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Designing a Serious Simulation Game Conceptual Model of DMAIC in Determining Improvement Recommendations of Pharmaceutical Industry

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ABSTRACT

The company's capsule drug production process with the pharmaceutical sub-sector has problems that often arise, namely the occurrence of defects in capsule drug strips, so the company suffers losses from increased production costs and the company also fails to achieve the production target of 98%. So that requires the process of re-processing the defective product. To reduce the level of product defects, the Six Sigma method being used. The improvements made are based on the 5W + 1H analysis with the results of an analysis of the causal factors, namely making SOPs related to time and amount work on visual inspection process. This study aims to understand the condition of the company with the 5W+1H analysis of the applied DMAIC method, as well as to determine alternative business strategies based on the Serious Simulation Game framework that can be applied. The expected results of this research are the preparation of alternative product development strategies and market development that are appropriate to be implemented by the company's strategic position.

Key Words: Conceptual Model, DMAIC, Serious Simulation Game.

1. INTRODUCTION

Pharmaceutical sub-sector companies face several problems on the production floor, especially in the capsule stripping process, namely the primary packaging process by wrapping the capsules using aluminum foil. Prior to the stripping process, there are several production processes including weighing, mixing, encapsulation, drying, capsule sorting, capsule printing, visual inspection, and primary packaging of capsule strips and finally secondary packaging.

If there is a leak in the capsule strip which causes air to enter and humidity occurs which can increase the water content in the strip, this can result in a decrease in the hardness of the capsule and also affects the expiration date of the drug so that it becomes faster than previously determined and can be toxic.

The strips are not symmetrical and there are empty pockets in one strip, including the untidiness of the packaging. If a defective product can pass in process control and reach consumers, this can result in damage to the company's image and reduce the demand or the number of company requests.

In drug products, packaging is used as a means of communication and is a source of information to consumers through labels or prints on the packaging. Brand prints or drug information on product packaging that are damaged or illegible make it difficult for consumers to identify the type of drug and the function of the drug so that mistakes can occur in taking the drug which can be fatal if the consumer takes the drug he is not supposed to take.

Quality control is the most important key for every company, especially pharmaceutical sub-sector companies, to ensure that each drug product produced has the quality that has been determined (Kholil, M.T. et al., 2021). Pharmaceutical sub-sector companies have carried out several quality control activities but still have not produced an optimal enough process and based on this, researchers can identify the causes of product defects in the stripping process in pharmaceutical sub-sector companies.

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if the consumer takes the drug he is not supposed to take. Table 1 shows the defect stripping capsule data for three months with four types of defects.

Table 1. Defect Stripping Capsule Data

Period		Number of Packing Strips	Type of Defect Strip				Number of Defects (%)	Percentage of Defects (%)
			Empty	Leaking	Tablet contents Over	The cut of strips do not fit		
Week 1	July	243600	3600	2400	1800	1800	9600	3,94
Week 2		245400	4200	2400	2400	600	9600	3,91
Week 3		244200	1200	1800	1200	600	4800	1,97
Week 4		243600	3600	3000	2400	1200	10200	4,19
Week 1	Aug	243600	3000	2400	600	1200	7200	2,96
Week 2		244800	2400	1200	1800	1800	7200	2,94
Week 3		244800	4800	3000	600	1200	9600	3,92
Week 4		245400	5400	2400	1800	2400	12000	4,89
Week 1	Sep	243600	4200	1800	1800	1200	9000	3,69
Week 2		243600	4800	1200	1200	1800	9000	3,69
Week 3		244800	2400	1800	600	1200	6000	2,45
Week 4		246000	6000	3000	2400	1800	13200	5,37
Total		2933400	45600	26400	18600	16800	107400	
Average		244450	3800	2200	1550	1400	8950	3,66

Serious simulation game is a game that has educational purposes, providing simulated scenarios that promote learning in a fun way (Abdellatif et al., 2018). Serious simulation games (SSG) are learning tools that are free from doubts about failure and can change thinking models (Hidayatno et al., 2018). In the development of serious simulation games, a Triadic Game Design philosophy is known, namely the philosophy of serious simulation game design that emphasizes the balance of 3 game elements, namely: reality, meaning, and play (Harteveld, 2011).

For this purpose, in this study an analysis of these defects was carried out with the aim of knowing in detail the causes of defects in the capsule stripping process using the DMAIC method to be able to analyze repairs to quality problems and product defects and to find out the factors that cause defects to produce products with zero defect quality in the stripping process. who then understands the condition of the company with 5W+1H analysis which will be applied based on the framework of the Serious Simulation Game.

