Volume 1 Number 2 July 2024
E-ISSN: 3047-4337
https://journal.antispublisher.com/index.php/IPTEKS/index

IMPLEMENTATION OF SIX SIGMA AND KAIZEN TO IMPROVE THE QUALITY OF HEALTH PLASTER PRODUCTS IN THE COATING PROCESS

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Article Info

Article history:
Received Jun 12, 2024
Revised Jul 17, 2024
Accepted Jul 22, 2024

Keywords:
Six Sigma; DMAIC; Kaizen; Quality Control

ABSTRACT

General Background: Product quality control is essential to ensure consistent quality from the beginning to the end of the production process. **Specific Background:** PT. FGH faces significant quality challenges, specifically during the health plaster coating stage, which has resulted in numerous product defects. **Knowledge Gap:** Although previous research has applied Six Sigma for quality improvement, detailed studies on health plaster manufacturing using combined Six Sigma and 5S Kaizen methodologies remain limited. **Aims:** This study aims to assess the product defect rate at PT. FGH using the Six Sigma methodology, measure defect levels via the sigma level through Defect Per Million Opportunities (DPMO) conversion, and propose improvement strategies through 5S Kaizen. **Results:** Findings reveal a DPMO of 7,039.4959, with a sigma level of 3.96, indicating that while the process capability values for Cp and Cpk are 1.00, suggesting production aligns with specification limits, tighter monitoring is required. Notably, product defects are predominantly folding, perforated edges, and asymmetry, comprising 80% of defects and leading to financial losses of IDR 340,524,744 over a one-year period. **Novelty:** This study uniquely combines Six Sigma and 5S Kaizen in addressing specific defect types and sources, including mechanical and human factors, within the health plaster industry. **Implications:** By implementing targeted process improvements, this research contributes a practical framework for defect reduction and cost mitigation in production, supporting broader quality control efforts in similar manufacturing sectors.

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DOI : https://doi.org/10.61796/ipteks.v1i2.202

INTRODUCTION

Quality can be interpreted as a real effort or effort from the producer to meet the level of consumer satisfaction in accordance with aspects of needs, expectations, and expectations [1]. Good product quality must pay attention to quality dimensions including product performance, product characteristics, reliability, suitability, durability, ability to repair, beauty of appearance, and quality perceived by consumers [2]. The quality of the product itself is one of the aspects that affects the purchase decision by consumers. The increase in the number of product demand also depends on the quality of the product produced, the better the product quality, the greater the product demand by consumers. On the contrary, the lower the quality of the product produced, the level of interest and consumer decision to use the product will also decrease. Product quality is very important for a consideration in the level of trust and satisfaction obtained [3]. 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 met, then the level of consumer trust to continue using and buying products is still established [4].

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 manufacturing process of the manufacturing industry of products from the beginning of the process to the end of the product process accepted by consumers. Quality control is carried out to maintain good product quality, thereby minimizing expenses by the company and making consumers feel satisfied with the products marketed [5]. Previous research has been conducted by Sutiyarno & Chriswahyudi at a snack company. The study showed that the six sigma and QFD (Quality Function Deployment) is able to identify the value of Sigma production, determine the process or part of the production process that contributes the most defective products and provide input related to the proposed changes to be made [6]. Another study conducted by Moi & Sing in the agricultural sector, showed that the integration of the kaizen, kaikaku, and 5S is able to increase worker productivity and effectiveness in completing tasks, provide improved occupational health and safety, and can reduce production waste generated [7]. Meanwhile, the research conducted by Rahman et al in the apparel industry sector, shows that the application of six sigma (DMAIC) is able to identify project actions to reduce the variability of product defect levels and increase productivity by producing quality products using process capability analysis (Cpk) [8].

PT. FGH is a manufacturing industry established in 1975 and engaged in the pharmaceutical sector. In his daily life, PT. FGH produces a type of pain relief product (analgesic), one of the company's flagship products is health plaster products. Health plaster products have been marketed throughout the region covering 40 countries including the Asia, the United States, and the Euro Area. The phenomenon that occurred at PT. FGH related to product quality, namely there are types of product defects during the coating process which are categorized into several types of defects, including products with folding defects of 34%, perforated edges of 25%, asymmetrical by 21%, dirty fabrics by 13%, and torn paper by 8% of the total production in the period of December 2022 – November 2023. Of the percentage of product defects, the company suffered financial losses, decreased product quality and less than optimal production process capabilities.

From the background description and referring to the results of the data above, the purpose of this study is to determine the amount of the number of defect values of health plaster products, determine the level of product defects using the sigma level with the conversion of DPMO values and develop a strategy for recommendations for proposed improvements using the implementation of kaizen 5S.

