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Quality Improvement of Health Plaster Products with Six Sigma Method and QCDSME Analysis

Ragillia Fitri Nur Janah[a,*], Hana Catur Wahyuni[a], Inggit Marodiyah[a]

[a] Industrial Engineering Program, Science and Technology Department, Universitas Muhammadiyah Sidoarjo. Jl. Raya Gelam 250 Candi, Sidoarjo, 61272
* Corresponding Author: Ragilliafitri07@gmail.com

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ABSTRACT

Health plasters are one of a pharmaceutical company's excellent items. There are still defective products in the manufacturing process, including torn paper, joint 1, not cut, perforated edges, joint 2, tucked, long-short, and asymmetrical. Research conducted between June and December 2021 reveals that 192.960 Kg of substandard items were discovered. The contribution of this research is to identify the underlying reasons of the problem and decrease the number of product faults. By using the QCDSME (Quality-Cost-Delivery-Safety-Morale) method analysis in the cost stage, this company is known to experience losses due to defective products of IDR 18,047,232 / year. The results of the analysis using the six sigma method at the analyze stage using the fishbone diagram tool are known that defective products are caused by the absence of size standards in the repair of plate and pressure roll positions, differences in operator responses, the absence of written procedures for handling product defects, and the existence of product roll rolls that are too loose or tight. The improvement proposal made next is to make a size standard for the plate position with a value of 12.5 ± 1 cm and a pressure roll with a value of 22 ± 1 mm with additional tools in the form of a ruler. After taking corrective steps and quality control on product defects, the results showed that the value of product defects decreased from the previous average of 1,119 pcs/day to 205 pcs/day, so that the company's loss value was reduced to IDR 3,306,240/year.

1. Introduction

Quality can be interpreted as a real effort or effort on the part of the producer to meet the level of consumer satisfaction in accordance with aspects of needs, expectations, and expectations (Tannady, 2015; Sugiarto, S. and Octaviana, V., 2021). Good product quality must pay attention to quality dimensions including product performance, product characteristics, reliability, suitability, durability, ability to be repaired, appearance beauty, and quality perceived by consumers (Haryanto & Novialis, 2019). Product quality itself is one of the aspects that influence purchasing decisions by consumers. The increasing number of product requests also depends on the quality of the products produced, the better the product quality, the greater the demand for products by consumers. Vice versa, the lower the quality of the product produced, the level of consumer interest and decision to use the product will also decrease. Product quality is very important for a consideration in the level of trust and satisfaction obtained (Ariella, 2018). Every consumer will certainly expect a company to make a product that provides its own satisfaction value when purchased, used, or consumed. If consumer desires and

satisfaction are fulfilled, the level of consumer confidence to continue using and buying products will remain (Parwati et al., 2019).

One of the efforts that can be made to maintain product quality is to control product quality. Product quality control is a technique or effort carried out in the industrial manufacturing process of making products from the beginning of the process to the end of the product process received by consumers. Quality control is carried out to maintain product quality so that it remains good, thereby minimizing the cost of expenses by the company and making consumers feel satisfied with the products being marketed (Wirawati, 2019). Some similar research contributions that discuss quality control include the title "Improvement of Zoning and Flow Treatment of Dirty Gallons with the 5R and SQCDME Methods" with the results of observations showing that the SQCDME method can help provide input for improvement, one of which is in the aspect of delivery, namely providing additional tools to facilitate the delivery of goods and in the aspect of the environment making layout changes in the production area (Abdussalam & Adi, 2023). Furthermore, in a study entitled "Analysis of Production Quality Control with the Six Sigma Method in the PT Asera Posidonia Drinking Water Industry in Palopo City" shows that the six sigma method can help in controlling product quality by performing the DMAIC (Define-Measure-Analyze-Improve-Control) stage, the average sigma level value is 1.929 with the number of possible defects of 335,287 for one million times the production process or 33.5% (Didiharyono et al., 2018).