2. RESEARCH METHOD

In this study, the method used by researchers for data processing is the Six Sigma method. Six Sigma stages carried out include define, measure, analyze, improve and control (Saryanto et al., 2020). Six Sigma implementation stages are as follows:

Stage 1: Define

The first stage that takes place in the Six Sigma method is the definition stage. The defining stage is used to define the problems that exist in pharmaceutical companies. At the definition stage, information about the problems experienced by the company is collected through a process of observing and compiling related party data. The problem with defective products that companies often experience is pickle capsules. Therefore, this research focuses on the production process and its processes.

Stage 2: Measure

DPMO calculations, Sigma capacity values and COPQ are carried out to see how much Sigma has reached the capacity of the production process and the yield value to determine capacity. This calculation is carried out based on production results and the number of defects produced during production, as well as the number of possible CTQ (Critical To Quality) causes of product defects (Irsyad, 2019).

Stage 3: Analysis

From the results of the DPMO calculation stage and the pareto results for disability and will then focus on finding the root cause of the highest disability obtained from the paretto diagram calculation using FMEA by finding the value of severity, occurrence, detection then all the calculation results are multiplied to get the highest RPN value as the focus of development furthermore(Fitriana et al., 2020).

$$RPN = S \times O \times D$$

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Stage 4: Improvement

At this stage it is the stage of giving suggestions to improve the process with the aim of reducing the level of defects in the welding process so as to reduce losses due to lower production results. At this stage it will be described using the 5W+1H chart (Susetyo et al., 2011).

Stage 5: Controlling

The control phase is the phase of controlling process performance and ensuring defects do not reappear. This stage is only a proposal to be implemented by the company. At this stage, an SOP (Standard Operational Procedure) is made which will be given to the company and it is hoped that if it is used as a standard SOP it can reduce defects.

Furthermore, research was carried out towards making contextual based on the Serious Simulation Game. Serious Simulation Game is a fun learning medium but still focused on goals based on a research (Destyanto et al., 2019). The ultimate goal of SSG is to increase player knowledge and is expected to stimulate players to develop the knowledge gained for continuous improvement needs. Conceptual models can help to describe problems, goals to how strategies are formed based on the inputs and outputs of the processes being carried out (Suparno & Ardi, 2022). Then proceed with positioning Learning Mechanics and Game Mechanics so that they can be made into a complete game.

3. RESULT

3.1 Define

Define is the stage of defining quality problems in the process of handling defects on stripping machines, starting from collecting data on the definition of each damage:

1. Strip is blank

One of the defects in the stripping process is that the capsule does not enter the strip pocket. This is due to the drug capsule getting caught in the capsule track before it is inserted into the aluminum foil strip.

2. The strip is leaking

This defect is in the form of a strip that is not tightly closed. So that air from outside can enter the capsule pocket and cause damage to the capsule inside. This defect can be caused by several things such as the sealing roll that is not hot enough, the sealing roll is damaged or has holes and the size of the capsule is not suitable.

3. Fill the excess capsule

This type of defect is caused by the size of the capsule that does not match the machine settings that have been set. So that there is a difference in the time the capsule falls into the capsule pocket and produces a strip with double capsules or a strip with pinched capsules.

4. Pieces of strips do not match

This defect is caused by machine settings for stripp pieces that don't fit properly, thus damaging the pocket and capsules inside the strip.

The following is total defect data from July to September:

Table 2 Detail Data Defect Stripping Capsule

No	Period	Type of Defect Strip			
		Empty	Leak	The cut of strips do not fit	Machine Setting
1	Week 1	3600	2400	1800	1800
2	Week 2	4200	2400	2400	600
3	Week 3	1200	1800	1200	600
4	Week 4	3600	3000	2400	1200
5	Week 5	3000	2400	600	1200
6	Week 6	2400	1200	1800	1800
7	Week 7	4800	3000	600	1200
8	Week 8	5400	2400	1800	2400
9	Week 9	4200	1800	1800	1200
10	Week 10	4800	1200	1200	1800
11	Week 11	2400	1800	600	1200
12	Week 12	6000	3000	2400	1800
Total		45600	26400	18600	16800
Average		3800	2200	1550	1400

From the table above, the blank strip defect is the highest type of defect produced, namely 45600 strips in a period of three months.

