Research Article

Analysis of Quality Control to Reduce Defective Products for Dry Syrup Using Six-Sigma Method in PT XYZ

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Article History: Received: 11 January 2021; Revised: 12 February 2021; Accepted: 27 March 2021; Published online: 16 April 2021

Abstract: Quality control is an activity to ensure the level of quality of any product in accordance with the specifications that have been set. PT XYZ is a manufacture industry engaged in pharmaceuticals, where companies are required to produce high quality products, because it is used for medicinal purposes. Defective products produced was as much as 6.01% exceeded the requirements of the company of 3.0%. This study used the six sigma method: define, measure, analyze, improve, control. Through this method, it can be determined that sigma value is amounted to 3.06 with 60.264.13 DPMO. At the analyze stage, the causative factors of damage were successfully obtained, including humans, materials, methods, and machines, where human factor became an important factor in this study. Defective products can be produced due to workers experiencing carelessness due to work fatigue. The method used to measure work fatigue were descriptive observational and chi square collation tests to determine the relationship to the factors causing fatigue. The results showed that there is a relationship of age and work period factors with work fatigue. Moreover, the results of this study are able to provide sigma value recommendations as well as improvement measures to reduce defective products during the production process.

Keywords: Ergonomics, quality control, six sigma, work fatigue

INTRODUCTION

The development of the manufacturing industry today is very strict, especially the pharmaceutical industry, thus encouraging companies to further develop the products they produce and increase productivity in order to compete with other companies (Wisnubroto et al., 2018).

Quality control is an activity carried out to ensure a quality level of a product in accordance with predetermined specifications. Quality control helps to maintain customer satisfaction by producing the best-quality products and helps quality managers identify and solve problems before products leave the facility. Quality control is considered very important in the production process, because it is an effort to maintain product quality in accordance with company specifications (Sari & Purnawati, 2018).

PT XYZ is a manufacturing industry engaged in pharmaceuticals, where companies are required to produce high quality products to be used for medicinal purposes. The company has made various efforts including the process of controlling the quality of the product which is also considered as a part of the production process. A product is defined as good, if the product has a very small level of defect and is able to meet customer desires (Fernando & Mustafa, 2017). Uncontrolled production processes can lead to high defective products, where the company avoids this because the defective product results in losses in the company.

A defective product is a product that does not meet the quality standards set by a company, which is subsequently able to cause losses, and affects the main goal of the company in obtaining a large profit, if it exceeds the limits set by the company.

Defective products obtained on the production of pharmaceutical dry syrup is 6.01%, while the terms of the company gives tolerance reject products amounted to 3.0%, so that it is necessary to conduct a process of reducing the defect products by using six sigma methods. The Six Sigma method is used to make improvements and increase of a continuous process.

Six Sigma is a management philosophy that focuses to remove the defects by way of emphasizing the understanding, measurement, and process improvement. The approach of Six Sigma with the method of Define, Measure, Analyze, Improve, and Control (DMAIC) can help identify problems that occur in a company, measure process performance and product performance, as well as analyze factors such problems to provide solutions and proposals for improvements to the performance of the company (Tannady, 2015).

One of the factors that become a problem in the quality control management process is ergonomic factors, where ergonomic factors are closely related to the production process. Moreover, ergonomic factors must be found in a company, because ergonomic factors involve humans as one of the media, which act as controllers in the production process, so that the goods produced are of high quality and are able to minimize the occurrence of defects (Juliana et al., 2018).

Fatigue is caused by several factors, namely internal factors and external factors. Internal factors discuss individual workers, while external factors discuss work and the work environment. Fatigue is a decrease in performance efficiency and strength in the body to do the same job (Wignjosoebroto, 2006).

The ergonomic approach to a production process must indeed be considered in order to assess the workload received by workers, which is the main focus in measuring workload, which is seen from the production operator's working period, age, and shift imposed by the company. The purpose of this ergonomic approach is to evaluate the amount of workload received by workers, then it can be used as an evaluation material for the company, so that there is no fatigue and work accidents and the result of defective products can be minimized (Agustinawati et al., 2019).

