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Production process improvements to minimize product defects using DMAIC six sigma statistical tool and FMEA at PT KAEF

Production process improvements to minimize product defects using DMAIC six sigma statistical tool and FMEA at PT KAEF

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Abstract. PT KAEF is one of the pharmaceutical manufacturing industries in Indonesia that produces various kinds of drug variants. Currently, PT KAEF is experiencing problems in the form of product defects that exceed the company's standard, which is 1%. By using the DMAIC Six Sigma Statistical tool (Define, Measure, Analyze, Improve, and Control), it is possible to evaluate the possibility of failure of the production system so that the cause of each product defect can be identified and get the right problem-solving solution and with Failure Mode Effects Mode can be known the solutions for the priority problems. From the search results, it can be seen that liquid products are the products with the most defects, with the causes of defects caused by errors in work procedures and the use of old machines. From the improvement results, it was found that the level of product defects decreased from 2,26% to 0,93% or in sigma level increase from 4,18 to 4,46.

1. Introduction

Global economic progress impacts all fields, including the pharmaceutical industry in Indonesia. Manufacturers are required to create quality, safe and valuable medicinal products. For this reason, the pharmaceutical industry in Indonesia needs to implement quality control to ensure that consumers get medicinal products of the desired quality. Quality is a dynamic condition associated with products, people or labor, processes and tasks, and environmental changes that meet or exceed consumer expectations [1-4].

PT KAEF is a pharmaceutical company in Indonesia that focuses on the pharmaceutical industry. Currently, PT KAEF is a very influential producer of prescription and non-prescription products in the national market, and at current condition is experiencing problems related to quality. Difficulties that arise in the production process need to be improved in quality to reduce product defects. Production data shows that a product defect causes the company's target not to be achieved. The production data of the number defects product is presented in Table 1.

Table 1. Defect rate average.

No	Product	Jul	Aug	Sep	Oct	Nov	Dec	Defect Rate
1	Liquid	2,82	2,50	2,23	2,18	1,76	2,07	2,26
2	Dry Syrup	0,52	0,50	0,53	0,54	0,55	0,60	0,54
3	Capsule	0.53	0,54	0,55	0,56	0,54	0,52	0,54

It can be seen in table 1 above that the percentage of defects is more than the company standard, which is 1%. It can be described as a liquid product with a 2.26% defect, 0.54% dry syrup product, and 0.54% capsule. The level of defect will affect its competitiveness. Therefore, companies should strive to control the process and product quality as much as possible to reduce the defect rate. Quality control can be carried out in various ways, including statistical and other methods [5]. There are variations in the manufacturing process that can affect the quality of the product you make. Therefore, these fluctuations need to be reduced [6].

2. Research Methodology

This study aims to resolve the causes of quality problems that occur in PT. KAEF. The following are descriptions of the research methods in this study.

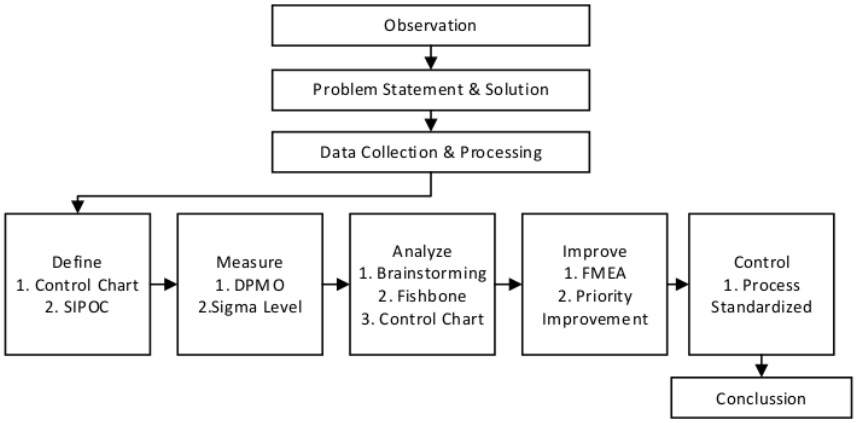

Figure 1. Research framework.

Observation is used to observe the actual conditions that occur so that the problem statement can be determined. If the cause of the problem is known, it can be easier to provide alternative solutions to the problem. Data processing to find out how to control and improve the quality of liquid products that are still below the company's standard provisions. The data processing stage described using the DMAIC stages, namely Define, Measure, Analyze, Improvement, and Control [7-10]. The following is a description of each stage:

a. DMAIC (Define, Measure, Analyze, Improve, Control) to optimize quality applied to the production department.
b. FMEA (Failure Mode and Effect Analysis) to identify the causes of failure/defects thoroughly accompanied by numerical weighting to determine the effects that need to be prioritized for improvement. The analysis is used to compare the results of improvements that have been improved, namely the current condition with the company's target [11-13]. Improvements are monitored continuously to reduce product defects at PT KAEF.