METHODS

A. *Research* Flowchart

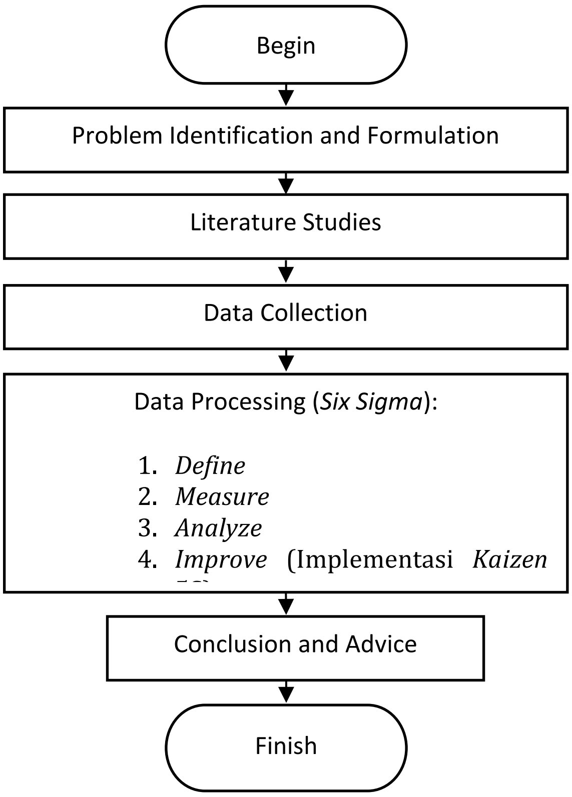

Figure 1. *Research* Flowchart

B. *Six Sigma*

Six sigma is a concept that prioritizes quality improvement products with a product defect of only 3.4 for every 1,000,000 product results produced by a company [1]. Implementation of improvements using the *six sigma* focused on statistically minimizing process variance and knowing *level* defects of a product based on 6 *sigma* [9]. Stages that must be done when using the *six sigma* as follows:

1. *Define*
   Conducting the process of collecting supporting data from indications of potential problem topics and conducting discussions with team members (*brainstorming*) [10].
2. *Measure*
   Identify the type of defect with the greatest value and affect the quality of the product, by determining the value of the *Critical To Quality* (CTQ) and measure the level *sigma* by converting the *Defect Per Million Opportunities* (DPMO). CTQ is a limit or standard of product characteristics that must be maintained so that product quality is maintained. CTQs are made or set by producers based on input from consumers. The steps that must be done to calculate the DPMO value are as follows [1]:
   a. *Defect Per unit* (DPU)

$$\text{DPU} = \frac{D}{U} \tag{1}$$

Source: [1]

b. *Total Opportunities* (TOP)

$$TOP = U \times OP \quad (2)$$

Source: [1]

c. *Defect Per Opportunities* (DPO)

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

Source: [1]

d. *Defect Per Million Opportunities* (DPMO)

$$DPMO = DPO \times 1.000.000 \quad (4)$$

Source: [1]

e. Sigma level using the help of *Microsoft Excel*

DPMO Value Conversion = NORMSINV ((1,000,000-DPMO)/1,000,000)+1.5) (5)

Source: [11]

Information:
D = *Defect*
U = *Unit*
OP = *Opportunities*

f. Classification of organizations based on *sigma level*

Tabel 1. *Level Sigma*

Level Sigma	*Defect Per Million Opportunity* (DPMO)	Category
6	3,4	*World Class*
5	233	Installment-Installment Industries
4	6.210	
3	66.807	
2	308.538	Non-Competitive
1	691.462	Very Uncompetitive

Source: [12]

3. *Analyze*
Conduct analysis related to the causes and effects of the problem. The source of the cause of problems in product quality is found based on the 7 M principles, namely *man power* (human), *machine* (engine), *methods* (how it works), *materials* (raw materials), media (place and time), *motivation* (motivation), and *money* (Finance) [6].
4. *Improve*
Optimize the solution of the improvement plan that will be carried out on each root cause found to maximize the desired results [13].
5. *Control*

Efforts to improve quality by standardizing procedures, documentation, and socializing work guidelines or new changes that have been made and mutually agreed upon [8].

