ISSN No:-2456-2165

Application of FMEA For Identifying Risk Failure of The Medicine Failure Process

(Study Case PT. Kimia Farma TBK Jakarta)

Erry Rimawan, Apriliana Cendraleka, Johan Permana, Dydi Purwanto
Magister of Management Mercubuana University
Jakarta

Abstract:- Quality control is one of the important things to maintain the company's reputation in the eyes of consumers. PT. Kimia Farma Tbk is a pharmaceutical company engaged in medicine. At present the product defects that occur in the company still exist beyond the company boundary provisions, which are above the percentage number set by the company, which is equal to 1%. So that the company immediately makes repairs so that there is no waste that harms the company.

With good and correct quality control, products will be obtained that can meet consumer desires. One of the tools used to help control quality is to use the Failure Modes and Effects Analysis method (FMEA).

The purpose of this study is to analyze the failure modes that cause product defects by using the FMEA method, getting the risk of the biggest production process failure in the value of the RPN (Risk Priority Number), providing proposed improvements for subsequent production. Based on processing with the FMEA method can identify modes of failure that occur in the process making drugs. The mode of potential failure in the process of making drugs consists of 6 types of failures.

Keywords:- *Quality; Failure Mode and Effect Analysis; Risk Priority Number.*

I. INTRODUCTION

Today the industrial world is growing rapidly, resulting in a variety of products being produced. The diversity of these products forces producers to continue to improve the quality of products produced in accordance with the wishes of consumers. However, there are still many industry players who pay less attention to product quality. Defective products are the main source of waste. Not a few companies face serious problems because of defective products that cause claims from consumers. If the defective product passes to the consumer and then causes a loss, the company must replace the loss experienced by the consumer. One of the negative effects caused is the collapse of the company's reputation in the eyes of consumers. If such a situation is not dealt with immediately, the company will lose potential customers. With good and correct quality control, products will be obtained that can meet consumer desires. One of the tools used to help control quality is to use the Failure Modes and Effects Analysis method (FMEA). FMEA is a methodology used to evaluate failures occurring in a system, design, process, or service.

Identification of potential failures is carried out by assigning scores or scores to each failure mode based on occurrence, severity and detection rates (Stamatis, 1995). In general, there are two types of FMEA, FMEA design and FMEA processes. In FMEA design, observations are focused on product design. While FMEA processes, observations are focused on production process activities. The method applied in this study is FMEA process, because observations are only carried out on ongoing production process activities and do not pay attention to product design. The purpose of applying this method is to minimize the possibility of defects.

PT Kimia Farma Tbk Jakarta is a pharmaceutical company engaged in the manufacture of medicines. At PT Kimia Farma Tbk Jakarta, quality control is still not optimal. This can be seen from the existence of a number of products that are defective in each production time. Based on historical data obtained, that the percentage of defects that have been carried out in May 2018 to September 2018 is still very high, the frequency of defects in drug products of PT. Kimia Farma Tbk Jakarta can be seen in Table 1.

Months	Number of Defects (pcs)	Number of Products (pcs)	Number of Percentage (%)
May 2018	934	65340	1,43 %
Juni 2018	632	62426	1,01 %
July 2018	572	48231	1,18 %
August 2018	1017	45783	2,22 %
September 2018	1292	52123	2,47 %

Table 1:- Historical data on the number of defects frequency of medicinal products PT Kimia Farma Tbk Jakarta during May 2018 - September 2018(Source : PT Kimia Farma Tbk, 2018)

ISSN No:-2456-2165

Table 1 shows the percentage figure of the number of defective products experienced by this company there are still high enough numbers above the percentage figure set by the company which is equal to 1%. The impact on the company if there is a defect that exceeds the provisions, namely the amount of residual drugs produced makes waste.

In addition, if there is a defect until it has passed the packing stage, the grade will be lowered according to the drug conditions disabled. This will make a loss for the company because low quality medicinal products cannot be exported and of course the price is far below the export price. Whereas the market share of PT. Kimia Farma is countries in the Indonesia and Asia Region so that the quality of medicines must be good.