LITERATURE REVIEW

Six Sigma is a method used to improve a production process that is focused on reducing the level of defects in both products/services that are outside specifications, simply can be interpreted as a process that has a probability of defects of 0.00034% or 3.4 defective units in a million production. Six Sigma has a comprehensive approach, namely by using the stages of define, measure, analyze, improve, and control (DMAIC), the steps are as follows (Syukron & Kholil, 2013).

1. The define stage

This is the stage of defining the production machine used by PT XYZ for the filling process for dry syrup preparations. PT XYZ uses the JIHCHENG JC_PCB machine, so that the types of rejects that occur during the production process will be successfully found. To define the problem in this phase, several statistical tools are used, specifically using the Pareto diagram.

2. Measure stage

This is the stage of determining the measurement of a problem that has been defined to be solved. Measurements taken are measuring the performance results and measuring the level of process capability. Measurement of performance results used in Six Sigma is the level of Defect Per Million Opportunity (DPMO) and the achievement of the level of sigma capability. Measurement of the level of process capability is conducted by using UCL and LCL, to produce output within the expected specification limits.

a. Measurement of performance results by calculating Defect Per-Million Opportunities (DPMO) and converting the sigma value based on the sigma table.

$$DPU = \frac{Total\ Reject\ Produksi}{Hasil\ Produksi} \quad (1)$$

$$DPMO = \frac{Total\ Reject\ Produksi}{Hasil\ Produksi} \text{ X } 1000000 \quad (2)$$

b. Measurement of the level of process capability using UCL and LCL.

1. Calculate the center line with the following equation:

$$\bar{p} = \frac{\sum pi}{\sum ni} \quad (3)$$

2. Calculate the possibility of defects for each production process with the following equation:

$$Pi = \frac{pi}{ni} \quad (4)$$

3. Calculate UCL and LCL with the following equation:

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{ni}} \quad (5)$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{ni}} \quad (6)$$

3. Analyze stage

This is the stage for finding solutions to solve problems based on the root causes that have been identified. One of the stages of analysis in this study is to identify problems from ergonomic factors, namely humans. Humans have a great influence in the production process of PT XYZ. Fatigue is a risk factor for humans to carry out their duties. In this study, the fatigue factor will be then analyzed in detail.

Previous study on work fatigue was carried out by measuring the work fatigue indicator (Putri, 2008). Work fatigue was measured by submitting an Industrial Fatigue Research Committee (IFRC) questionnaire. The Industrial Fatigue Research Committee (IFRC) Questionnaire is a questionnaire originating from Japan, the questionnaire contains 30 questions related to symptoms of work fatigue. The answers to the IFRC questionnaire are divided into:

1. Very Often (SS) : 4
2. Often (S) : 3
3. Sometimes (K) : 2
4. Never (TP) : 1

The level of fatigue can be determined by adding up the scores on each question, the number is then adjusted according to the following categories:

Score 30 : No fatigue
Score 31-60 : Fatigue is mild
Score 61-90 : Moderate fatigue
Score 91-120 : Severe Fatigue
(Wirasati, 2003)

There is a correlation between fatigue and work productivity. Physical and psychological fatigue on workers will have an impact on work productivity and company productivity (Budiono, 2008). Work fatigue can be prevented by implementing working hours and rest hours as stated in the Manpower Act Number 13 of 2013.

Chi-square is a non-parametric comparison test conducted on two variables with a nominal scale

The Chi-square test can be formulated as follows:

$$\chi^2 = \sum_{i=1}^{n} \frac{(O_i - E_i)^2}{E_i} \quad (7)$$

Where:
$\chi 2$ = Chi-square distribution
Oi = An observed frequency
Ei = An expected frequency, asserted by the null hypothesis

4. Improve stage

The improve stage is an action plan to carry out corrective actions and improve the quality of the resulting product after determining the cause of the damage due to the types of product defects, so a recommendation for general corrective action is prepared in an effort to reduce the level of product damage.