The phenomenon that occurs at a pharmaceutical company related to product quality is that there are types of product defects with the category of torn paper amounting to 48.996 Kg, joint 1 42.950 Kg, not cut 27.907 Kg, perforated edges 20.410 Kg, joint 2 17.496, tucked 13.891 Kg, long-short 11,958 Kg and asymmetrical 9.352 Kg with the total number of defective products produced amounting to 192.960 Kg so that the company receives a loss of Rp 18,047,232 / year. The company continues to strive to improve product quality by reducing the number of defective products produced. The following is a table of data on the category of defective products produced by the company during the health plaster production process with data collection starting from the June-December 2021 periode is shown in the Table 1.

Table 1. Product Defect Rate Data

Type of Product Defect	Quantity (Kg)	Percentage (%)	Cumulative
Torn Paper	48.996	25%	25%
Joint 1	42.950	22%	48%
Uncut	27.907	14%	62%
Perforated Edge	20.410	11%	73%
Joint 2	17.496	9%	82%
Tucked	13.891	7%	89%
Long – Short	11.958	6%	95%
Not Symmetrical	9.352	5%	100%
TOTAL	192.960	100%	

From the background that has been explained, the contribution of this research is finding the root causes of problems and reduce the level of product defects in the production process of making health plaster products by referring to the results of data on the level of product defects using the six sigma and QCDSME methods. So that efforts to reduce product defects and improve product quality can run optimally.

2. Method

The research steps begin by collecting literature studies or literature reviews, identifying and formulating problems, collecting data. Then proceed with data processing using the six sigma method (DMAIC) and QCDSME analysis. The last step taken is to provide conclusions and suggestions.

2.1. Six Sigma

Six sigma is one of the methods for quality control and improvement used by several companies and organizational bodies (Escobar, C., A., et. al., 2022). Six sigma is a concept that emphasizes a significant improvement in product quality with product defects of only 3.4 for every 1,000,000 products produced by a company (Tannady, 2015).

The stages that must be carried out when using the six sigma method are as follows:

1. Define

At the define stage, the process of collecting supporting data that shows the extent to which there are indications of potential problems. Define also defines what the process goals are consistently between meeting the needs and desires of consumers. The formulation stage is carried out by determining the theme of a problem and conducting discussions with members or people who play an important role in a problem (brainstorming) (Rokhmah et al., 2023).

2. Measure

At the measure stage, the identification of the types of defects that have the greatest effect on product quality is carried out by determining the Critical to Quality (CTQ) value of the type of defect. CTQs are key product characteristics in order to provide satisfaction value based on customer wants and needs. The next step is to measure the sigma level and Defect for Million Opportunities (DPMO) value by converting the value to the sigma table. The calculation of DPMO and sigma level has the aim of measuring sigma capability and capability. The steps taken to calculate the DPMO value are as follows (Tannady, 2015).

a. Defect per unit

$$DPU = \frac{D}{U} \quad (1)$$

b. Total Opportunities (TOP)

$$TOP = U \; x \; OP \quad (2)$$

c. Defect per Opportunities (DPO)

$$DPO = \frac{D}{TOP} \quad (3)$$

d. Defect per Million Opportunities (DPMO)

$$DPMO = DPO \; x \; 1{,}000{,}000 \quad (4)$$

e. Sigma level using Microsoft Excel (Yohanes & Ekoanindiyo, 2021) Value conversion

$$DPMO = NORMSINV\left((1{,}000{,}000 - DPMO)/1{,}000{,}000\right) + 1.5 \quad (5)$$

Description:

D = Defect

U = Unit

OP = Opportunities

3. Analyze

At the analyze stage, an analysis will be carried out related to the cause and effect of the problems that occur. The source of the problem in product quality was found based on the 7 M principles, Man, Machine, Method, Materials, Media (place and time), Motivation, and Money. The factors that cause the problem will then be described at each important point using seven tools, namely using a p control

map and a fishbone diagram. The identification of an analysis carried out will provide the results of the cause of the problem critically and clearly (Sutiyarno & Chriswahyudi, 2019).