If this happens continuously, it will harm the company. So, it is necessary for companies to know the types of failures that can arise during the production process. Based on the potential failure, it is necessary to determine the type of failure that must be prioritized in advance so that it is immediately repaired so that the product is not recovered with the same type of failure process. Based on these problems, the purpose of the research is to identify the problem of determining priority types of failures in the process of Failure Mode and Effects Analysis (FMEA) so that the quality of medicinal products is expected from PT Kimia Farma had been increased.

II. LITERATURE

A. Failure Model and Effects Analysis (FMEA)

Failure Mode and Effect Analysis (FMEA) is the technique that functions to identify the potential failure mode of a product during its life cycle, the effects of this failure; and the critical level of the effect of this failure in product use. FMEA can be explained as a group of activities which include (Prajapati, 2012) :

- Recognize and evaluate the failure of the product or process and the effects it causes.
- Identify actions that can eliminate or reduce the possibility of failure
- Document the process.

The main objective of FMEA is to find and correct the main problems that occur at each stage of the design and production process to prevent bad products from reaching customers, which can endanger the company's reputation (Teoh & Case, 2004)

FMEA (Failure Mode and Effect Analysis) is used to identify source sources and root causes of a quality problem. FMEA is a structured procedure for identifying and preventing as many failure modes as possible. A failure mode is anything that is included in a disability, a condition outside the specified specifications, or a change in the product that causes disruption of the function of the product (Gaspers, 2002).

The stages of FMEA itself are as follows (Teoh & Case, 2004):

- Determine the components of the system / tool to be analyzed.
- Identify the potential failure / failure mode of the observed process.
- Identify the effects (potential effects) of potential failure modes.
- Identify the potential cause of failure mode that occurs in the ongoing process.
- Establish values (by way of field observation and brainstorming) in the point of seriousness due to errors in local processes, continuation and to consumers (severity) and frequency of occurrence (occurrence), as well as control devices due to potential cause (detection). The value of RPN (Risk Potential Number) is obtained by multiplying the value of SOD (Severity, Occurrence, Detection).
- The RPN value indicates the seriousness of potential failure, the higher the value of the RPN it shows the more problematic. There are no reference figures for the RPN to make improvements. Immediately make repairs to potential causes, control devices and effects caused.

Severity is an assessment of how serious the effect of the potential failure mode is on the customer. The value that describes the severity can be seen in the table severity below.

Rangking	Criteria
1	Negligible severity
2	Mild severity
3	Moderate severity
4	High severity
5	Potential safety problem

Table 2:- Table Severity Source : Teoh & Case (2004)

Occurrence indicates the frequency of a problem that occurs due to a potential cause. The values that describe occurrence can be seen in the occurrence table below:

Degree	Based of Frequencies of Event	Rating
Remote	0,01 per 1000 item	1
Low	0,1 per 1000 item	2
	0,5 per 1000 item	3
Moderate	1 per 1000 item	4
	2 per 1000 item	5
	5 per 1000 item	6
High	10 per 1000 item	7
	20 per 1000 item	8
Very High	50 per 1000 item	9
	100 per 1000 item	10

Table 3:- Occurance Table

ISSN No:-2456-2165

B. Multi Atribut Failure Mode Analysis (MAFMA)

Multi Attribute Failure Mode Analysis (MAFMA) is a method that integrates conventional Failure Mode and Effect Analysis (FMEA) by considering economic aspects (Braglia, 2000). In conventional FMEA, only a few attributes of failure are considered without regard to very important factors, namely economic factors (Zheng, Liu, & McMahon, 2010)

FMEA is an analysis technique by a team or expert to identify potential failure modes and their causes, in the manufacturing process. This FMEA process plays a role in: identifying process functions; identification of products and processes that have the potential to experience failure mode; analyze the effects arising from failures on consumers; identification of causes of failure and variables in the process used to reduce the occurrence of failure; identification of variables in the process to control the process; ranking for each failure mode in determining priorities for corrective action; document results (Laskova & Tabas, 2008)

In the MAFMA method, determining the cause of potential failure is determined based on the highest weight value. The MAFMA method calculates by integrating four factors in FMEA, namely the chance of failure (assurance) change of non detection, severity, and expected cost. Failure costs are calculated by qualitative comparison (qualitative pairwise comparisson).

