Six Sigma Approach to Control the Quality of Tablet (Case Study: Pharmaceutical Company)

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Abstract:

Quality of product is one of the competitive advantages for the company. Pharmaceutical as the company producing tablet product is critical to make sure that the product safe for consumption. Not only impact the health of consumers, but also enable the company to decrease production cost. Pharmaceutical This research was done to control the quality of tablet product. Data collected is product defects of tablet at stripping process. The methodology uses six sigma approach. Finding of this research able to minimize the loss sales of product defects.

Keywords: *Six Sigma, Quality, Defect, DMAIC*

Introduction

Many articles were written regarding the quality of pharmaceutical products in order to protect the customer (Woodcock, 2004). Six Sigma is used to help the company cut costs and improve the processes at an operational level. This highly statistical quality improvement technique helps to formulate and deploy strategies of the company (Smith, et al, 2002). Companies maintaining practise consistent with sustainable development strategies achieve a competitive advantage (Pfeffer,2010).

The purpose of Six Sigma in statistical terms is to reduce process variation, so that virtually all the products or services provided meet or exceed customer expectations. This is defined as being only 3.4 defects per million occurrences (Hughes, 2004).

There has been a significant awareness to quality of pharmaceutical products since the launching of FDA current good manufacturing practices. Due to increasing competitive market pressures, more and more pharmaceutical companies are beginning to adopt process improvement strategies that are established in other industries such as Six Sigma. Issues driving these needs include the necessity to improve cycle time, marketing and packaging efficiencies to monitor supply chain and streamline manufacturing processes to maintain profitability and remain competitive in today's global market (Pokharkar,2010). The problems occur in operation process of the pharmaceutical company:

1. The ingredients in each tablet are not proportionally the same.
2. The tablet not formed perfectly according the shape required.
3. The tablet is not hard enough or too breakable when dropped.
4. The tablet is not dissolved in a determined time period.
5. The stripping of the tablets is not stick perfectly so there's a leak in the strip.

For this case concern to discuss the last problem, about stripping, because leak in the stripping process is the main problem that prevents tablet to be sent to the warehouse directly after produced thus it caused delays to be distributed to company distributors and eventually caused significant sales loss of the tablet.

The problems occurred in the stripping process can be caused by several factors including problems from the tablet material such as imperfect form, fragile or damaged in the WIP storage. Problems also occurred from the human error such as less experienced, exhausted or less control from supervisor. Problems can also occur when the method used was not according to procedure. The last factor is from the machine such as machine failure, temperature setting not optimal, lack of maintenance, etc.

Methods

Six Sigma Improvement model is known as DMAIC (Heizer et al, 2014). The five-step process improvement consists of Defines, Measures, Improves and Control. The step of Six Sigma in using DMAIC process is shown in Table 1.

Table 1.
The step of Six Sigma in using DMAIC Process

Six Sigma steps	Key processes
Defines	Define the requirements and expectations of the customer
	Define the process by mapping the business flow
Measure	The process and collects data
Analyze	Analyze the causes of defects and sources of variation
Improve	Improve and develop process to eliminate the variations and implement enhanced plan
Control	Develop a strategy to monitor and control the improved process

Data collected is number of defects from stripping process production as shown in the Table 2.

Table 2.
Number of production and stripping defect

BATCH	PRODUCTION	INSPECTED	DEFECT
1	500.000	50.000	7.400
2	500.000	50.000	3.800
3	500.000	50.000	6.400
4	500.000	50.000	8.000
5	500.000	50.000	4.200
6	500.000	50.000	6.000
7	500.000	50.000	4.600
8	500.000	50.000	7.000
9	500.000	50.000	6.800
10	500.000	50.000	5.600
11	500.000	50.000	4.200
12	500.000	50.000	7.200
13	500.000	50.000	6.000
14	500.000	50.000	6.800

15	500.000	50.000	4.400
16	500.000	50.000	5.200
17	500.000	50.000	6.000
18	500.000	50.000	9.600
19	500.000	50.000	7.600
20	500.000	50.000	73.400
21	500.000	50.000	7.200
22	500.000	50.000	5.600
23	500.000	50.000	6.200
24	500.000	50.000	6.200
25	500.000	50.000	5.600
26	500.000	50.000	6.400
TOTAL			227.400

Results And Discussion

Define

This step purpose to determine the project focus, such as project charter and customer critical to quality (Kubiak, et al, 2009). The operation process chart (OPC) is created. This OPC show a more detail of the step of the process conducted of the product. The production process of tablet can be seen in Figure 1. Tablet needs raw materials which are chemical materials as the determined formula. The process of producing tablet starts from granulation all of the raw materials and mixing them. Next is tableting which is forming the raw materials mixture to become a tablet in the specified shape. After that, the tablets are coated in the coating process then the tablets are going through the stripping process where each strip usually contains 10 tablets. After the stripping process, the product are moved to packing area to be packed in a small box consists of 20 strips. So each batch of tablet production supposed to release 2.500 boxes of 20 strips tablet.