4. Improve

The improve stage is used to maximize and optimize the improvement solutions that will be carried out on each root cause found. So that when the realization is carried out, the actions taken are very appropriate actions and are in accordance with the desired expectations (Smętkowska & Mrugalska, 2018).

5. Control

This last stage is used as a quality improvement effort by standardizing procedures, documentation, and socializing new work guidelines or changes that have been made and agreed upon. So that there is a new responsibility to ensure that a product is in accordance with the SOP made, so that quality improvement efforts can run smoothly with maximum results (Rahman et al., 2018).

2.2. Process Capability

Process capability is an analysis of variables relative to the requirements of a product specification produced as a tool in the development of production results to reduce existing variability (Oyedeji, O., et. al., 2020). Process capability is also an effort to show that the performance process carried out is able to produce a product or specification set by the company in accordance with consumer expectations, expectations, and needs (Gaspersz, 2002).

One of the indicators in process capability is as follows (Gaspersz, 2006):

1. Process capability ratio (Cp Index). To determine the value of the Cp index, the following formula is used:

$$Cp = \frac{(USL - LSL)}{6\sigma} \quad DPMO = NORMSINV\left((1{,}000{,}000 - DPMO)/1{,}000{,}000\right) + 1.5) \tag{6}$$

2. Process capability index (Cpk), used to measure how much of the production process is actually in accordance with the predetermined specification standards. To find out the Cpk value, the following formula is used:

$$Cpk = (1 - k)\, Cp \tag{7}$$

$$k = \frac{\left|(USL + LSL)/2 - \underline{x}\right|}{(USL - LSL)/2} \tag{8}$$

Description:

$USL = Upper\ Specification\ Limit$

$LCL = Lower\ Specification\ Limit$

$\sigma = Standart\ Deviasi$

$\underline{x} = Average\ Value$

The relationship between Cp and Cpk values in production process capability is as follows (Rimantho & Athiyah, 2019):

a. Cp = Cpk value, the process is in the middle of the product specification.

b. Cp value > 1.33, the production process capability is very good.

c. Cp value < 1.00, the process does not produce products that meet specifications.

d. Cpk value is negative, the average process is outside the product specification limits.

e. Cpk value = 1.0, one process variation is at one of the specification limits.

f. Cpk value < 1.0, the process produces products not according to specifications.

g. Cpk value = 0, the process has an average value with the specification limits.

h. Cpk value = 1, the process has a value equal to the specification limit.

2.3. QCDSME

QCDSME is one of the analysis methods used to identify an existing problem, where the aspects being analyzed will be focused on the core of the problem according to the needs of the QCDSME value (Quality-Cost-Delivery-Safety-Morale-Environment) that is oriented towards the value of customer, employee and company satisfaction (Juwandi & Kamsin, 2020).

The analysis values in QCDSME can be described as follows (Stani et al., 2023):

1. Quality, namely ensuring the quality of a product to continue to meet the quality standards expected by consumers, as well as improving product quality through planned programs.
2. Cost, which is the efficiency of the expenses used without sacrificing the quality of the product itself.
3. Delivery (Timeliness), namely the efficiency of the time used during the production process from the beginning of the process until the product reaches the hands of consumers, thereby reducing the downtime of a company.
4. Safety, which prioritizes safety values for all workers and everyone who plays an active role during production activities.
5. Morale, which prioritizes the value of satisfaction for all workers and all people who participate in activities, especially customers or consumers as connoisseurs of a finished product. So that they feel more valued and motivated to continue to provide good participation to the company.
6. Environment, which focuses on always maintaining environmental conditions, by reducing waste disposal efforts that have an impact on the health of the environment itself.

3. Results and Discussion

In this research, the first step that must be done is to process data using Six Sigma (DMAIC) and QCDSME analysis with data obtained from the field observation process and interviews with operators who are working and confirming directly to the production chief.

