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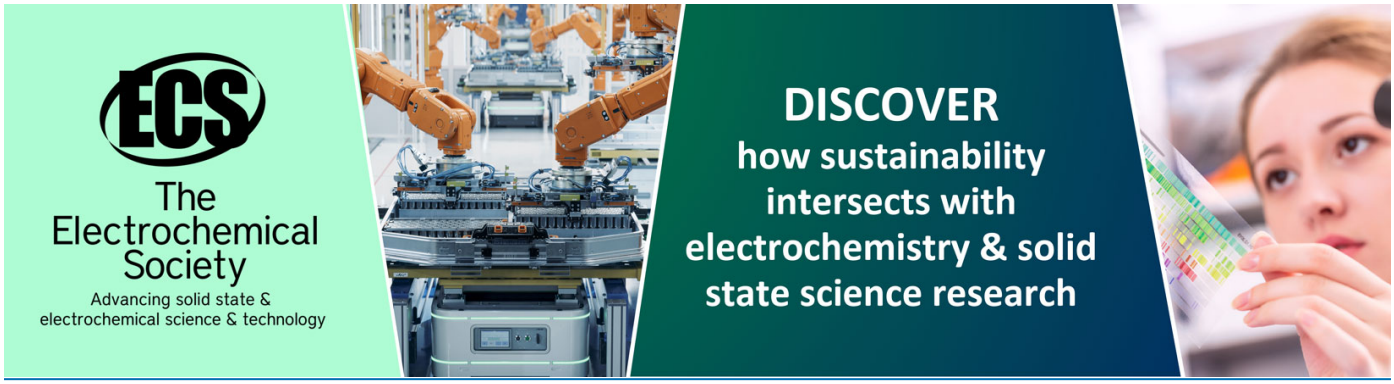

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Minimizing damage of product using six sigma and triz methods

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Abstract. Quality control of a product must be considered by all manufacturing companies to maintain product quality. One of the manufacturers of solid drug makers in the city of Medan has problems in the process of packaging/stripping. In the stripping process, there are four types of defects in X solid medicinal products that are leaky / deflated, the packaging is bad, not filled, and in the packaging, the contents are broken. To minimize defective products researchers used the Six Sigma and TRIZ methods. This study aims to determine the value of Defects Per Million Opportunities (DPMO) and sigma level and identify the risk of failure that occurs with the Failure Mode and Effects Analysis method (FMEA) and the Theory of Inventive Problem Solving (TRIZ) method as problem solvers. The result of the value of sigma level before improvement around 3.61 with the possibility of defects approximately 16981 for a million processes. Then, after improving the sigma value to 4.06 with the possibility of a process failure of 1547. The proposed improvements are training or socialization, carry out routine machine maintenance and to give the warning to monitor the performance of each operator.

1. Introduction

XYZ is a company engaged in manufacturing pharmaceutical parts that produce various types of drugs, one of which is X solid medicine. In the production process, the company still has problems in the stripping process. Based on data obtained during May 2019, the company produced 3.689.925 / strip of X solid drugs. In a day the company produces X solid drugs around ± 120.000 strips/day, where the percentage of product defects almost every time exceeds the tolerance limit of 5%. Disability often occurs due to various factors, while some categories of defects are leaky / deflated, the packaging is poor, not filled, and in the packaging, the contents are broken. The consequences are the risk of defects in the product and rework. Therefore, countermeasures need to be taken to reduce defective products, the impact of the reduction in defective products will benefit the company. Based on these problems, the purpose of this study is to identify the causes of disability, find out the cause of the biggest defect, calculate the DPMO value and sigma level, and identify the risk of failure that occurs with the FMEA method and proposes improvements with the TRIZ method as a problem solver.

2. Method

This research was conducted by the interview method and using data from the company regarding data on the amount of production and the number of defective products and characteristics of defective products that occurred in the stripping process in May 2019. Data processing was done using the Six Sigma method with proposed improvements using TRIZ. Six Sigma is continuous improvement by following the stages of DMAIC (Define, Measure, Analyze, Improve, Control) [1], but in this research, the Control phase is not done. In the improve phase, it will propose improvements by using TRIZ.