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After getting the disability data, then proceed with the process of comparing the existing data with the parreto chart to find out the highest frequency of defects. CTQ (Critical to Quality) to determine the focus of key quality characteristics. Comparison results with the Pareto chart can be seen in the figure 1.

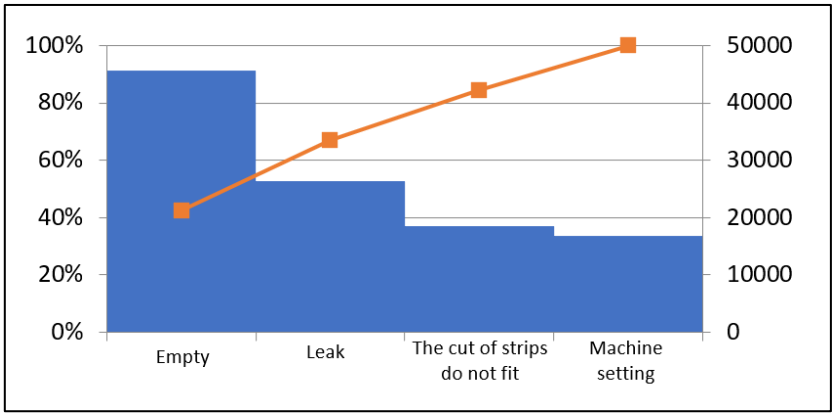

Figure 1 Pareto Chart

Based on the Pareto diagram in Figure 1, it is known that defects that have a value above 20% which will be the focus of research are empty strips of 42% and leaky strips of 25% of these defects which will be the focus of problem solving. Because if controlling all types of existing defects will be inefficient because it will take a lot of time, money and energy.

3.2 Measures

The calculation of DPMO (Defects Per Million Opportunities) and sigma level this time is based on the number of key defects, the number of production and the number of defects which in this study uses data from April -March.

The defect data that will be used to calculate the sigma value and DPMO (defect per million opportunity) value can be seen in Table 3 below.

Table 3 Defect Data

Period		Number of Packing Strips	Defect Stripp
Week 1	Jul	243600	6000
Week 2		245400	6600
Week 3		244200	3000
Week 4		243600	6600
Week 1	Aug	243600	5400
Week 2		244800	3600
Week 3		244800	7800
Week 4		245400	7800
Week 1	Sep	243600	6000
Week 2		243600	6000
Week 3		244800	4200
Week 4		246000	9000
Total		2933400	72000

From the data above, the data input into Sigma is the total production per month from July to September, which is 2,933,400 products, and production defects per month from July to September are 72,000 products that are not according to standards or NG (No Good) and the last parameter is CTQ as much as 1 key process based on the results of the paretto diagram.

Before further calculations are carried out, verification will be carried out using manual calculations as follows:

- DPO calculation

dpo= (Number of defects)/(total production x CTQ)

dpo= 6000/(243600 x 1)

dpo = 0.02463054

- Calculation of DPMO

dpmo = dpo x 1,000,000

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dpmo=0.02463054 x 1,000,000

dpmo = 24,630.54

- Convert sigma levels

Based on the results of the dpmo calculation, a conversion was then carried out on the DPMO value and obtained a Sigma value of 4.39 and in accordance with application calculations.

Furthermore, sigma calculations were carried out in the following weeks from July to September, the results of which can be seen in Table 4 below.

Table 4. The Calculation of Sigma Value

Period		Number of Packing Strips	Defect Strip	DPMO	Sigma Value
Week 1	Jul	243600	6000	24630,5	3,47
Week 2		245400	6600	26894,9	3,43
Week 3		244200	3000	12285	3,75
Week 4		243600	6600	27093,6	3,43
Week 1	Aug	243600	5400	22167,5	3,51
Week 2		244800	3600	14705,9	3,68
Week 3		244800	7800	31862,8	3,36
Week 4		245400	7800	31784,8	3,35
Week 1	Sep	243600	6000	24630,5	3,47
Week 2		243600	6000	24630,5	3,47
Week 3		244800	4200	17156,9	3,62
Week 4		246000	9000	36585,4	3,29
Total		2933400	72000	24544,9	3,47

From the data above, it can be seen that when calculating the DPMO value of the total stripping process in the span of 3 months there were 2,933,400 pcs and had a sigma value of 3.47 sigma with 1 CTQ. From the results of the COPQ calculation, the company still suffers losses of 25% -40%, therefore it is necessary to improve each of its production processes in order to reduce losses and increase its sigma value.