3.1. Define

At the formulation stage, it is done by determining the CTQ (Critical to Quality) value and identifying the subject matter to be resolved using the Pareto diagram tool. CTQ (Critical to Quality) shown in the Table 2.

Table 2. CTQ (*Critical to Quality*)

No.	CTQ	Quantity (Kg)
1	Torn Paper	48.996
2	Joint 1	42.950
3	Uncut	27.907
4	Perforated Edge	20.410
5	Joint 2	17.496
6	Tucked	13.891
7	Long - Short	11.958
8	Not Symmetrical	9.352
	Total	192.960

To identify the main causes of product defect problems during the production of health plasters at pharmaceutical company's is to use the Pareto diagram tool, as shown in the Fig. 1.

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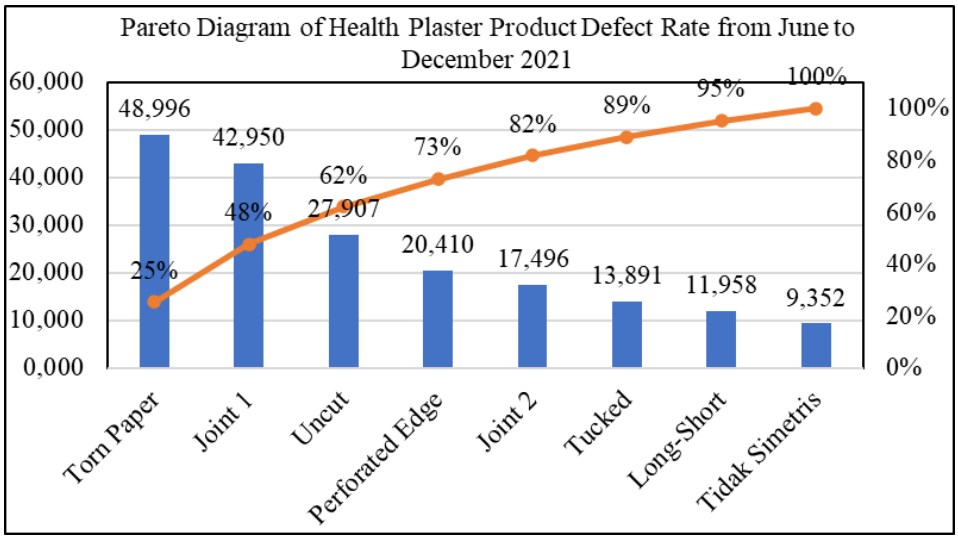

Fig 1. Pareto Diagram of Health Plaster Product Defects

3.2. Measure

At the measurement stage, calculations will be made to determine the CTQ (Critical to Quality) value using the DPMO (Defect for Million Opportunities) calculation as follows Table 3.

Based on the calculation table above, from an average of 683.060 pcs of products produced during the June-December 2021 period, an average defective product of 1,119 pcs was found. So that the DPMO value is obtained, which is an average of 208.5929. Using the sigma conversion table, the average sigma level is 5.05.

3.3. Analyze

At the analysis stage using several tools contained in the seven tools with the help of the QCDSME (Quality-Cost-Delivery-Safety-Morale-Environment) method which will be described as follows:

1. Control map p, used to determine the control of the number of units of the number of products that do not comply with the standard. So that the company can see how much product quality control has been done. Diagram of the p control map on product defects can see in the Fig. 2.