5. Control stage

The control stage is the final analysis stage of the process of applying the Six Sigma method which emphasizes on the process of documenting and disseminating actions that have been taken previously.

The same study on the Six Sigma method conducted by Patel and Desai (2018) mentioned that the Six Sigma method can be used in the manufacturing industry by using different indicators to test the success of the method. In this study, the implementation of the Six Sigma method is an indicator of performance increase in the manufacturing industry.

Furthermore, a study which was conducted by Nascimento et al (2019) stated that the six sigma principle can result in continuous and gradual improvement in the oil and gas sector. Then, the six sigma method can be combined with the lean production method to support operations management needs.

In addition, the same study on work fatigue was conducted by Lahay et al. (2018) which stated that the examination of the relationship between work fatigue and age and length of work in their study was successfully analyzed using the one-way analysis of variance (ANOVA) which resulted in the effect of working age on work fatigue in brick-making workers.

Moreover, the same study on work fatigue was also conducted by Agustinawati et al. (2019), which revealed that in their study, they tested the relationship between workload and fatigue using a cross-sectional approach processed with the Kolmogorov-Smirnov normality test and the Spearman correlation test which resulted in a relationship between workload and work fatigue among the craftsmen of the bokor industry in Menyali village.

The present study was a study conducted in the manufacturing industry engaged in the pharmaceutical sector, where product quality is considered the most important thing. So that, the suitable method used in this study was Six Sigma (DMAIC), where this method can be used to reduce defective products and improve product quality and use ergonomic methods, namely work fatigue on operator performance so that it will improve product quality and productivity of operator performance at PT XYZ. In addition to these two methods, this study also used a Cause and Effect diagram which will show the main causes of the acetic product produced during the process.

METHOD

The study was prepared with the steps to achieve the objectives of the study. The steps in the preparation of the study will be described in Figure 1.

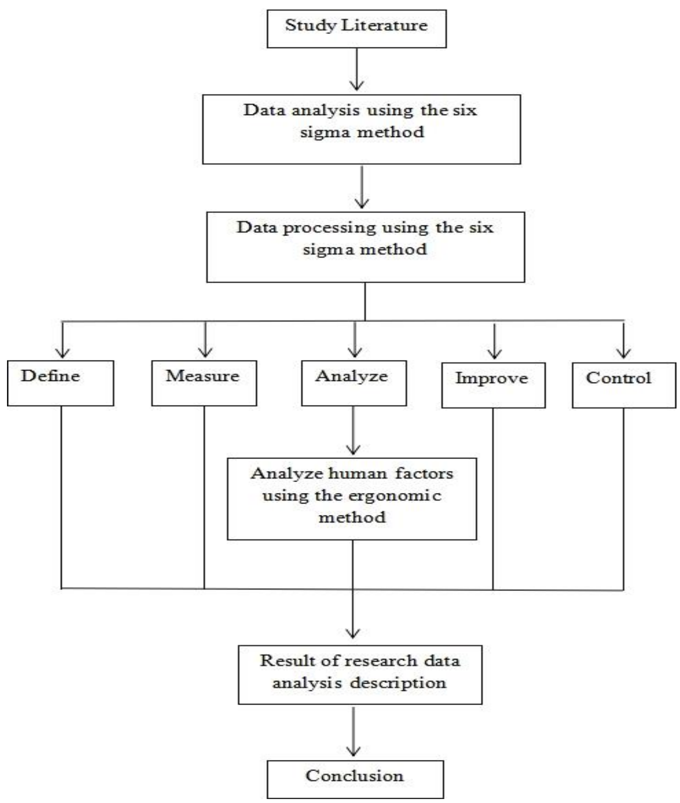

Figure 1. Activity Flowchart

The data processing process in this study used the Six sigma method at PT XYZ with quantitative methods. This study was conducted by collecting data and processing data for information. In processing the data, the stages were carried out using the six sigma method:

1. Define

This stage identified the problems that exist in this study by selecting the problems concerning the product. In order to facilitate the definition of the problem in this phase, several statistical tools were then used, namely using the

Pareto diagram. This Pareto diagram aimed to evaluate the significance of the factors in causing product defects in the production process.