Based on the image of the control chart above, it can be seen that the data obtained are all within the control limit, so to find out the extent to which the existing production process has achieved good results or not the calculation of process capability will be done.

TRIZ stands for Russian, namely Theory Resheniya Izobreatatelskikh Zadatch or in English called Theory of Inventive Problem Solving (TIPS) is a method used in solving a problem based on various previous experiences in removing contradictions [2].

According to (Suryawan, 2014) [3] the problem-solving process using the TRIZ method has three stages, namely:

1. Identify problems, namely by finding out all possible factors that can be a problem.
2. Classifying problems by determining supporting factors and opposing factors into 39 technical parameters and using contradictory matrices to find solutions to the next settlement pattern.
3. Finding solutions to problems that must be worked out in solving contradictions using 40 creative principles.

3. Results and discussions

The product that is the focus of this research is the X solid drug product in the stripping process. The product was chosen because it is a product that almost every time has a disability. Based on the results of interviews and observations obtained four types of disability defects that are leaky / deflated, the packaging is bad, not filled, and in the packaging, the contents are broken. Data used in this study is disability data on May 2019.

3.1. Define

In this study, priority was given to handling problems for one type of product. In this company, solid drug products often experience product defects, especially in the process of sorting [3].

3.2. Measure

In the measure, step is done on the determination of CTQ (Critical to Quality). Determination of CTQ from X solid medicinal products in the stripping process is some products have leaked / bad packaging, products that are not filled, and the contents are broken [4] . The total production produced during May 2019 was 3,689,925 strips, and defective products were found at 258,862 strips. From these data, a control map can be created. As shown in Figure 1 below.

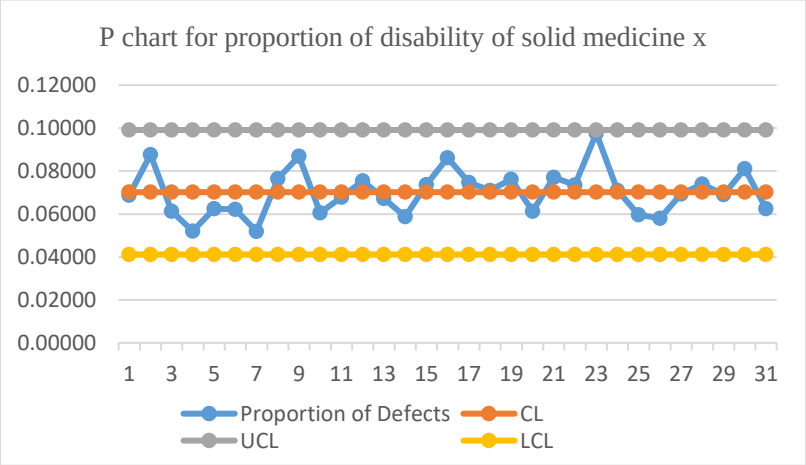

Figure 1. P-chart of disability of x solid medicine.

Based on the image of the control chart above, it can be seen that the data obtained are all within the control limit, so to find out the extent to which the existing production process has achieved good results or not the calculation of process capability will be done [5].

The following is the Capability Process calculation:

a = 1 - (Percentage of defective products) / (100 x 2)

= 1 - 6,7923 / (100 x 2)
= 0.9660

The value of a is the area of the z curve (normal distribution curve)
Value The conversion area of the normal curve into the z value is 1.83
Process capability:

Cp = (z value) / 3
= 1.83 / 3
= 0.61

The Cp value of the current X drug product is 0.61. Because the value is smaller than 1, it shows that the process of X drug product is still in the low category.

3.2. 1. Six sigma and defect per million opportunities (DPMO) level measurement.
This calculation is done to measure the ability and sigma capabilities of the current process. The results of the DPMO calculation can be seen in Table 1 below [6].

Table 1. Calculation of DPMO and sigma value in May 2019.