Conclusions and Suggestions are the last stages of this research. Conclusions are drawn from the results of problem-solving that are in line with the research objectives. From the results of this study, this research can give suggestions that help be followed up for the benefit of the company and the improvement of further research.

3. Results and Discussion

The production process for liquid product starts from the input of raw materials to become products and is explained with an operation process chart map as follows in Figure 2.

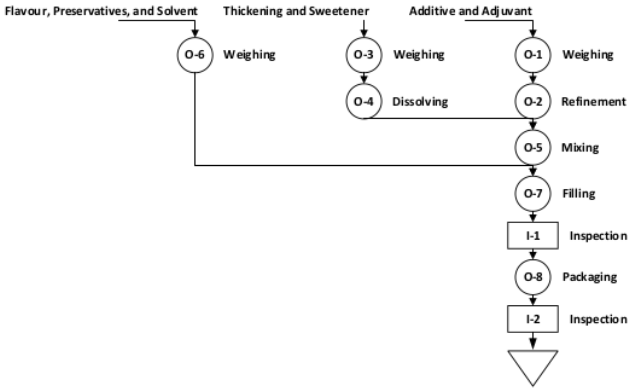

Figure 2. OPC for liquid products.

. Define Stage

Based on Table 1, it can be seen that the highest percentage of defects is in liquid products. To identify critical causes of defects that occur, CTQ is used, which is a factor of the process that directly impacts achieving the desired quality. Based on observations at PT. KAEF, the CTQ factor that occurs can be seen in Table 2.

Table 2. Critical to quality.

No	Defects	Number Of Defect	% Defect
1	Damaged Physical Packaging	866	59.03
2	Lack Of Completeness Of Contents	271	18.47
3	Incorrect Coding	193	13.16
4	Mix -Ups	91	6.20
5	Incorrect Labeling	37	2.52
6	Contamination	9	0.61
	Total	1467	100.00

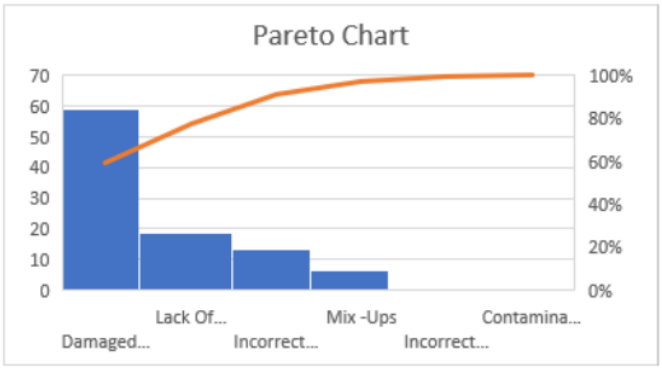

Figure 3. Pareto diagram.

Based on the Pareto chart as shown in figure 3, the biggest problem with damaged physically packaging has the highest level of product defects. Therefore, the problem taken is repairing the physical imperfections of damaged packaging.

3.1.1. SIPOC Diagram (Supplier, Input, Process, Output, Customer)

The SIPOC diagram was created better to understand the process from the supplier to the customer. The following is a SIPOC diagram for the production of liquid products.

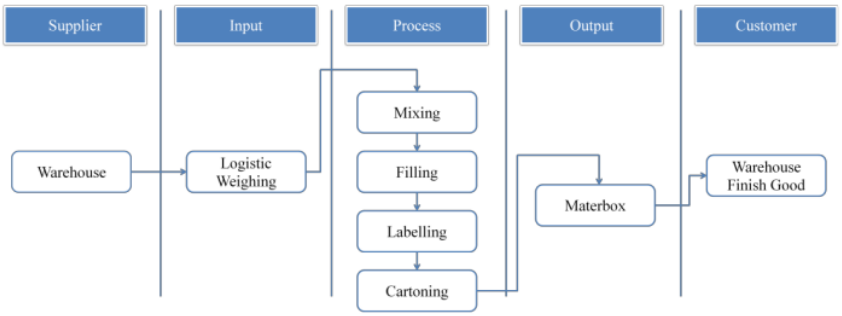

Figure 4. SIPOC diagram.