C. Control Map

Control map or control map (*control chart*) is a statistical method that distinguishes between variations or deviations due to general causes and special causes. Control maps are also used to conduct quality improvement processes, determine process capabilities, help determine effective specifications and find the causes of non-standard products [14]. In the control map, there are the values of the restrictions that are applied as follows:

1. The value of the proportion of product defects (), to find out the value is used the following formula:$\bar{P}\bar{P}$

$$\bar{P} = \frac{\sum Di}{\sum ni} \tag{6}$$

Source: [15]

2. The upper limit (UCL), middle limit (CL) and lower limit (LCL) values, to find out the limits of the upper, middle and lower values are used the following formulas:
   a. Upper limit value (UCL)

$$\text{UCL} = \ + 3\text{S}\bar{P}_{\text{p}} \tag{7}$$

Source: [1]

   b. Middle bound value (CL)

$$\text{CL} = \frac{\sum Di}{\sum ni} \tag{8}$$

$$\text{CL} = \bar{P} \tag{9}$$

Source: [1]

   c. Lower limit value (LCL)

$$\text{LCL} = \ - 3\text{S}\bar{P}_{\text{p}} \tag{10}$$

Source: [1]

   d. Nilai *Sigma* (S_p)

$$\text{Sp} = \sqrt{\frac{(\bar{P}\ (1-\bar{P})}{n}} \tag{11}$$

Source: [1]

Information:
$\bar{P}$ = Proportion of defective products
ΣDi = Number of product defects
Σni = Number of *units* of products inspected

D. Process Capabilities

Process capability is 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 [12]. One of the indicators in the process capability is as follows [16]:

1. Process capability ratio (*Cp Index*), to find out the value of *the Cp index*, the following formula is used:

$$Cp = \frac{(UCL-LCL)}{6\sigma} \tag{12}$$

Source: [16]

2. The ratio of process ability (*Cpk*), to find out the Cpk value , the following formula is used:

$$Cpk = (1 - k)\,Cp \tag{13}$$

Source: [16]

$$k = \frac{\left|(UCL+LCL)/2-\bar{x}\right|}{(UCL-LCL)/2} \tag{14}$$

Source: [16]

Information:
UCL = *Upper Control Limit*
LCL = *Lower Control Limit*
σ = Standard Deviation
$\bar{x}$ = Average value

Relationship between values *Cp* and *Cpk* In the production process capability criteria, the following values are used as a reference [17]:

a. Cp *value* = *Cpk*, the process is between the product specifications.
b. Cpk value = 0, the process has an average value with specification constraints.
c. Cpk value = 1, the process has a value equal to the specification limit.
d. The *Cpk value is negative*, the average process is outside the limits of the product specifications.
e. The Cp value < 1.00, the production process is not good and does not meet the specifications.
f. The Cp value > 1.33, the production process is very good.

E. *Kaizen*

Kaizen is a Japanese word term derived from the word "*Kai*" means change and "*zen*" means good or good. *Kaizen* get is interpreted as an effort or improvement plan that is carried out continuously [7]. *Kaizen* It is not dramatic, meaning that the application process is based on common sense at a relatively low cost. Purpose *Kaizen* namely to achieve effectiveness and efficiency, create human resources who are disciplined, hardworking, meticulous, respect for time, are oriented towards success, and do other positive things [18].

Values *Kaizen* The 5S can be described as follows[19]:

1. *Seiri* (sorting), identifies and sorts all unnecessary items from the work area according to their type and function.
2. *Seiton* (arrangement), all necessary items are placed and neatly arranged according to their place to facilitate search, use, and storage.
3. *Seiso* (cleaning), cleaning the work area to keep it neat, clean, and organized.
4. *Seiketsu* (maintenance), maintaining and maintaining the work area regularly by complying with activities (*seiri*, *seiton*, and *seiso*) according to existing procedures.
5. *Shitsuke* (habituation), making 5S a lifestyle that forms habits for company culture, thus maintaining the values of discipline and success.

RESULT AND DISSCUSION

A. *Define*

PT. FGH is a manufacturing industry company in the pharmaceutical sector that produces a variety of health plaster products. The process of making health plasters must go through several stages, including the coating stage. At the coating stage, several categories of product defects were found, including folded products, perforated edges, asymmetrical, dirty fabrics and torn paper.

1. Menentukan CTQ (*Critical To Quality*).

Tabel 2. CTQ (*Critical To Quality*)

No.	CTQ	Information	Impact
1.	Fold	The condition of the surface of the product has creases on both sides.	1. The product does not pass the *quality* party and is categorized as *a Not-Good* (NG) product. 2. Products cannot be marketed in general to consumers. 3. The company suffered a loss of time and materials because it had to repeat the production process from scratch. 4. Production quality decreases, because the process capability is not optimal.
2.	Perforated Edges	The condition of the edge of the surface of the product has small holes in the thread stitching.	
3.	Asymmetrical	The surface condition between the fabric and the paper on the product is not the same size.	
4.	Dirty Cloth	The condition of the fabric used for the dirty coating process.	
5.	Torn Paper	The condition of the paper used for health plaster is torn.	