Production	Defect	CTQ	DPO	DPMO	Sigma Value
118,089	8.118	4	0.01719	17186.19	3.62
119,965	10.507	4	0.02190	21895.97	3.52
118,760	7,274	4	0,01531	15312.39	3.66
119,776	6,233	4	0.01301	13009.70	3.73
119,365	7,455	4	0.01561	15613.87	3.65
118,745	7,387	4	0.01555	15552.23	3.66
119,967	6,233	4	0,01299	12988.99	3.73
117,365	8,970	4	0,01911	19107.06	3.57
120,000	10,425	4	0,02172	21718.75	3.52
118,973	7,209	4	0.01515	15148.40	3.67
119,273	8,087	4	0.01695	16950.61	3.62
118,973	8,970	4	0.01885	18848.81	3.58
120,000	8,074	4	0.01682	16820.83	3.62
119,980	7,044	4	0.01468	14677.45	3.68
118,379	8,717	4	0.01841	18409.09	3.59
119,373	10,293	4	0.02156	21556.38	3.52
119,377	8,922	4	0.01868	18684.50	3.58
119,736	8,501	4	0.01775	17749.47	3.60
119,788	9,122	4	0.01904	19037.80	3.57
119,736	7,329	4	0.01530	15302.42	3.66
119,353	9,206	4	0.01928	19283.13	3.57
119,375	8,779	4	0.01839	18385.34	3.59
119,365	11,647	4	0.02439	24393.67	3.47
115,687	8,209	4	0.01774	17739.68	3.60
118,679	7,070	4	0.01489	14893.12	3.67
119,867	6,944	4	0.01448	14482.72	3.68
119,287	8,264	4	0.01732	17319.57	3.61
117,925	8,713	4	0.01847	18471.49	3.59
116,275	8,030	4	0.01727	17265.10	3.61
119,737	9,717	4	0.02029	20288.22	3.55
118,755	7,413	4	0.01561	15605.66	3.65
3,689,925	**258,862**				
	Average		**0.01754**	**17538.66**	**3.61**

From the results of these calculations, the stripping process has a sigma level of 3,61 with possible damage of 17,538 to a million productions. This is certainly a very big loss if not handled because more and more products that fail in the stripping process certainly cause losses to the company.

3.3. Analyze

At this stage, an analysis of the root causes of quality problems that cause disability in the processes and products that have been previously identified will be analyzed [7].

3.3.1. Fishbone diagram.

Identification of the source of the cause of the defect can be done by using a fishbone diagram that will make it easier to provide an improvement. The defective fishbone diagram is not filled can be seen in Figure 2 below [8].

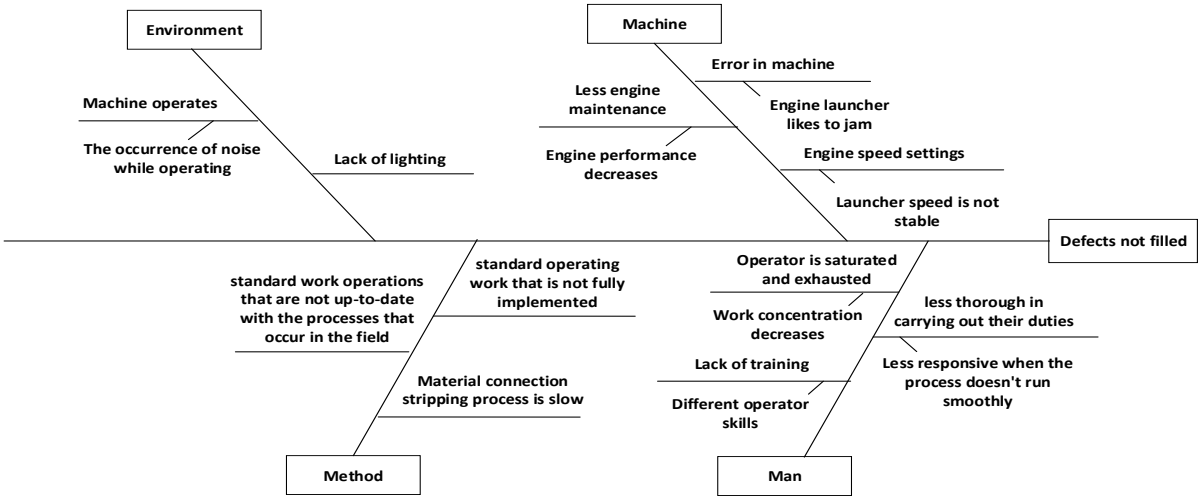

Figure 2. Fishbone diagram for defect is not filled.