The explanation in the figure 4 is a) Suppliers provide the resources or materials needed by the company to produce goods in the form of drugs from the warehouse, b) Inputs are materials and or resources provided by suppliers to be transformed in the production process, c) Process is a series of actions and activities that convert materials (active substances and additives) into liquid drug preparations through processes, namely Mixing, Filling, Labeling, and Cartoning, d) Output in the form of drugs produced by the production process to be ready for distribution to customers in master box packaging, e) Customers (customers) or downstream processes that receive the output from the accepted process to the well-finished warehouse (finished drug warehouse), which is ready to be handed over to the distributor, namely the pharmaceutical wholesaler company.

3.2 Measure Stage

3.2.1 Process Capability Analysis

To predict how consistently the process meets the specifications determined by the company, the calculation of process analysis capability can be known. Then the calculation of production analysis capability is:

$$\overline{P} = \frac{Total\ defect}{Total\ production} \quad (1)$$

$$= \frac{1467}{65000} = 0{,}023 \quad (2)$$

$$Cp = 1 - \overline{P} \quad (3)$$

$$= 1 - 0{,}023 = 0{,}977 \quad (4)$$

From the calculation above, the Cp value is 0.977, which means the ability of the liquid production process to produce a standard production process is 97.7%.

3.2.2 DPMO and SQL

Defect Per Million Opportunity (DPMO) is a measure that shows defects per million opportunities, while Sigma Quality Level (SQL) offers a sigma value that describes the level of process performance. The calculation begins by finding the Defect Per Unit (DPU) value first by using the formula:

$$\text{DPU} = \frac{Defect}{Sampling\ unit} \quad (5)$$

$$\text{DPO} = \frac{DPU}{Total\ CTQ} \quad (6)$$

$$\text{DPMO} = \text{DPU} \times 1.000.000 \quad (7)$$

$$\text{Sigma Level} = (\text{NORMSINV}(1-\text{DPMO})) + 1{,}5 \quad (8)$$

Table 3. Sigma level for liquid products.

	Month	Jul	Aug	Sep	Okt	Nov	Des	Total	Average
	Sampling Unit	10500	11500	10500	11000	11500	10000	65000	10833
CTQ	Damaged Physical Packaging	161	174	160	144	112	115	866	144
CTQ	Lack Of Completeness Of Contents	60	49	35	42	41	44	271	45
CTQ	Incorrect Coding	49	28	19	38	32	27	193	32
CTQ	Mix -Ups	18	21	13	10	13	16	91	15
CTQ	Incorrect Labeling	7	13	6	5	2	4	37	6
CTQ	Contamination	1	3	1	1	2	1	9	2
	Defect	296	288	234	240	202	207	1467	244,50
	% Defect	2,82	2,50	2,23	2,18	1,76	2,07	13,56	2,26
	DPU	0,03	0,03	0,02	0,02	0,02	0,02	0,14	0,02
	DPO	0,00	0,00	0,00	0,00	0,00	0,00	0,02	0,01
	DPMO	4698	4174	3714	3636	2928	3450	22600,51	3766,75
	Sigma Level	4,10	4,14	4,18	4,18	4,26	4,20	25,05	4,18

Based on table 3 above, it can be seen that the average DPMO value of the liquid product is 3766,75, meaning that for every one million products produced, there are 3766,75 possible defects in the product. In comparison, the average sigma level is 4.18.

3.3. Analyze Stage

The third stage of the DMAIC concept is the analysis stage. The analysis process is carried out using Pareto diagrams and fishbone diagrams. The primary purpose of the analysis stage is to find the main focus of the repair process as well as find the root cause of several types of defects that occur in the repair process.

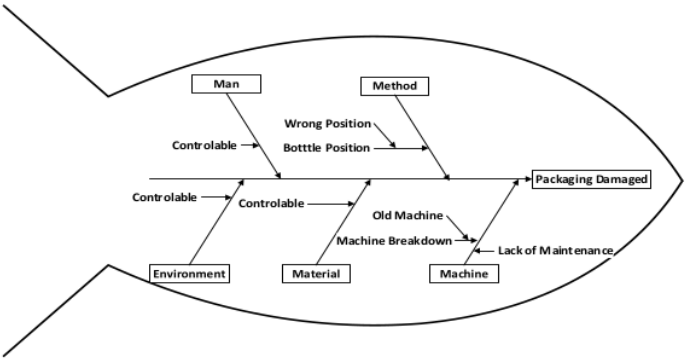

Figure 5. Fishbone diagram.

In Figure 5, there are three identifications of the causes of physical failure of damaged packaging in the method, namely not carrying out regular machine maintenance, improper placement of bottles and

in the machine, namely the age of the device is old. In this case, it is necessary to improve the defect rate so that the company's target is achieved.