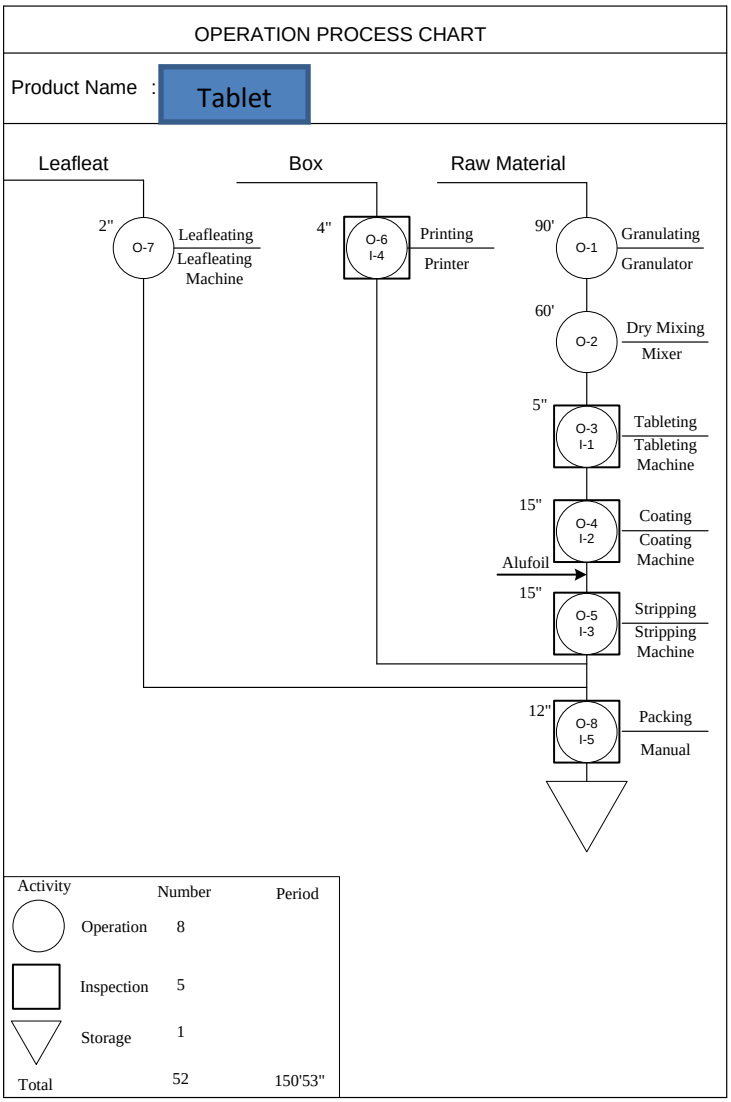

Figure 1.
Operation Process Chart of Tablet

Measure

Collect actual data to estimate the capability of the current process in meeting customer requirement (Gijo et al., 2011). Calculate DPMO and level of sigma using six sigma calculators provided in the website westgard and the results as shown in figure 2.

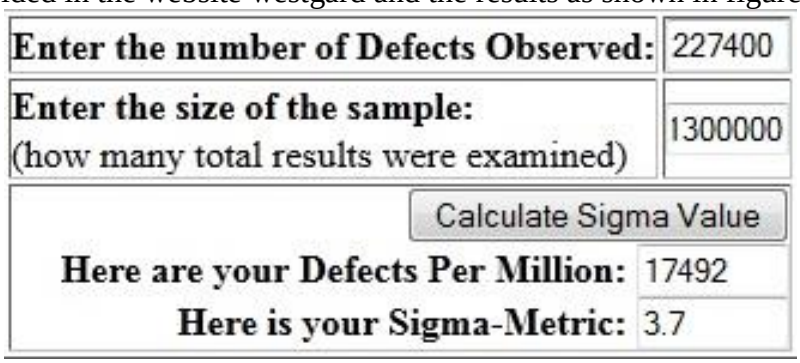

Figure 2.
Six Sigma Calculation

Analyze

This phase identify,organize, and validate potential root causes (Arthur, 2010). Factors that caused defects using fishbone diagram is elaborated as shown in Figure 3. The analysis conducted only in the stripping process of tablets.