In research conducted at PT. FGH for making CTQ is based on the results of interviews and observations in the field with production heads, squad heads, and machine operators on duty.

2. Table of health plaster product defects for the period of December 2022 – November 2023.

Table 3. Product Defect Data

Types of Product Defects	Quantity (Kg)	Percentage (%)
Fold	1.522,726	34%
Perforated Edges	1.111,341	25%
Asymmetrical	917,634	21%
Dirty Cloth	576,325	13%
Torn Paper	336,838	8%
TOTAL	4.464,864	100%

From table 3 of the product defect data, it can be seen that folding product defects occupy the first position as the largest contributor to defects with a total of 1,522,726 Kg, followed by perforated edge defects of 1,111,341 Kg, asymmetrical defects of 917,634 Kg, dirty fabric defects of 576,325 Kg and torn paper defects of 336,838 Kg out of a total of 4,464,864 Kg of product defects in the data collection period of December 2022 – November 2023.

3. Create *a pareto* chart to illustrate product defect data that is an indication of the topic of the problem.

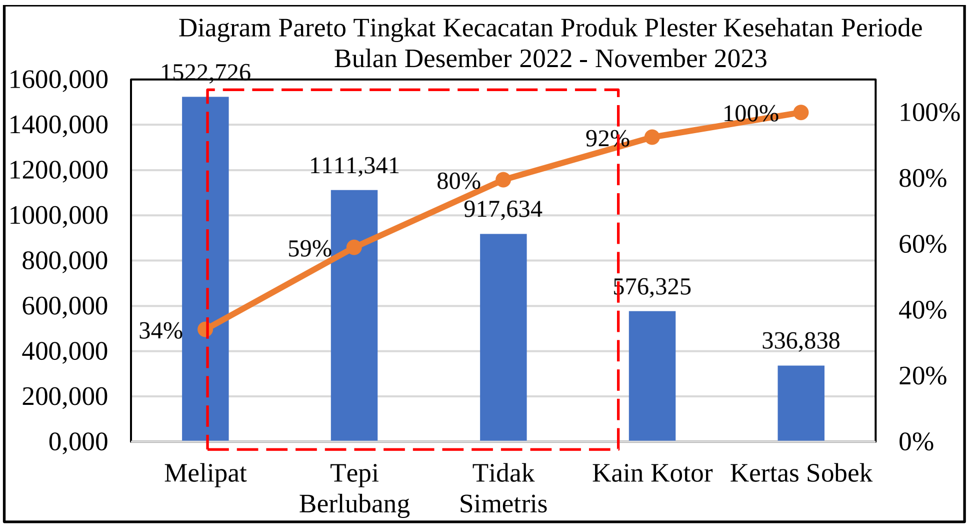

Figure 2. *Pareto Product* Defect Diagram

Following the principle *pareto* 80:20 which states that 80% of events or consequences are caused by only 20% of problems [20]. Identification of the cause of the problem can be solved by only making repairs to the category of product defects that have a percentage of *range* which is close to 80% [21]. On the diagram *pareto* Figure 1 It is known that of the 5 categories of product defects, only 3 categories dominate, namely folding defects, hollow edges and asymmetrical so that it is prioritized to immediately carry out a repair plan

B. *Measure*

1. Measuring *sigma levels* by converting DPMO (*Defect Per Million Opportunities*) values.

Table 4. *Level Sigma*

Period	*Unit*	*Defect*	*Opportunities*	*Defect Per Unit*	*Total Opportunities*	*Defect Per Opportunities*	*Defect Per Million Opportunities*	*Level Sigma*
December	6.713.280	264.235	5	0,0394	33.566.400	0,0079	7.872,0044	3,91
January	7.801.920	291.549	5	0,0374	39.009.600	0,0075	7.473,7819	3,93
February	5.140.800	219.958	5	0,0428	25.704.000	0,0086	8.557,3581	3,88
March	8.406.720	311.095	5	0,0370	42.033.600	0,0074	7.401,0957	3,94
April	7.741.440	246.992	5	0,0319	38.707.200	0,0064	6.381,0460	3,99
May	7.408.800	284.508	5	0,0384	37.044.000	0,0077	7.680,2607	3,92
June	5.503.680	184.477	5	0,0335	27.518.400	0,0067	6.703,7790	3,97
July	9.918.720	286.476	5	0,0289	49.593.600	0,0058	5.776,4812	4,03
August	11.612.160	369.298	5	0,0318	58.060.800	0,0064	6.360,5374	3,99
September	7.771.680	238.413	5	0,0307	38.858.400	0,0061	6.135,4271	4,00
October	10.735.200	366.058	5	0,0341	53.676.000	0,0068	6.819,7655	3,97
November	8.436.960	308.473	5	0,0366	42.184.800	0,0073	7.312.4141	3,94
Total	97.191.360	3.371.532	60	0,4224	485.956.800	0,0845	84.473,9510	47,49
Average	8.099.280	280.961	5	0,0352	40.496.400	0,0070	7.039,4959	3,96