3.4. Improvement Stage

Failure Mode and Effect Analysis (FMEA) is used to determine the priority of repair after the cause of the error in the production process is known. Based on the data collection made, the next step is to create an FMEA table that provides value weighting using Severity, Occurrence, and Detection to generate a Risk Priority Number (RPN) value.

3.4.1. Determine the level of seriousness that occurs (Severity)

The severity of the effect is described on a scale of 1-10. The higher the ranking, the more serious the impact. The severity value of the resulting consequences can be seen in Table 4.

Table 4. RPN value of CTQ.

Potential Failure Modes	Pottential Effect (S) Of Failures	SEV	OCC	DET	RPN	Rank
Packaging Damaged	Wrong Bottle Position	7	6	7	294	1
	Lack of Maintenance	7	4	8	224	3
	Obsolete Machine	6	5	8	240	2

3.4.2. FMEA Analysis

Based on data processing results using FMEA, the highest RPN value in the physical defect of damaged packaging is inappropriate bottle placement. The bottle is in the wrong position with a value of 294. This is because no supervision makes workers negligent in placing bottles in the filling machine. There are bottle placement problems shifted. Therefore, the resulting product produces failures such as physically damaged packaging. Lack of maintenance can also happen because of no preventive maintenance, so that that machine will be damaged frequently. The machine that PT. KAEF uses dominated with the old machine and needs more attention about their part. After we know the potential effect of failure, then we can make an action plan.

Action Planning for Failure Modes is made to determine the most appropriate action that has a high risk of failure. The data used are the results that have been obtained from the Failure Modes and Effects Analysis (FMEA) analysis by looking at the order of the highest RPN to be given attention. Furthermore, appropriate solutions are made to eliminate the root cause of the problem. Action Planning for Failure Modes table for dimensional defect problems can be seen in Table 5.

Table 5. Action planning for failure modes.

Rank	Actionable Cause	Potensial Solutions	Design Validation
1	Lack of Supervision by the Head of Section	The Head of the Production Department must carry out regular supervision and create a work appraisal system for operators	Employee Work Report
2	No Sparepart	Analysis and Making of Spare Parts Every 6 Months	Sparepart Using Data
3	Lack of Maintenance Schedule	All Company Employees Perform Preventive Maintenance Every 3 Months By Cleaning And Performing Routine Inspections, Making Schedules To Perform Machine Maintenance	Maintenance Schedule Logbook Filling

Improvements made based on these solutions are expected to increase the value of process sigma, which is used as a benchmark for process quality to produce quality products. In general, the

improvement of the above matters will improve the performance of the liquid preparation production process.

Table 6. Estimation improvement result.

Month		Jul	Aug	Sep	Okt	Nov	Des	Total	Average
Sampling Unit		10500	11500	10500	11000	11500	10000	65000	10833
CTQ	Damaged Physical Packaging	0	0	0	0	0	0	0	0
	Lack Of Completeness Of Contents	60	49	35	42	41	44	271	45
	Incorrect Coding	49	28	19	38	32	27	193	32
	Mix -Ups	18	21	13	10	13	16	91	15
	Incorrect Labeling	7	13	6	5	2	4	37	6
	Contamination	1	3	1	1	2	1	9	2
Defect		135	114	74	96	90	92	601	100,17
% Defect		1,29	0,99	0,70	0,87	0,78	0,92	5,56	0,93
DPU		0,01	0,01	0,01	0,01	0,01	0,01	0,06	0,01
DPO		0,00	0,00	0,00	0,00	0,00	0,00	0,01	0,01
DPMO		2143	1652	1175	1455	1304	1533	9262	1543,64
Sigma Level		4,36	4,44	4,54	4,48	4,51	4,46	26,78	4,46

3.5 Comparison of current conditions with proposed conditions

Evaluation of the repair activities carried out to see how much effect the results of these improvements can be proven by comparing the results of the repairs with the results before the repairs.

Table 7. Comparison current and improvement condition.

Month	Jul	Aug	Sep	Okt	Nov	Des	% Defect	Sigma Level
Before Improvement	2,82	2,50	2,23	2,18	1,76	2,07	2,26	4,18
After Improvement	1,29	0,99	0,70	0,87	0,78	0,92	0,93	4,46

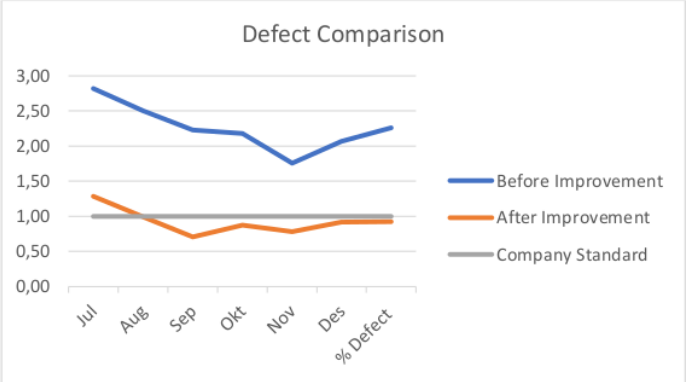

Figure 6. Defect comparison.