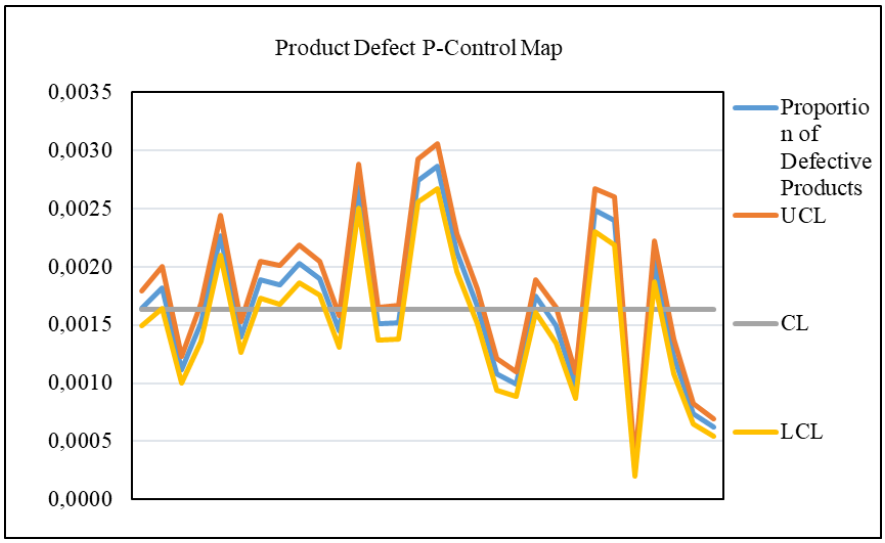

Fig 2. Product Defect P-Control Map

Table 3. DPMO and Sigma Level Calculation Results

Periode	U	D	OP	DPU	TOP	DPO	DPMO	Level Sigma
1	676,200	1,110	8	0.0016	5,409,600	0.0002	205.1908	5.03
2	499,800	910	8	0.0018	3,998,400	0.0002	227.5910	5.01
3	735,000	820	8	0.0011	5,880,000	0.0001	139.4558	5.13
4	529,200	806	8	0.0015	4,233,600	0.0002	190.3817	5.05
5	676,200	1,535	8	0.0023	5,409,600	0.0003	283.7548	4.95
6	705,600	985	8	0.0014	5,644,800	0.0002	174.4969	5.08
7	676,200	1,275	8	0.0019	5,409,600	0.0002	235.6921	5.00
8	617,400	1,140	8	0.0018	4,939,200	0.0002	230.8066	5.00
9	705,600	1,430	8	0.0020	5,644,800	0.0003	253.3305	4.98
10	793,800	1,510	8	0.0019	6,350,400	0.0002	237.7803	4.99
11	705,600	1,020	8	0.0014	5,644,800	0.0002	180.6973	5.07
12	676,200	1,820	8	0.0027	5,409,600	0.0003	336.4389	4.90
13	676,200	1,022	8	0.0015	5,409,600	0.0002	188.9234	5.06
14	646,800	985	8	0.0015	5,174,400	0.0002	190.3602	5.05
15	735,000	2,014	8	0.0027	5,880,000	0.0003	342.5170	4.90
16	705,600	2,021	8	0.0029	5,644,800	0.0004	358.0286	4.88
17	735,000	1,560	8	0.0021	5,880,000	0.0003	265.3061	4.96
18	676,200	1,121	8	0.0017	5,409,600	0.0002	207.2242	5.03
19	529,200	571	8	0.0011	4,233,600	0.0001	134.8734	5.14
20	793,800	788	8	0.0010	6,350,400	0.0001	124.0867	5.16
21	793,800	1,390	8	0.0018	6,350,400	0.0002	218.8838	5.02
22	588,000	880	8	0.0015	4,704,000	0.0002	187.0748	5.06
23	735,000	719	8	0.0010	5,880,000	0.0001	122.2789	5.17
24	646,800	1,610	8	0.0025	5,174,400	0.0003	311.1472	4.92
25	499,800	1,198	8	0.0024	3,998,400	0.0003	299.6198	4.93
26	793,800	205	8	0.0003	6,350,400	0.0000	32.2814	5.50
27	617,400	1,264	8	0.0020	4,939,200	0.0003	255.9119	4.97
28	499,800	616	8	0.0012	3,998,400	0.0002	154.0616	5.11
29	882,000	651	8	0.0007	7,056,000	0.0001	92.2619	5.24
30	940,800	582	8	0.0006	7,526,400	0.0001	77.3278	5.28
Average	683,060	1,119	8	0.0017	5,464,480	0.0002	208.5929	5.05

From the p control map Fig.2, it can be concluded that the value of the proportion of the number of defective products is still within normal limits, because the value of the proportion of the number of defective products is still in the upper limit area with a maximum value of 0.0031 and a lower limit with a minimum value of 0.0002. Even so, the company still suffers a loss of Rp 18,047,232/year due to the defective products produced. So, it is necessary to control product quality to minimize the cost of losses received by the company.