2. Measure

This stage measured the performance based on the value parameter of DPMO and process capability. From the DPMO value and the same sigma value (1) and (2), then the condition can be directly seen in the current company. Capability measurement was done by counting equations (3), (4), (5), and (6) which aimed to determine the good capability owned by the company.

3. Analyze

At this stage, a cause analysis of the main problem was carried out by using cause and effect diagrams as well as evaluating the results of the Pareto diagram that had been made.

4. Improve

The stage was conducted to take corrective action of the problem by conducting valid tests and experiments to produce optimal solutions.

5. Control

The final stage in the Six Sigma method was control which aimed to standardize and control the improvement and prevent new problems that arise.

RESULT AND DISCUSSION

1. Define Stage

There were two kinds of damage that occurred during the production process, namely the bottle caps and bottles. Damage that occurred to the bottle cap was caused by a capper machine, where the damage consisted of a torn bottle cap and an italic printed logo. While the damage that occurred to the bottle was emerged when filling the powder and when the bottle was moved from the trolley to the filling machine. The damage consisted of broken bottles due to improper placement of bottles with powder filling machines (Hopper machines) and broken bottles due to negligence of production operators while moving the bottles from the trolley to the filling machine impetuously, so that many bottles fell to the floor and eventually broke, and the bottles were dirty due to the washing process which was not optimal..

Table 1 and Table 2 are the total production data and defect data of the company's products for 1 year.

Table 1. Data on Total Production and Total Rejects

No	Product	Total Reject Production	Production Result
1	Product A	758	15809
2	Product B	766	15794
3	Product C	830	15809
4	Product D	972	15797
5	Product E	1050	15757
6	Product F	1106	15727
7	Product G	908	15767
8	Product H	1144	15761
9	Product I	758	11927
10	Product J	734	11940
Total		9026	150088

Table 2. Types of Rejects Generated During the Production Process

No	Product	Bottle		Bottle cap	
		Broken Bottle	Dirty Bottle	Torn bottle cap	The logo is italicized
1	Product A	250	129	236	143
2	Product B	285	98	274	109
3	Product C	382	33	352	63
4	Product D	315	171	324	162
5	Product E	478	47	436	89
6	Product F	453	100	428	125
7	Product G	302	152	342	112
8	Product H	485	87	473	99
9	Product I	256	123	236	143
10	Product J	289	78	267	100
Total		3495	1018	3368	1145

To sort quantity of reject production results based on the quantity of the biggest to the smallest defect, a Pareto diagram was then made in this study.

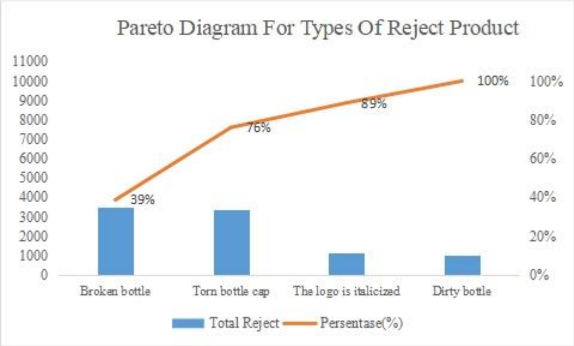

Figure 1. Pareto Diagram for Types Of Reject Product

From Figure 1, the causes of the main defect was emerged by broken bottles with the percentage of total disabilities amounted to 38.72%. Another cause was the torn cover of 37.31%, logo printed italicized of 12.69%, and dirty bottles of 11.28%

2. Measure stage
   a. Performance measurement was carried out by using the Defect Per parameter Milion Opportunities (DPMO). To measure Six Sigma levels from the production of dry syrup, equations (1)-(2) were then used.