An example of a description of the calculation for the December period is as follows:

a. Calculation of Defect *Per Unit* (DPU) value

$$DPU = \frac{D}{U}$$

$$= \frac{264.235}{6.713.280}$$

$$= 0,0394$$

b. Total Opportunities *(TOP)* value calculation
TOP = U x OP
= 264.235 x 5
= 33.566.400
c. Calculation of *Defect Per Opportunities* (DPO) value
DPO = $\frac{D}{TOP}$
= $\frac{264.235}{33.566.400}$
= 0,0079
d. Calculation of Defect *Per Million Opportunities* (DPMO) value
DPMO = DPO x 1.000.000
= 0,0079 x 1.000.000

= 7.872,0044

e. Sigma level *calculation*
Level sigma = NORMSINV ((1.000.000-DPMO)/1.000.000)+1.5)
= NORMSINV ((1.000.000-7.872,0044)/1.000.000)+1.5)
= 3,91

Based on the calculation data from table 4 *of the sigma level,* it is known that, out of an average of 8,099,280 units of products inspected during observation, 280,961 *units of* defective products were found. So that the level of disability based on 5 types of disabilities (CTQ) was obtained with a DPMO value of 7,039.4959 *units*. If converted to *the sigma level*, a *sigma* value of 3.96 is obtained.

2. Create a control map p to measure the amount of the proportion of defective products that do not conform to the control limits.
To find out the limitations of the control value on health plaster product defects, the following calculation steps are carried out:
a. *Center Line* (CL)
CL = $\frac{\sum Di}{\sum ni}$
= $\frac{3.371.532}{97.191.360}$
= 0,0347
b. *Upper Control Limit* (UCL)
UCL = + 3S$\bar{P}_p$
= 0,0347 + 3 ($\sqrt{\frac{(0,0347(1-0,0347)}{8.099.280}}$
= 0,0347 + 3 (0,0000643)
= 0,0349
c. *Lower Control Limit* (LCL)
LCL = - 3S$\bar{P}_p$
= 0,0347 - 3 ($\sqrt{\frac{(0,0347(1-0,0347)}{8.099.280}}$
= 0,0347 - 3 (0,0000643)
= 0,0345

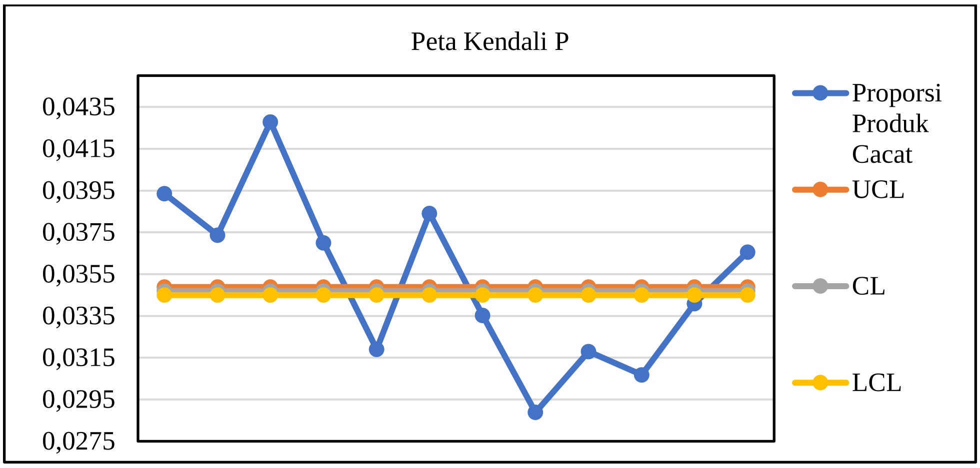

Figure 3. P Control Map

Based on figure 3 of the p control map, it can be concluded that the value of the proportion of defective products is not at the normal limit, because the value of the proportion of defective products exceeds the maximum value limit (UCL) of 0.0349 and the minimum value limit (LCL) of 0.0345.