3.3 Analyze

Analysis of Fishbone Diagrams

Basically, a cause-and-effect or fishbone diagram can be used to identify the root cause of a problem, generate ideas for solutions to a problem in the process of stripping any defects that arise which are categorized as causes into several factors. The following below is a Brainstorming and the results of interviews and discussions with Leaders, Quality and Operators regarding the causes of defects.

Blank Strip Deformed Fishbone Diagram

Sharp spot defects are defects that arise due to the failure of the capsule to fit into the aluminum foil strip. This happens because of a blockage in the capsule path to the aluminum foil strip sealing stage caused by variations in the shape of the capsule (material). The following is the result of an interview with the Section Head of Capsule Stripping regarding the causes of failure in the stripping process which causes defects in the empty strip:

Leaky Strip Fishbone Diagram

Leaking strip is a defect that arises due to failure of the timing of the capsule's descent from the strip path to the aluminum foil sealing strip stage. This happens because the shape of the capsule and the capsule shell are too slippery. The following is the result of an interview with the Section Head of Capsule Stripping regarding the causes of failure in the stripping process which causes leaky strip defects:

Failure Mode and Effect Analysis (FMEA) analysis

Failure Mode and Effect Analysis (FMEA) is used to determine the level of importance of each existing problem by considering its severity, occurrence, and detection based on the causes of failure and the failure factors. So, in the end it will produce a Risk Priority Number (RPN) value. The input used in the Failure Mode and Effect Analysis (FMEA) is obtained from the results of the analysis using a fishbone diagram. The following are improvements using FMEA (failure mode and effect analysis):

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Determining the Value of Risk Priority Number (RPN)

Next is to calculate the Risk Priority Number. This stage aims to find priority resolution of problems that are determined based on the RPN value. The following is the RPN calculation formula:

RPN = S x O x D

Calculation of RPN values can be seen in Table 5 below.

Table 5 Calculation of Risk Priority Number

Defect Type	*Potential Failure Mode*	*Potential Failure of Effect*	*S*	*O*	*D*	*RPN*
Empty Strips	Material	Capsule shape is not up to standard	5	4	6	120
		Various capsule sizes	4	6	7	168
	Machine	Engine sensor performance is not optimal	3	3	2	18
	Man	Inexperienced	3	3	1	9
		Not well trained	2	2	1	4
Leak Strips	Material	Slippery capsule	3	3	4	36
		Various capsule sizes	4	6	7	168
	Machine	Sealing roll is not hot enough	2	1	3	6
		Engine sensor performance is not optimal	3	4	2	24
	Man	Inexperienced	3	3	1	9
		Not well trained	2	2	1	4

According to Table 5 above, it is known that the most priority factor is to find the root cause of the problem and provide recommendations for preventive or corrective actions, namely the capsule shape not according to the standard gets an RPN value of 120, variations in capsule size with an RPN value of 168 and slippery capsules with an RPN value of 36.

3.4 Improve

Table 5W+1H

After the main causes of empty strip defects and leaky strips in the stripping process in pharmaceutical sub-sector companies are known through the highest RPN results contained in the FMEA questionnaire, it is then necessary to determine an action plan to overcome the strip defect problem using 5W + 1H (What, Why, Where, When, Who, How) tools. The following is a table of the results of the 5W + 1H analysis to find the right solution to overcome the problem of excess water based on the scoring results of the FMEA questionnaire.

Table 6 Analysis of 5W + 1H

5W+1H	Capsule shape is not up to standard	Slippery capsule	Various capsule sizes
What	Standardize the optimal time and number of workers for visual inspection of capsules	Standardize the optimal time and number of workers for visual inspection of capsules	Strict capsule size standards in the capsule sorting process and carry out the separation of reprocessed capsules from capsules resulting from the normal capsule sorting process
Why	Avoiding the escape of capsule products with non-standard shapes to pass to the stripping process	Avoiding the escape of capsule products with non-standard shapes to pass to the stripping process	Narrows the range of variation in capsule size
Where	Visual inspection process	Visual inspection process	Visual inspection process
When	After being approved by the relevant parties	After being approved by the relevant parties	After being approved by the relevant parties
Who	Production Team	Production Team	Production Team