Table 3. Measurement of DPMO and Sigma Value for Dry Syrup Production Process

No	Production result	Total Reject Production	DPU	DPMO	Sigma value
1	15809	758	0.04794737	47947.37175	1.54
2	15794	766	0.04849943	48499.43016	1.53
3	15809	830	0.05250174	52501.73952	1.43
4	15797	972	0.06153067	61530.67038	1.2
5	15757	1050	0.06663705	66637.0502	1.06
6	15727	1106	0.07032492	70324.91893	0.96
7	15767	908	0.05758863	57588.63449	1.30
8	15761	1144	0.07258423	72584.22689	0.90
9	11927	758	0.06355328	63553.28247	1.15
10	11940	734	0.06147404	61474.03685	1.21
Average	15008.8	902.6	0.06026414	60264.13616	1.228

b. Measurement of process capability using UCL and LCL parameters, with equations (3)-(6).

Table 4. Measurement of Control Limits for Dry Syrup Production Process

No	Production result	Total Reject Production	Proportion (P)	UCL	LCL
1	15809	758	0.04794737	0.065810569	0.054465536
2	15794	766	0.04849943	0.065813262	0.054462843
3	15809	830	0.05250174	0.065810569	0.054465536
4	15797	972	0.06153067	0.065812723	0.054463382
5	15757	1050	0.06663705	0.065819921	0.054456184
6	15727	1106	0.07032492	0.065825338	0.054450767
7	15767	908	0.05758863	0.065818119	0.054457986
8	15761	1144	0.07258423	0.0658192	0.054456905
9	11927	758	0.06355328	0.066668792	0.053607313
10	11940	734	0.06147404	0.066665236	0.053610869
Total	150088	9026			

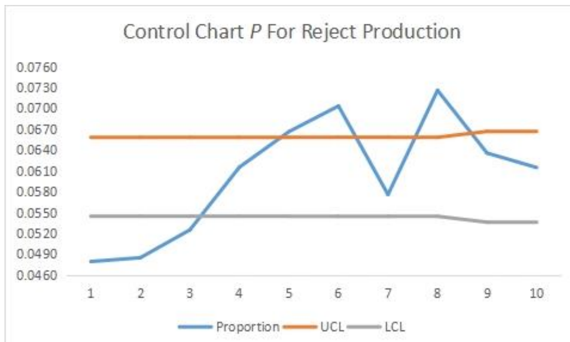

Figure 2. Control Chart for the Amount of Damaged Products from the Dry Syrup Production Process.

Figure 2 shows that there is a possibility of rejecting the control line. This shows that when the company's production process is in uncontrolled conditions, it is necessary to take some corrective actions, so that the resulting variations in each production process can be controlled easily.

3. Analyze stage

Based on the identification carried out, the factors that influence and cause product damage in general were humans or employees, raw materials, machines, and methods.