Costs due to this failure cannot arise if there are no failures or defects in the products produced. These costs include costs due to scrap, which are irreparable products, costs due to rework, costs for failure analysis, re-inspection costs and others costs due to defective products.

III. METHODOLOGY

The research methodology contains the steps taken in the study. In this study, the research methodology is shown in Fig 1.

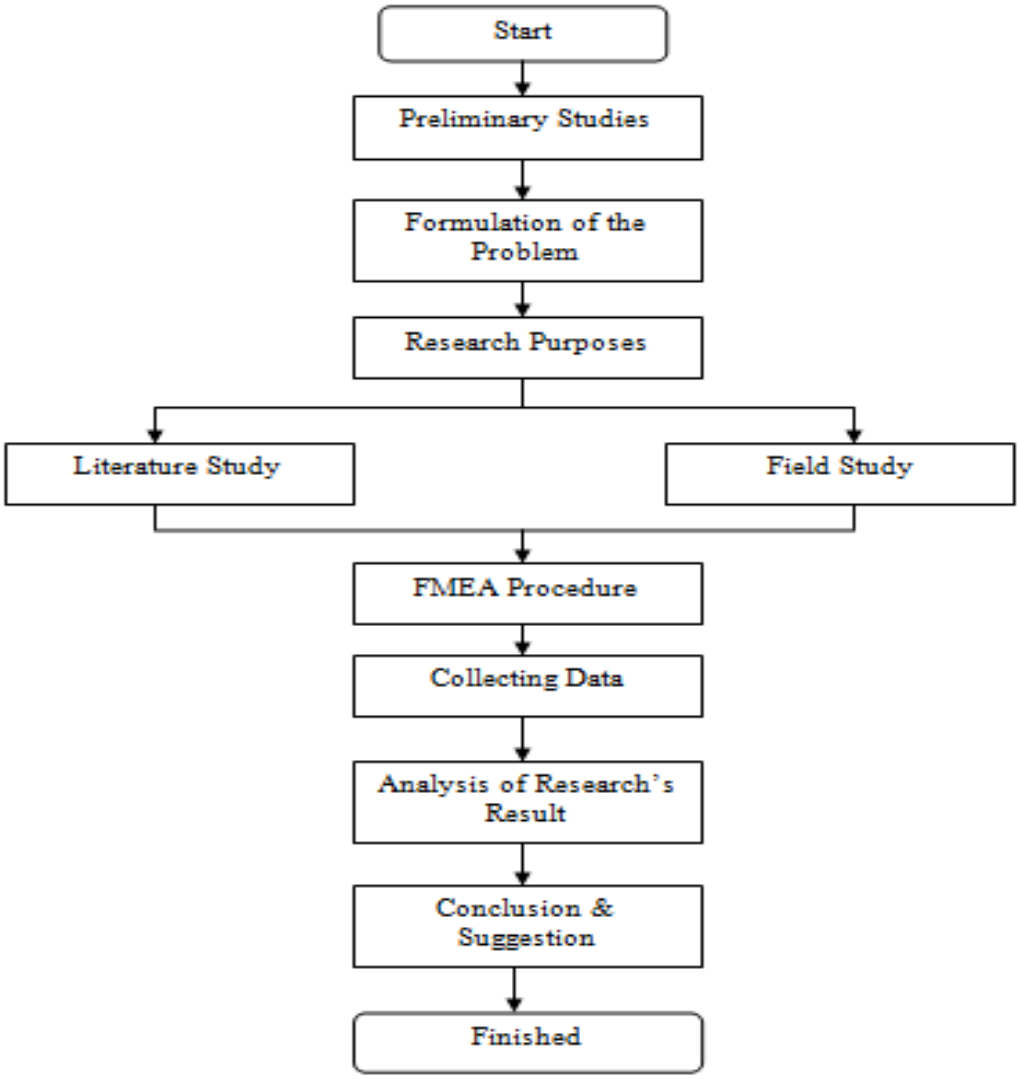

Fig 1:- Meththodology (Source : Researcher, 2018)

➢ *Quality*

Basically a modern quality system can be characterized by the following five characteristics (Laskova & Tabas, 2008):

- Modern quality systems are customer oriented
- Modern quality systems are characterized by the existence of active participation led by top management in a continuous process of quality improvement
- The modern quality system is characterized by an understanding of each of the specific responsibilities of quality
- Modern quality systems are characterized by activities oriented to damage prevention measures, not focusing on efforts to detect damage. Modern quality systems are characterized by a philosophy that assumes that quality is the way of life (Gasperz, 2005).