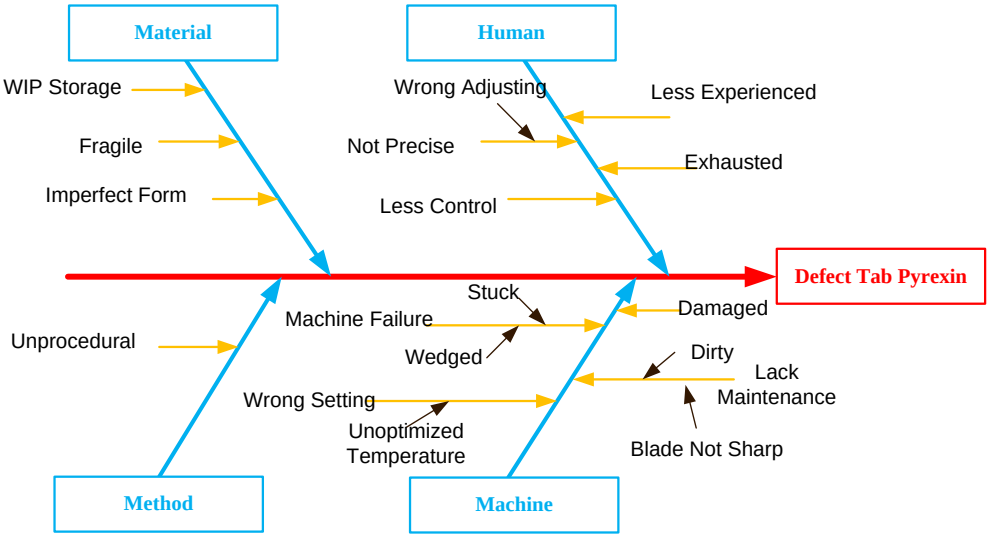

Figure 3.
Fishbone Diagram

Improve

Identify a solution to the problem that the project aims to address (Keller, 2010). In this case use 5W-1H method which mean that every improvement action for the problems are listed in the action plan which consist of every improvement detail according to the principle of What, When, Where, Who, Why, and How.

1. What, the improvement action needed to minimize production defect of tablet.
2. Where, the area of improvement action took place to minimize production defect of tablet.
3. Why, the reason to do improvement action to minimize production defect of tablet.
4. Who, the person who will do and be responsible for the improvement action to minimize production defect of tablet.
5. When, the period time to do improvement action to minimize production defect of tablet.
6. How, the way used to do improvement action to minimize production defect of tablet.

The improvement action proposed for company to minimize production defect of tablets are shown in Table 3.

Control

In this step, document procedures, train all employees for new processes, and create monitoring and reaction plan for new processes (Pyzdek et al, 2009). it is important to ensure that control can correction can be done to any variances avoiding possibly costly defects and loss of quality. This step intended to control the improvement action which is the beginning of a continuous improvement.

Table 3.
Improvement Action Using 5W+1H Method

What	Where	Why	Who	When	How
Temperature-setting adjustment	On the production floor	To minimize tablet damage and stripping leak	Technician	Before each production batch	Optimizing temperature setting
Stripping-process control	On the production floor	To minimize tablet stuck and disturb the stripping process	Stripping supervisor	During the stripping process	Controlling the stripping process
Raw materials inspection	In the raw materials warehouse	To meet the product requirement	Supervisor of raw material department	Arrival of raw materials	Inspecting of raw materials
Operator Capability	Production department	To minimize unqualified stripping result	Production manager	Every 6 months	Training the operators
Work-in-Process storage	In the WIP warehouse	To minimize product damage	WIP Warehouse supervisor	During the storage period	Minimizing the amount of WIP stack

Firstly simulate the process improvement calculation. This calculation is done to show the improvement of the process performance which can be seen from the DPMO Value and Sigma Level. The calculation shows that by decreasing the number of defect will have impact to decrease total loss of sales. As shown in Table 4, if the company were able to decrease number of defect by 10% from current total defect, it will also decrease the total sales loss to Rp. 84.524.580,- and so on. If the company eventually succeeded to decrease the number of defect up to 99,9% then the company will be able to minimize the total sales loss until only Rp. 93.916,-.

Table 4.
Defect Decrease Calculation

	Current	10%	20%	30%	40%	50%	60%	70%	80%	90%	99%	99,9%
Total Defect	227.400	204.660	181.920	159.180	136.440	113.700	90.960	68.220	45.480	22.740	2.274	227
DPMO	17.492	15.743	13.994	12.244	10.495	8.746	6.997	5.248	3.498	1.749	175	17
Sigma Level	3,7	3,7	3,7	3,8	3,9	3,9	4,0	4,1	4,2	4,5	5,1	5,7
Total Sales Loss	Rp. 93.916.200	Rp. 84.524.580	Rp. 75.132.960	Rp. 65.741.340	Rp. 56.349.720	Rp. 46.958.100	Rp. 37.566.480	Rp. 28.174.860	Rp. 18.783.240	Rp. 9.391.620	Rp. 939.162	Rp. 93.916

Conclusion

Six Sigma is used to examine, manage, and enhance operational performance by eliminating and preventing defects in products and related to the operational activity. Six Sigma is to improve the quality of process outputs by identifying and reducing the defects and minimizing variability in manufacturing and business processes. In this pharmaceutical company one of the problems is about the stripping. It is because leak in the stripping process that prevents tablet to be sent to the warehouse directly after produced thus it caused delay to be distributed and eventually caused significant sales loss.

Based on the DMAIC analysis above to minimized the number of defects are by optimizing temperature setting, controlling the stripping process, inspecting of raw materials, training the operators, and minimizing the amount of work-in-process stack. By doing these improvement actions, it is expected that the number of defects can be reduced so eventually the total loss of sales that resulted from the defects can also be minimized.

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