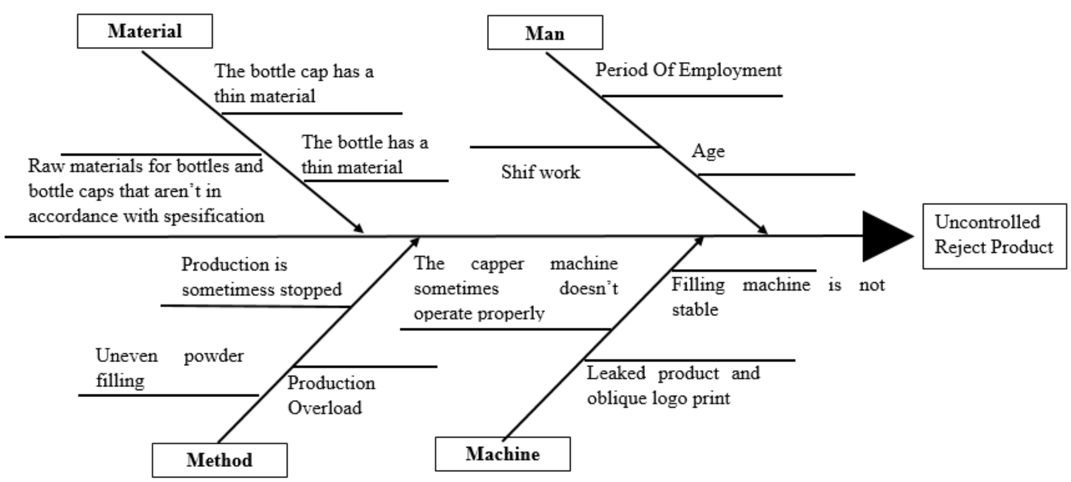

Figure 3. Cause and Effect Diagram

Based on the results of the Pareto diagram that had been made, the largest percentage of rejects was in broken bottles and torn bottle caps caused by human carelessness. So, in this study, it will be further analyzed in terms of ergonomics, which indicate that the main factor is humans. The human element is an important element for the continuity of production. Based on the results of observations that had been carried out by sampling 50 people, it can be concluded as in Table 5, using IFRC calculations.

Tabel 5. The Result Of The Questionnaire

Information	Score
Very often	26
Often	20
Sometimes	4
Never	0

In Table 5, it is concluded that PT XYZ employees were frequently experiencing work fatique, the factors that cause work fatigue experienced by PT XYZ employees are as follows:

1. Age

The results of correlation observation between age and work fatigue can be seen in Table 6.

Table 6. The Correlation Between Age and Work Fatigue

			Work fatigue			Total	*P* value (Chi Square)
			mild	moderate	heavy		
Age	< 25 years	Count	4	14	9	27	0.09
		% within work fatigue	100.0%	70.0%	34.6%	54.0%	
	> 25 yeas	Count	0	6	17	23	
		% within work fatigue	0.0%	30.0%	65.4%	46.0%	
Total		Count	4	20	26	50	
		% within work fatigue	100.0%	100.0%	100.0%	100.0%	

It was found that workers aged <25 years were more likely to experience moderate work fatigue (70%) than workers aged> 25 years (30.0%). At the level of severe fatigue, workers aged> 25 years experienced heavy work fatigue (65.4%) compared to workers aged <25 years (54.0%). At the level of mild fatigue, only workers aged <25 years experienced mild work fatigue. The statistical results of the correlation test stated that there is a relationship between age and work fatigue experienced by workers at PT XYZ, because the results of the p value of chi square were amounted to 0.009 ≤ 0.05.

2. Years of service

The results of correlation observation between work period and work fatigue can be seen in Table 7.

Table 7. The Correlation Between Work Period and Work Fatigue

			Work fatigue			Total	*P* value (Chi Square)
			Mild	Moderate	heavy		
Years of service	< 5 year	Count	4	13	10	27	0.032
		% within work fatigue	100.0%	65.0%	38.5%	54.0%	
	>5 year	Count	0	7	16	23	
		% within work fatigue	0.0%	35.0%	61.5%	46.0%	
Total		Count	4	20	26	50	
		% within work fatigue	100.0%	100.0%	100.0%	100.0%	

It was found that workers who had worked for <5 years were more likely to experience moderate work fatigue (65.0%) compared to workers who had worked for >5 years (35.0%). At the level of severe fatigue, workers who had worked for >5 years mostly experienced heavy work fatigue (61.5%) compared to workers who had worked for <5 years (38.5%). At the level of mild fatigue, only workers who had worked for <5 years experienced mild work fatigue. The statistical results of the correlation test stated that there is a relationship between the factor of work period and work fatigue experienced by workers at PT XYZ, because the results of the p value of chi square were amounted to $0.032 \leq 0.05$.

3. Work shift

The results of correlation observation between work shif and work fatigue can be seen in Table 8.