2. Fishbone diagram, used for cause-and-effect analysis of product defects including human factors, machines, materials and methods. The picture of a fishbone diagram on health plaster product defects can see in the Fig. 3.

   Based on Fig. 3, it can be explained that the factors that cause product defects include humans, machines, materials and methods as follows:

   a. Human, different operator responses caused by operator changes and differences in handling methods.

   b. Machine, the position of the plate and pressure roll is not right because there is no standard size so that it makes the flow of the product unstable.

   c. Material, the product roll is too loose or tight due to the connection of paper insulation so that the flow of the product is unstable.

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d. Method, there is no written procedure for handling defective products because the procedure has not been established.

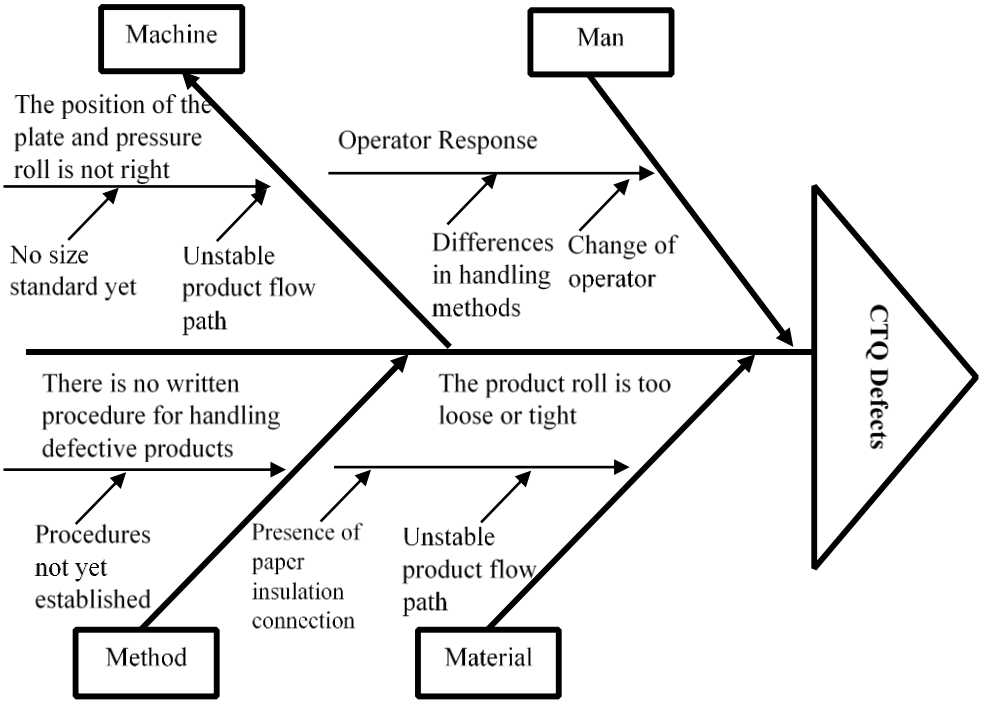

Fig 3. Fishbone Diagram of Defect CTQ

3. QCDSME analysis, used as an assessment reference to determine the impact of losses received by the company in the Quality-Cost-Delivery-Safety-Morale-Environment parameter. Loss analysis using QCDSME can be seen in Table 4.