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5W+1H	Capsule shape is not up to standard	Slippery capsule	Various capsule sizes
How	Making SOPs regarding the time and number of workers in the visual inspection process	Making SOPs regarding the time and number of workers in the visual inspection process	The production team made changes to the SOP for the capsule sorting process regarding the changes

3.5 Control

After the improve phase is complete, the next phase is the Control phase. After the improvements made in the improve phase it is proven to reduce the level of defects in the capsule stripping process. Then the next step is how the progress that has been achieved can be maintained so that it does not return to its original condition which was worse before the improvement step was carried out. So that the progress that has been achieved does not return to the initial stage, it is necessary to standardize work instructions in the hope that the performance of one operator and another operator does not differ significantly so that a Standard Operating Procedure is necessary. In addition, so that the performance does not decline again, we suggest that it is necessary to carry out 5S audits periodically which can support the quality of the products produced to be stable.

3.6 Conceptual Model of Serious Simulation Game

The conceptual model was created to facilitate the division of the framework which will later become the basis for determining learning mechanics and game mechanics in Serious Simulation Games. The basic conceptual model was created from the information and DMAIC processing and analysis that was done.

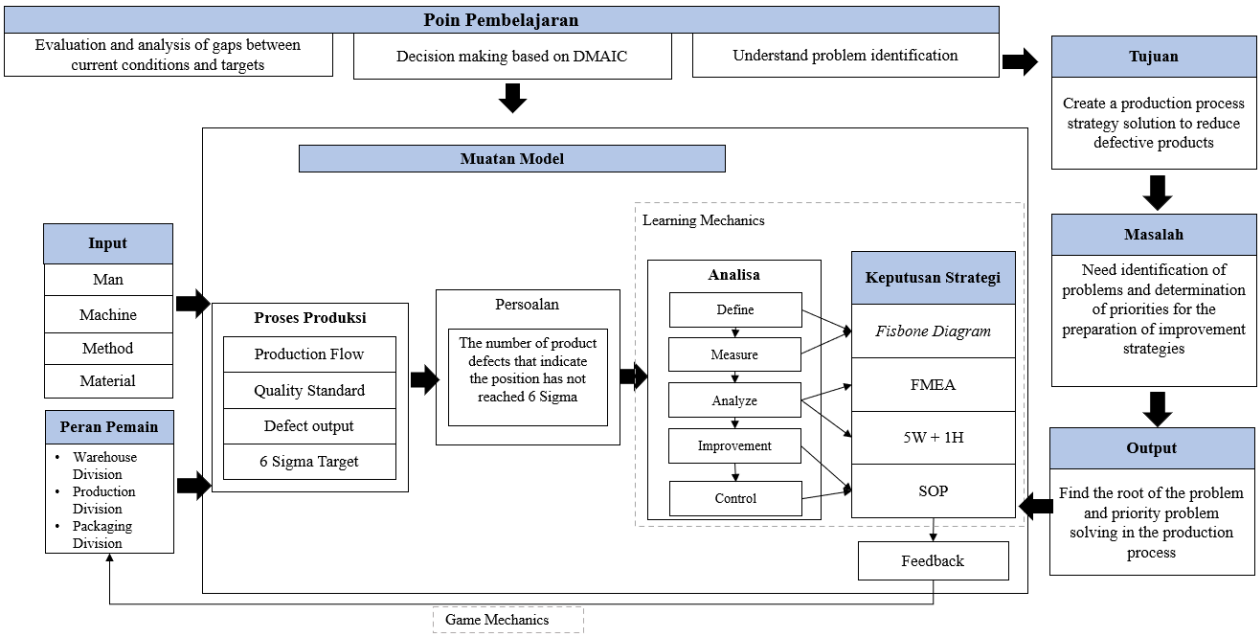

Figure 2. Serious Simulation Game conceptual model based on DMAIC

In Figure 2 the learning mechanics are given in the section on converting DMAIC analysis to strategic decisions Fishbone Diagram, FMEA, 5W + 1H and SOP as the initial goal of making research so that players can brainstorm the results of the analysis that will be made into a strategy. Game mechanics appear as a simulation in the form of feedback in the form of scenarios that may arise from strategic decisions taken that affect players. Although the majority of the production division is engaged in operational defects, the players are divided into three, namely the warehouse division, production division, and packaging division. This is done because the production policy carried out will have an effect on the warehousing and packaging department. So that in making a strategy it will also consider the division side related to the production process as well. The decision-making process and feedback to players is repeated to hone a decision-making mindset that is not only concerned with one aspect.

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