3. Calculate the value of process capability (*Cp* and *Cpk*).
   a. Calculate process capability (*Cp*) value

$$Cp = \frac{(UCL-LCL)}{6\sigma}$$
$$= \frac{(0{,}0349-0{,}0345)}{6(0{,}0000643)}$$

= 1.00 means that the process capability is good and needs strict control.

   b. Calculate the kane process capability value (*Cpk*)

$$k = \frac{|(UCL+LCL)/2-\bar{x}|}{(UCL-LCL)/2}$$
$$= \frac{|(0{,}0349+0{,}0345)/2-0{,}0347|}{(0{,}0349-0{,}0345)/2}$$
$$= 0$$

Cpk = (1-k) *Cp*
= (1-0) 1.00
= 1.00 means that the process capability has a value equal to the specification limit.

4. Calculate the potential value of the loss.

From the calculation of Cp and *Cpk values*, it is known that the process capability is good in accordance with the limits of the specification but it needs to be strictly controlled. Nevertheless, the company still suffered financial losses from the number of defective products produced of 3,371,532 *units* during the period of December 2022 – November 2023, the potential value of losses received by the company was IDR 340,524,744 (IDR 101 x 3,371,532 *units*).

C. *Analyze*

The cause-and-effect analysis of the problems in the resulting product defects is carried out to help make it easier to group the causes and provide alternative solutions for repair plans that will be carried out using *fishbone* diagrams as follows.

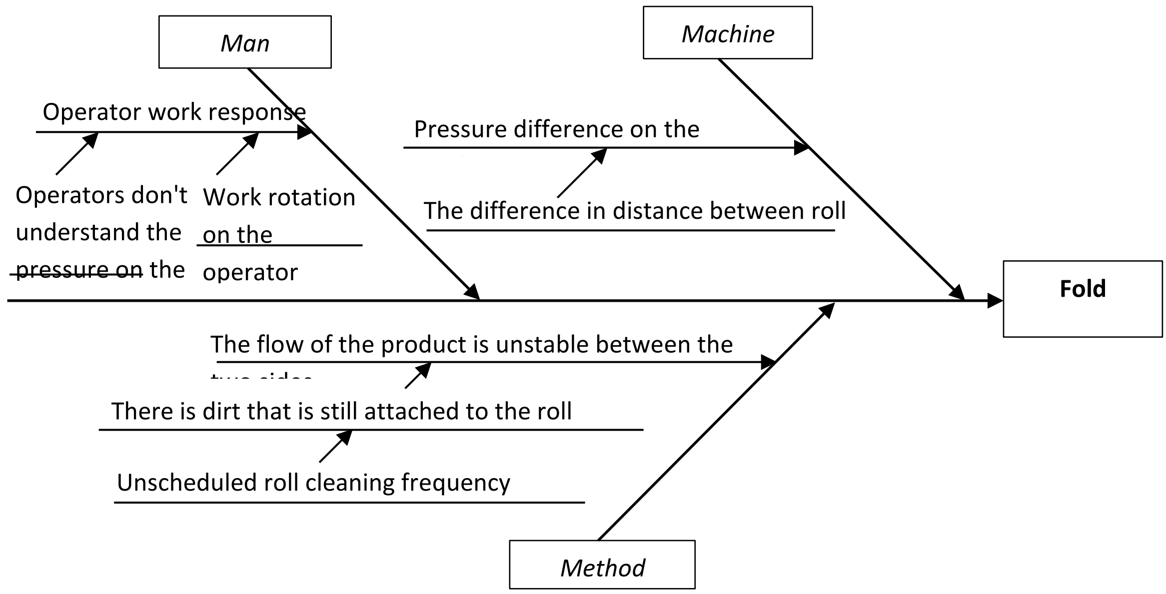

Figure 4. Folding *Defective Fishbone* Diagram

From Figure 4 of the *fishbone* diagram on the folding product defect, it can be analyzed that the cause of the folding defect is influenced by 3 main factors, namely *man*, *machine* and *method*. The *man factor* occurs due to the rotation of work and the level of understanding of the operator so that the response made when handling the defective product folds varies. The *machine factor* is caused by the difference in distance between the support rolls so that the pressure produced affects the product. Meanwhile, the *method factor* is caused by the frequency of roll cleaning has not been scheduled, as a result of which the condition of the roll cleanliness level is still lacking. From dirt that sticks to the roll, it can cause the flow of the product to be unstable on both sides.