Table 4. QCDSME Analysis

No.	Parameter	Results
1	Quality	Product quality decreases with an average product defect of 1,119 pcs/day, making it prone to defective products that pass to consumers.
2	Cost	The value of losses due to product defects amounted to Rp 18,047,232 / year.
3	Delivery	The production process will be hampered because operators are too often sorting products. Delivery process will be hampered due to reduced stock in the warehouse.
4	Safety	There is a condition of excessive eye fatigue due to continuous product sorting, so that workers' concentration will decrease.
5	Morale	The existence of a bad paradigm for workers that affects their thought processes and attitudes, thus affecting their performance.
6	Environment	Additional solid hazardous waste disposal from defective products of 997 Kg/year.

3.4. Improve

In the improvement stage, a table of proposed improvement plans based on the analysis that has been carried out can be seen in the Table 5.

3.5. Control

At the control stage, standardization of work procedures will be carried out in accordance with the proposed improvements above. Furthermore, the new procedures that have been made by the division head must be immediately socialized to all employees who work in the area. The standardization made is as follows:

1. Revision of the fixed procedure for handling product defects.
2. Making a logbook that contains recording and checking the standard size of the plate and pressure roll.

Table 5. Proposed Improvement Plan

Factor QCDSME	Man	Machine	Material	Method
Quality	Conduct training for new operators. Introduced machine parts to new operators.	Make a size standard for plate position of (12.5 ± 1 cm) and pressure roll of (22 ± 1 mm).	Weight belts are provided to hold the rotating product roll.	Create a new work procedure in writing about handling product defects along with a logbook for checking plate size standards and pressure rolls.
Cost	Reduce over-time for product sorting and replace it with rotating breaks.	Utilize the addition of a ruler on the machine to make it easier for the operator when measuring the position of the plate and pressure roll.	Choosing raw materials as needed at affordable prices and not excessive.	Conduct direct socialization to operators.
Delivery	Periodically check the condition of the machine, work environment and equipment before use.	Increase the machine speed if the product is in good condition and decrease the machine speed if the condition is otherwise.	Make and use materials according to a set schedule.	Conduct regular checks on the new work procedures that have been established, to avoid deviations.
Safety	Use PPE and increase vigilance when working, especially work areas related to sharp objects, heat, and heavy equipment.	Provide a written warning sign on the area of the machine that is considered dangerous, and provide a cover in the form of a spoon to cover the sharp area.	Selecting materials that already have safety certification from the authorized party.	Ensure that the working environment, machines, and operators are safe, comfortable, and healthy.
Morale	Provide motivation and create a positive work environment and mindset.	Operate the machine according to the specified SOP.	Using raw materials according to predetermined SOP.	Create work methods that are in accordance with the conditions in the field and still pay attention to the mental health factors of the operators who are working.
Environment	Provide insights and training on the importance of maintaining the condition of the surrounding environment.	Using environmentally friendly machines.	Grouping of waste material according to its type and then the disposal process is carried out according to the SOP.	Conduct work methods according to SOP so as not to cause adverse effects on the surrounding environment.

4. Conclusion

Based on the results of the analysis of the six sigma and QCDSME methods that have been carried out, it is found that the average product defect amounts to 683.060 Kg or 1,119 pcs / day and is at a sigma level of 5.05. In the analysis using the fishbone diagram, it can be seen that the causes of product defects include the absence of size standards in the repair of plate and pressure roll positions, differences in operator responses, the absence of written procedures for handling product defects, and the existence of product roll rolls that are too loose or tight. So that the QCDSME analysis stage shows a potential loss value of IDR. 18,047,232 / year. To reduce the loss value, there are several improvement proposals that have been made, namely making a standard size on the plate with a value of 12.5 ± 1 cm and a pressure roll with a value of 22 ± 1 mm with the help of a ruler for measurement and revising the fixed procedure for handling product defects. After implementing improvements to product defects, it was found that the number of defects decreased to 4.112 Kg or 205 pcs/day with a loss value of IDR. 3,306,253/year.

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