack of concentration at work. This leads to negligence and burnout at work.

b. Lack of training (training) for operators in machine setting problems. This causes a lack of knowledge of machine settings when trouble occurs on the machine.

2. Material

The quality of the packing material for infusion bottles / raw materials from suppliers is not good. This can be the cause of damage during product packaging.

3.Machine

a. Machine speed settings that are not in accordance with standards can affect rejects because they can release particles in each part and may enter the packaging.

b. Too much trouble can release operator particles that work and stick to existing parts which can become contamination.

4. ENVIRONMENT

a. Room temperature can be a problem because if the room temperature is hot, it can cause humidity in the room

b. Cleaning the room that is less than optimal can result in remaining dirt that could become contamination.

Following are the results of the RPN (Risk Priority Number) calculation analysis:

RPN = S x O x D

Table 2 RPN Calculation table

Defect type	Failure modes	Potential Failure of effect	S	O	D	RPN
Fiber rejection	Room	Humid room temperature is not maintained	8	5	7	280
	Operator	The operator has not yet mastered the machine	9	8	8	576
	Machine	Poor maintenance program	7	6	6	252
	Materials	Raw materials/packaging is not good	5	5	4	100

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	Procedure	Poor production process procedures	8	8	8	512

It can be concluded that the most rejects are operators with a value of RPN: 576 and focusing on the most rejects are operators and there is a second warning there is a procedure section with a value of 512.

3.1.4 Improvement

After knowing that the largest reject (fiber reject and the largest RPN) is in the operator which having problem with lack of knowledge about machines & procedures, then improvement actions are carried out using 5W + 1H (What, Why, Where, When, Who, How).

Table 35W+1H Analysis

5W+1H	Human Characteristics	Lack of operator experience	Poor instructions
What	Standardize good candidates	Lack of proper and correct production process training	Give good and correct directions about the tasks
Why	To avoid people with bad characteristics	To get operators who respond quickly and care about the situation	Narrow down the occurrence of miss communication
Where	Filling production process	Filling production process	Filling production process
When	Conducted before the production process runs	Conducted before the production process runs	Conducted before the production process runs
Who	Filling production team	Filling production team	Filling production team
How	Creating SOPs related to selecting good candidates, especially attitude	Provision of a good production process flow training schedule and standardization of production	A briefing is carried out to the personnel in charge of the filling area before the production process

3.1.5 Control

For a production process to run smoothly, a control stage is needed to see the results of research and the results of control using point training, which can be assessed by how big the problems will be caused during the production process. Point problems can be said to be a level of problems that will impact the production process: 1. Not influential problems; 2. The quite influential problems; 3. very influential problems.

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First thing to consider that there is a need for a thorough understanding of operators about procedures and machine understanding. It can be developed by being given time to be given training about the company and the flow of the production process and to refresh training every 6 months.

Table 3Types of production process training

No	Types of production process training	Reasons for training	Point
1	Sanitize hands for at least 15 minutes	Conducted because operators often touch goods which possibly cause the contamination	3
2	How to dress	Can be the cause of contamination originating from the operator's body	2
3	Movement of production process operators	To maintain the release of particles in the human body	3
4	Procedure for cleaning the machine	To clean the operator's body from dirt	1
5	No contact with walls and unnecessary physical contact	To prevent contamination	3

Second thing to consider is the need for repairs and a planned schedule of machine repairs. Maintenance every month is necessary because the infusion bottle machine is used every day, consequently can cause several components are no longer suitable for use. Therefore, to avoid problems that allow disruption of the production process, here is a maintenance table:

Table 4Maintenance

No	Maintenance conducted every month	Point
1	Giving oil / lubricant to the gear	2
2	Cleaning of engine motor gear area	1
3	Motor calibration	3
4	Check the motorcycle v belt	3
5	Worn gear replacement	3
6	Thorough cleaning of the inside of the machine	3
7	Calibration of the infusion bottle machine monitoring system	2
8	Engine effectiveness calibration	3

The last thing to consider is in reducing humidity, the room temperature is required to be maintained every one hour. It is important to control the room temperature so that it does not exceed the standard limits. Therefore, SPV Production is expected to always control room temperature and always coordinate with technicians to regulate room temperature which greatly affects RH.

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4. CONCLUSION

4.1 Conclusion

Based on the research that has been done, it can be concluded as follows:

1. It is known that the number of CTQ (Critical to Quality) is 3 includes fiber, dirt, and packaging rejects which often arise in the production process problems of infusion bottle pharmaceutical companies and the most rejects are fiber rejects.

2. Based on the results of the cause & effect diagram, the most rejects are in humans (operators), wherethere were too many unnecessary activities in the infusion bottle research.

3. To develop the value of human resources, especially for operators, the KAIZEN 5S method is needed as follows:

Seiri (Brief)

Operators are expected to be able to differentiate what is needed. It means that the work priority is according to urgency, thus the production process is not hampered.

Seiton (Neat)

Operators are given instructions to put things neatly, so it is not difficult to find, such as tweezers, measuring cups, pens, and work sheets.

Seiso (Clean)

In this point, it is hoped that the operator knows that work in the pharmaceutical sector requires cleanliness, where the machine and supporting equipment that will be used should be clean and sterile.

Seikutse (Take care)

Machine maintenance is necessary where the operator is aware that spareparts should be maintained and submitted to the top management to request time for maintenance.

Shitsuke (Diligent)

To make all stages can be carried out, operators are required to be industrious in carrying out 5S KAIZEN and they should operators are loyal to do their job.

4. The calculation of DPMO (Defects per Million Opportunities or failures per million opportunities) with an average is 40486 with a sigma value of 3.24 and the largest FMEA RPN (Risk Priority Number) value for operators who yet mastered the production process flow correctly, it can be concluded that the ability of the production process is still lacking which pushing it to the re-improvement.

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