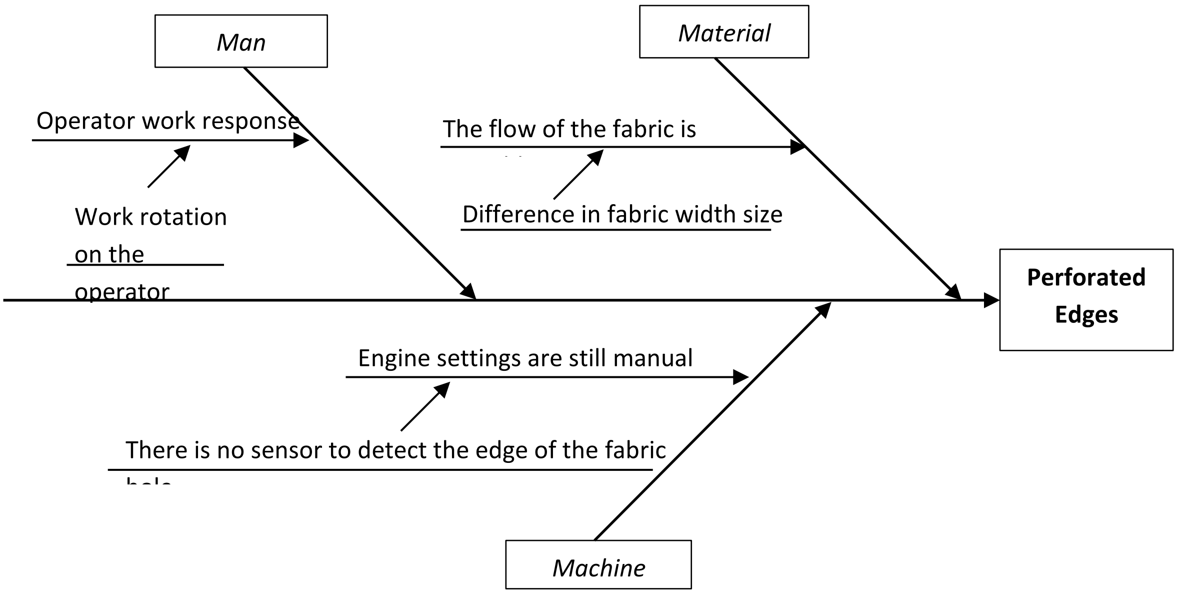

Figure 5. Fishbone Diagram of Perforated Edge Deformity

From figure 5 of the *fishbone* diagram on the perforated edge defect, it can be analyzed that the cause of the perforated edge defect is influenced by 3 main factors, namely *man, material* and *machine*. The *man factor* occurs due to the rotation of work so that the response made when handling products with perforated edges varies. Material factors are caused by differences in the size of the width of the fabric so that the flow of the fabric is unstable. Meanwhile, the *machine factor* is caused by the absence of a sensor installed to detect the edges of the fabric holes, as a result of which the machine settings are done manually.