Figure 6 described about comparison of current condition with repair condition. Evaluation of the repair activities carried out to see how much effect the results of these improvements can be proven by comparing the results of the repairs with the results before the repairs.

It can be seen from table 7, the comparison between the future sigma value and the current sigma value can increase the sigma value in the following way: Make employee performance reports by assessing whether the operator has followed the work instructions that have been made. There is a checklist for using spare parts data to facilitate monitoring of the availability of spare parts to be used. The machine can produce optimal performance by performing preventive maintenance, and a machine maintenance schedule logbook can prove machine monitoring. To prevent mix-ups, employees are given training and referrals scheduled by the PGA section on the characteristics of pharmaceutical preparations. SOP for attaching identity labels correctly and adequately to prevent inappropriate material taking is helpful to avoid mix-ups during the production process. Supervisors and employees care about others to improve the quality of the production process by making routine check schedules to verify each stage of the production process. With a label indicating a ready-to-use line, every employee does not feel confused or wrong in working, aiming to avoid contamination of the products to be produced.

3.6 Control Stage

At the control stage, namely monitoring the repaired processes to determine whether the improvements were correctly implemented or not, if the control remains stable within the specified limits, then the control stage is running well. The results have been made work standards by making standard operating procedures (SOP) and work instructions (WI).

The placement of the bottle is not appropriate, so that the bottle is in the wrong position, the working standard is made as follows.

Work Instructions For Placing Bottles Ready For Filling				
Document Number	Effective Date	Revision	Work Instruction	Page
SOP-1/1	1 Augustus 202	1	Filling	1
Description				
1. Clear Bottles Are Placed In A Predetermined Area With An Identity Label Marking				
2. Insert The Clear Bottle Into The Bottle Blowing Machine In A Way That It Should Not Be Inserted In A Crossed State Or Through The Conveyor				
3. Bottle Blowing Machine Is Filled According To Predetermined Limits (Following The Predetermined Limit Line)				
4. The Operator Carefully Follows The Bottle Placement Process And Ensures The Bottle Is In Perfect Condition				
Sign:				

Figure 7. Work instructions for placing bottles.

The age of the machine is old, the engineering section makes a checklist of data on the use of spare parts as follows:

No.	Sparepart	Total	Remains	Taken By	Sign	PIC Sign
1	Sprocket Filling Machine	5				
2	Sprocket Mixing Machine	3				
3	Ruber	4				
4						
5						
6						

Figure 8. Checklist of spare parts usage.

Periodic maintenance is not carried out, by filling out a logbook that can be verified, it will monitor machine maintenance periodically, such as the following logbook:

No.	Machine	No. Seri	Duration (hrs)	Maintenance date	Using Date	Using For Products	No. Batch	Sign
1	Filling	SN5212	4	20 July 2021	21 July 2021	123	A12	V
2	Mixing	SN6370	4	21 July 2021	22 July 2021	123	A15	V
3	Cartooning	SN7344	3	24 July 2021	25 July 2021	123	A15	V
4	Filling	SN5212	4	1 Agustus 2021	2 Agustus 2021	123	A17	V
5	Mixing	SN6370	4	2 Agustus 2021	3 Agustus 2021	123	A20	V
6	Cartooning	SN7344	3	10 Agustus 2021	11 Agustus 2021	123	A21	V
7								
8								

Figure 9. Maintenance machine logbook.

4. Conclusion

Based on the results of data processing and analysis that has been done regarding this research, it can be concluded that:

With the improvement, the quality of liquid products increases, and the condition after modification exceeds the company's target, which can be proven by the company's sigma value of 4.18-sigma to 4.46-sigma. The causes of disability are caused by the placement of the bottle is not appropriate so that the bottle is in the wrong position, the machine is old, no periodic maintenance, and no routine check schedule so operators are negligent in their work.

Suggestions for improvements to make are calculating spare parts needed every three months, preventive maintenance every month, making bottle placement work instructions, making spare parts and inventories checklists, making machine usage logbooks, conducting training and refreshment for all production employees, and making ready-to-use line labels.

Acknowledgement

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