3.4. Improve

In the improve phase, it is an action plan to improve the quality of Six Sigma. At this stage, Failure Mode and Effect Analysis (FMEA) is used to identify the risk of failure and TRIZ as a problem solver.

3.4.1. Failure mode and effect analysis (FMEA),

By using the FMEA method, the most dominant causes of defects can be identified through the results of the RPN (Rising Priority Number) values obtained [9], The results of the RPN can be made with a Pareto diagram like Figure 3 below.

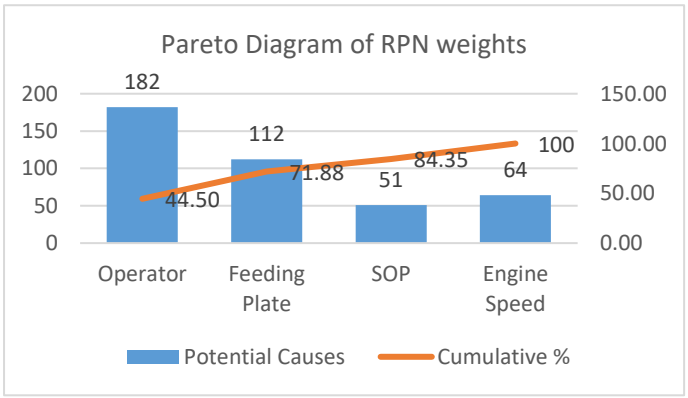

Figure 3. Weight of RPN causes of disability not filled.

Based on the picture above, it is known that the biggest cause of defects that are not filled is the operator, feeding plate.

3.4.2. TRIZ.

The theory of Reheniya Izobreatatelskikh Zadact which in English means the Theory of Inventive Problem Solving. The TRIZ method first identifies the problems found in Figure 2, Fishbone diagram. After knowing the results of the cause-effect diagram in the form of factors that influence the occurrence of the causes of defects are not filled, then is to categorize into a matrix of contradictions based on 39 parameters TRIZ [10]. The following are the parameters of the contradictions of the incomplete defects seen in Table 2.

Table 2. Parameters of contradiction of disability not filled.

No	Causes	Improving Parameter (Objectives to be improved)	><	Worsening Parameter (The goal to be eliminated)
1	Work concentration decreases	(14) Strength	><	(22) Lost of energy
2	Less responsive when the process doesn't run smoothly	(33) Ease of operation	><	(25) Lost of time
3	Different operator skills	(27) Reliability	><	(25) Lost of time
4	The engine launcher likes to jam	(38) Extent of automation	><	(36) Device complexity
5	Engine performance decreases	(32) Ease of manufacture	><	(25) Lost of time
6	Engine Speed Settings	(29) Measurement precision	><	(37) The difficulty of detecting and measuring
7	An SOP is not fully implemented	(33) Ease of operation	><	(35) Adaptability or versatility
8	Material connection line	(9) Speed	><	(25) Lost of time
9	SOP that is not up to date	(32) Ease of operation	><	(35) Adaptability or versatility
10	Lack of lighting	(18) Illumination intensity	><	(19) Use of energy by moving an object
11	Noise when the engine is operating	(32) Ease of manufacture	><	(37) The difficulty of detecting and measuring

Based on table 1 to overcome the cause of a problem, a way is needed to solve the problem based on improving parameters but there is an impact given when it will fix a problem called a contradiction. After obtaining the contradiction matrix, several solutions were produced according to the matrix of solutions available in the TRIZ method [11]. Some choices of solutions in the matrix are then chosen as the most ideal solution and match the company seen in Table 3.

Table 3. Selection of ideal solutions from 40 inventive principles.