➢ *Failure*

There are 3 (three) types of product failures that occur in production activities (Lough, Stone, & Turner, 2009), namely:

- *Direct Sale*

Direct selling failure is a type of failed product or defective product that does not pass the inspection, but it is still feasible to be sold directly to consumers who are ready to accommodate this type of defective product.

- *Reworked*

This failure is a type of defect that can be put into the production process again for further processing, to produce another product in a condition that is no longer defective.

- *Direct Disposal*

This failure is the most severe type of defective product. This means that this defective product is the result of a production process that has no meaning anymore. In a sense, the defective product is also impossible to sell, because the failure rate of this type of product is failure that cannot be worked out.

➢ *Failure Modes and Effects Analysis (FMEA)*

FMEA is a technique used to find, identify, and eliminate potential failures, errors, and known problems from systems, designs, processes, or services before they reach consumers. FMEA here is an FMEA Process to detect risks identified during the process.

➢ *FMEA Process (PFMEA)*

PFMEA is one type of FMEA. PFMEA prioritizes analysis of failure modes through the production process, and does not depend on changes in product design that can cause failure in a process.

PFMEA is usually completed according to the consideration of labor, machinery, methods, material, measurement, and environment. Each component has its own component, which works individually, together, or even an interaction to produce a failure.

➢ *Severity*

Severity is an assessment of the seriousness of the effects caused. In the sense that each failure that arises will be assessed how much the level of seriousness. There is a direct relationship between the effects and severity. For example, if the effect is a critical effect, then the severity value will be high. Thus, if the effect is not a critical effect, the severity value will be very low.

➢ *Occasion Rate*

Occurance is the possibility that the cause will occur and produce a form of failure during the product usage period. Occurance is a rating value that is adjusted to the estimated frequency and or cumulative number of failures that can occur.

➢ *Detection Method*

The value of detection is associated with current control. Detection is a measurement of the ability to control / control failures that can occur.

➢ *Risk Priority Number (RPN)*

This value is a product from the results of multiplying the severity, incidence, and detection rate. RPN determines the priority of failure. RPN has no value or meaning. This value is used to rank potential process failures. The value of the RPN can be indicated by the equation as follows:

IV. RESULT & DISCUSSION

Analysis of Factors Causing the Failure of Magaside Products by Using the Failure Mode and Effects Analysis Method (FMEA)

The steps that must be taken in this method are as follows:

- Determine the components of the system / tool to be analyzed
- Identify modes of failure of the observed process
- Identify the result of ((potential effect) that caused a potential failure
- Identifying the cause (potential cause) of the mode of failure that occurs in the process that takes place
- Establish values (by means of field observations and brainstorming)
- Determine the value of RPN, which is a value that indicates the seriousness of potential failure For Magasida which produced by PT. Kimia Farma Jakarta, determining the potential failure modes seen from the materials used, work methods, labor, and each machine or running process can be seen in Table 4. After determining the value of severity, occurrence, and detection, RPN values can then be calculated for each of these failure modes.

Tools or Processes	Potential Failure Mode
Shieve Shaker	Relling engine power is less than 5 HP
Granule Test Equipment	Heat from the boiler <1200 C The rotating motor is damaged
Bulk Density Tester	Cylinder delivery power is less than 5 HP Damaged electrical sensor ring
Tablet Disintegration Tester	Heat from the boiler <1200 C Relling engine power is less than 5 HP
Hardness Tester	Shuttle damaged Broken connector

Table 4:- Potential Failure Modes of PT Kimia Farma Tbk

Table 5 represents the order of failure modes based on the largest RPN value. The failure mode with the largest RPN value is a priority for corrective action.