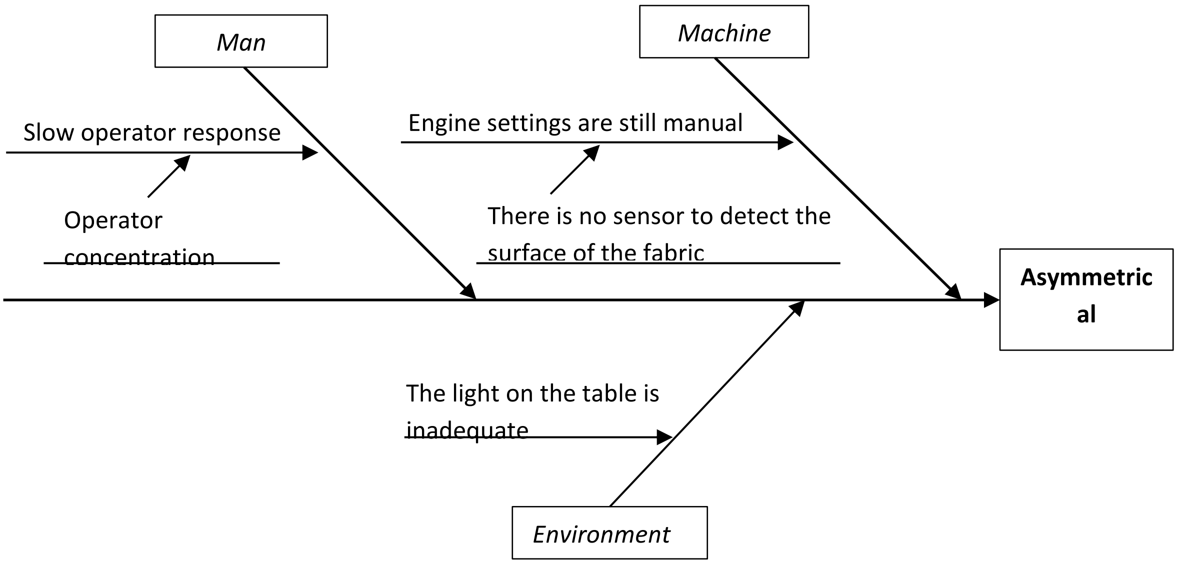

Figure 6. *Fishbone Diagram* of Asymmetrical Deformities

From Figure 6 of the *fishbone* diagram on asymmetrical product defects, it can be analyzed that the cause of asymmetrical defects is influenced by 3 main factors, namely *man, machine* and *environment*. The *man factor* occurs because the operator's concentration level decreases as a result of the slow response given. The *machine factor* is caused by the absence of a sensor that detects the surface of the fabric, as a result of which the machine setting is still manual. Meanwhile, the *environmental factor* is caused by inadequate light on the table, as a result of which it can hinder the performance of the operator.

D. *Improve*

As an effort to improve the problem that causes product defects, in its realization it uses the implementation *of kaizen* 5S to facilitate repairs so that it is more focused and directed.

Table 5. Kaizen *5S* Implementation

Factor / Aspek *Kaizen*	*Man*	*Machine*	*Materials*	*Methods*	*Environment*
Seiri (Sorting)	Conducting selection for operators who have the ability to work according to their needs	Using machines according to the specifications and working capacity	1. Using raw materials or supporting materials in accordance with the recording in the *production* batch record 2. Provide identification labels on raw materials or supporting materials to avoid misuse	Using work methods or work procedures in accordance with the SOPs of each work area	Identify or record room temperature, lamps and work locations before and after the production process in accordance with the SOPs of each work area
Seiton (Structuring)	Placing operators in work areas that suit individual and team capabilities	Prepare and check the condition of machines and supporting equipment before and after the production process	Prepare raw materials and supporting materials according to the records in the *batch record* to facilitate work	Prepare and learn how to work or work procedures in accordance with the SOPs of each work area	The location or work area is arranged and arranged in accordance with the applicable rules to facilitate work
Seiso (Cleaning)	Before entering the production area, each operator is required to wash their hands and use uniforms or PPE according to their respective work areas	Cleaning the machines used both before and after the production process	Raw materials and supporting materials for the production process must be in clean and sterile conditions to avoid product contamination	Establish scheduled procedures and working methods for the cleaning process, raw materials, and production support equipment	Carry out maintenance in each work area to avoid environmental conditions that are not in accordance with SOPs, for example, there are fungi or insects that enter from

					areas outside the production
Seiketsu (Maintenance)	Providing training to improve operator capabilities, for example through *internal company* workshops	Maintain cleanliness and check machine maintenance regularly	Taking and using raw materials and supporting materials in accordance with the previous 3S aspects	Carry out procedures or ways of working in accordance with the previous aspects of 3S	Carry out maintenance and identification of work sites in accordance with the previous 3S aspects
Shitsuke (Habituation)	Always familiarize yourself with the 5S lifestyle as a company culture to maintain success and achieve targets and apply discipline to the company's employees				

E. *Control*

At the control stage, the author only provides input to immediately take corrective steps on the cause of folding defects, hollow and asymmetrical edges because they have the highest percentage of product defects. From the proposed improvement plan, the control mechanism that must be made by the company's management is as follows:

1. Create procedures for operator rotation according to the capabilities possessed and needed.
2. Make sanitation or cleaning procedures for operators, machines, equipment, and the work environment.
3. Conduct regular inspections by the management to supervise and control procedures and work environments in accordance with the applicable Standard Operating Procedures (SOP).

CONCLUSION

Fundamental Finding: This study confirms that product defects during PT. FGH's health plaster coating process are significant, with a Defect Per Million Opportunities (DPMO) of 7,039.4959 and a sigma level of 3.96. The process capability indices Cp and Cpk both measure 1.00, indicating alignment with specification limits but also revealing the need for stringent quality control. **Implication:** Implementing Six Sigma with 5S Kaizen methodologies can effectively address and reduce primary defect types—folding, perforated edges, and asymmetry—potentially saving the company significant financial losses, which totaled IDR 340,524,744 in one year. **Limitation:** While this research provides valuable insights into defect causes and reduction strategies, it is limited to the health plaster coating process and specific defect types, leaving other production stages unexamined. **Further Research:** Expanding the Six Sigma and 5S Kaizen application to other stages of health plaster production and testing additional quality control methodologies, such as Total Quality Management (TQM), could provide a more comprehensive approach to defect reduction and process improvement.

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