No	Conflict Parameters	Results of the TRIZ Matrix Solution	Sub Principles of Inventive Principle	Ideal Solution
1	(33) Ease of operation >< (25) Lost of time	(9) Preliminary Anti Action (Prevention) (21) Skipping / Rushing Through (Perform certain processes or stages) (6) Universality (Maximizing all functions)	a) When going to do an action, the effects of good and bad are taken into account (b) Creating a prototype of an object or system to avoid unwanted events later on, (a) Perform certain steps (e,g, damage tests, dangerous tests or not) with acceleration (a) Making part of an object or system by performing multiple functions to eliminate the need for the other parts, (b) Using standard features,	# 9 Preliminary Anti Action: Lack of responsiveness due to lack of responsibility when the process does not go well, the concentration of work decreases due to saturation or fatigue, (Ideal solution: There is a draft performance report to monitor the work processes of each operator,)
2	(27) Reliability >< (25) Lost of time	(10) Preliminary Action (Preparation)	(a) Perform preparatory actions for an object or system, both complete and part of the system or object, (b) Regulate Objects or systems so that they can escape from the comfort zone without taking a long time,	# 10 Preliminary Action: Different operator skills cause the operator to act according to what is known only and also habits, (ideal

		(30) Flexible membranes or thin film	(a) Use a flexible frame and thin layers instead of three-dimensional structures, (b) Isolating objects from the external environment using a flexible frame and a thin layer	solution: holding a briefing or training)
		(4) Asymmetry	(a) Change the shape of an object or system from symmetrical to asymmetrical (b) if an object is asymmetrical, increase its asymmetrical degree	
3	(39) Ease of manufacture >< (25) Lost of time	(35) Parameter changes (Transformation)	(a) Change the parameters of an object or system (for example for gas, liquid or solid) (b) Change concentration or consistency, (c) Change the level of flexibility (d) Change the atmosphere for more optimal settings (e) Changing characteristics or techniques	# 35 Parameter changes: because the engine's performance decreases due to engine failure so the engine likes to jam, (Ideal solution: regular machine maintenance)
		(28) Mechanic substitution (Change of system/technique)	(a) Replacing things that are mechanical with sensory methods (optics/vision, acoustics/hearing, taste or smell), (b) Use electric, magnetic, and electromagnetic fields to interact with objects, (c) Change of settings for the machine, (d) used together with other fields,	

From table 3, it can be seen that from each ideal solution based on the problem. a proposed improvement is made to overcome it. One of the proposed improvements is to make a report on operator performance [12][13]. This proposal is to further discipline operators by giving sanctions if they are not responsible and making training and outreach regarding periodic stripping processes and periodic routine maintenance of machines. The design of the proposed operator performance report can be seen in Table 4.

Draft of proposed operator performance report,

Operator Performance Report

No		Competency Aspect	Value					Profile
			1	2	3	4	5	
1	The ability of the stripping process	Mastering the stripping process following the SOP of the company that has been set, Able to understand company standards that have been set, Able to complete the stripping process promptly and following the quality of the product set by the company,						Photo operator
2	Machine usage	Knowing the functions that are inside the machine, Able to master the machine in its implementation, Able to control the engine when the stripping process is running, Knowing the engine constraints that occur when there is an incompatibility, Set the process of setting up the machine to run smoothly, Able to resolve if a problem occurs when using the machine,						Name : Position : Scoring Scale 5 = Very Good 4 = Pretty Good 3 = Good 2 = Deficient
3	Product quality	Knowing product quality standards that have been set by the company, Check product quality inconsistencies if a defect occurs, Able to deal with mismatches in product quality,						1 = Very Bad
4	Teamwork	Able to coordinate in completing the stripping process, Able to divide tasks in the process of stripping, Able to communicate well, Able to provide input on the stripping process						Signature Director

4. Conclusions

From the research that has been done, conclusions can be drawn, namely, as follows:

1. Quality control carried out by PT. XYZ has not been effective because many regulations are not obeyed by operators, causing defective products.
2. Factors that caused disability are the condition of the engine that lacks maintenance, lack of responsibility and discipline/operator compliance, and the method used.
3. Proposed improvements to reduce disability in the stripping process are to carry out regular machine maintenance, training, sanctions if violating regulations for operators to monitor their performance and check the stripping process. As for making warnings to do machine settings first, so that it can reduce the possibility of disability.

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