Rangking	Severity	Occurence	Detection	Failure Mode	RFN
1	6	5	4	Relling engine power is less than 5 HP	120
2	5	4	5	Heat from the boiler <1200 C	100
3	3	4	6	The rotating motor is damaged	72
4	5	5	2	Damaged electrical sensor ring	50
5	4	3	2	Broken connector	24
6	1	2	6	Shuttle damaged	12

Table 5:- RPN Ranking for Each Mode of Failure (Source : PT. Kimia Farma Tbk, 2018)

After getting the ranking from the RPN in the FMEA process, that is, it proposes improvements to the failure modes that have been ranked in order of priority. It aims to improve quality control at this time in the company.

Proposed improvements are not only given to values above 75, but all modes of failure that have been identified are still given proposed improvements as a consideration for the company. Proposals for improvements made based on the priority order can be seen in Table 6.

Rangking RFN	Failure Mode	RFN	Proposed Improvement
1	Relling engine power is less than 5 HP	120	Provides 500 VA voltage stabilizer on the winding machine
2	Heat from the boiler <1200 C	100	Provides 1000 VA voltage stabilizer to the boiler
3	The rotating motor is damaged	72	Provides 1000VA voltage stabilizer on the boiler Provide lubricants every month on bearings
4	Damaged electrical sensor ring	50	Cleaning electrical sensor and ring every day
5	Broken connector	24	Oil lubrication on the bearing and crank every 1 week Maintaining the circulation of the oil pump when the engine is operating
6	Shuttle damaged	12	Clean the gun and comb during the washing process

Table 6:- Proposed improvements (Source : Researcher, 2018)

V. CONCLUSION

Modes of potential failure in the process of making drugs at PT. Kimia Farma Tbk consists of 6 types of failures. The failure mode is obtained based on the failure of the function and type of machine that operates in the process of making drugs. The failure in the process of making the drug which was found by researchers included the relling engine power is less than 5 HP, heat from the boiler <1200 C, the rotating motor is damaged, damaged electrical sensor ring, broken connector, and shuttle damaged.

The risk of failure in FMEA results is used as a priority in proposed improvements. For the biggest failure risk on RPN FMEA is that has a RPN value above 75 which is relling engine power is less than 5 HP and heat from the boiler <1200 C

However, all identified modes of failure are still given improvement proposals according to company conditions. The proposed improvements given to the company as a whole are companies to pay more attention to engine maintenance so that the engine avoids its failure to function.

REFERENCES

[1]. Braglia, M.; Frosolini, M. & Montanari, R. 2003. *Fuzzy TOPSIS Approach for Failure Mode, Effects and Criticality Analysis. Quality and Reliability Engineering International*, Vol.19(5). pp. 425 - 443.
[2]. Gasperz, Dr. Vincent. 2005. *Total Quality Management*. Jakarta : PT Gramedia Pustaka Utama.
[3]. Laskova, A., & Tabas, M. 2008. *Method for the Systematical Hazard Identification.* Process Safety Progress. Vol. 27(4). pp. 289 - 292.
[4]. Lough, K. G., Stone, R., & Tumer, I. Y. 2009. *The Risk in Early Design Method*. Journal of Engineering Design, Vol. 20 (2). pp. 155 - 173.
[5]. Prajapati, DR. 2012. *Implementation of Failure Mode and Effect Analysis* : A Literature Review. IJMIE. Vol. 2(7)
[6]. Stamatis, D. H. 1995. *Failure Mode and Effect Analysis : FMEA from Theory to Execution. Milwaukee* : ASQC Quality Press
[7]. Teoh, P.C., & Case, K (2004), *Modeling and Reasoning for Failure Modes and Effects Analysis Generation.* Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture. Volume 218 (3). pp. 289- 300.
[8]. Zheng, L. Y., Liu, Q., & McMahon, C. A. 2010. *Integration of Process FMEA with Product and Process Design Based on Key Characteristics*. Proceedings of the 6th CIRP-Sponsored International Conference on Digital Enterprise Technology. Vol. 66. pp. 1673-1686.