Table 8. The Correlation Between Work Shift and Work Fatigue

			Work fatigue			Total	*P* value (Chi Square)
			Mild	Moderate	heavy		
Shift Work	1 Shift	Count	4	8	11	23	0.267
		% within work fatigue	100.0%	40.0%	42.3%	46.0%	
	2 Shift	Count	0	5	7	12	
		% within work fatigue	0.0%	25.0%	26.9%	24.0%	
	3 Shift	Count	0	7	8	15	
		% within work fatigue	0.0%	35.0%	30.8%	30.0%	
Total		Count	4	20	26	50	
		% within work fatigue	100.0%	100.0%	100.0%	100.0%	

It was found that workers with a morning work shift tended to experience mild fatigue (100%) compared to workers with a day work shift and a night work shift. At the moderate level of work fatigue, most of those who experienced fatigue were workers with a morning work shift (40.0%) compared to workers with a day work shift (25.0%) and a night work shift (35.0%). At the level of heavy work fatigue, most of those who experienced it were workers with a morning work shift (46.0%) compared to workers with a day work shift (24.0%) and a night work shift (30.0%). The statistical results of the correlation test stated that there is no relationship between work shift factors and work fatigue experienced by workers at PT XYZ, because the p value chi square results were amounted to $0.267 \geq 0.05$.

4. Improve stage

Process of dry syrup production for one year contributed a sigma value of 3.06 or was at a sigma value of 3 with the possibility of defects amounting to 60,264.13 DPMO. This showed that the company is actually still able to reduce the level of defects that occur in the dry syrup production process, therefore it is necessary to recommend improvements for the company by increasing the sigma value. Defective tolerance of the company is 3%, while the calculations in can defective percent is 6.01%. Therefore, it is necessary to recommend the increasing of sigma value as in Table 9.

Table 9. Recommendations for Increasing Sigma Value for Dry Syrup Production Process

No	Production result	Total Reject Production	Recomendation		
			4 Sigma (0.62%)	5 Sigma (0.023%)	6 Sigma (0.00034%)
1	15809	758	98.0158	3.63607	0.0537506
2	15794	766	97.9228	3.63262	0.0536996
3	15809	830	98.0158	3.63607	0.0537506
4	15797	972	97.9414	3.63331	0.0537098
5	15757	1050	97.6934	3.62411	0.0535738
6	15727	1106	97.5074	3.61721	0.0534718
7	15767	908	97.7554	3.62641	0.0536078
8	15761	1144	97.7182	3.62503	0.0535874
9	11927	758	73.9474	2.74321	0.0405518
10	11940	734	74.028	2.7462	0.040596
Total	150088	9026	930.5456	34.52024	0.5102992

Based on the identification results, factors that affect and become the cause of product damage were successfully obtained, so that, it is necessary to take some corrective action as in Table 10.

Table 10. Proposed Corrective Action

Element	Causative factor	Proposed corrective action
Man	Period of employment	Training for new operators,so that the operation of the filling machine can produce a good product. As well as the provision of achievements for operators who have the longest working period.
	Age	It is better if operators who are more than 40 years old are given a job that isn’t too tight because they tend to experience work fatigue, as well as for those over 50years old the company should make rules regarding dismissal or retiremeent due to the operator’s physical condition.
	Shif work	There should be equal distribution of jobdesk according to working hours
Material	The bottle cap has a thin material	Preferably before the use of raw materials, it must first be checked about the bottles cap used
	The bottle has a thin material	Preferably before the use of raw materials, it must first be checked about the bottles used
	Raw materials for bottles and bottle caps that aren’t in accordance with spesification	Must be able to ensure that the raw material for bottle caps and bottles ordered in accordance with specifications
Method	Production is sometimess stopped	It is better if the production of dry syrup preparations is done continuosly, so that errors don’t occur and theres is no change in levels of the raw material of the product
	Uneven powder filing	Powder filling must be evenly distributes according to size and spesifications
	Production overload	Production must be in accordance with definite size standars and based on the composition of the available materials
Machine	Filling machine is not stable	Carried out periodic checks or cleaning the engine when the production process is finished and making repairs to engine components that are disturbed
	Leaked product and oblique logo print	Ensure the product is not defective
	The capper machine sometimes doesn’t operate properly	Ensured that the capper machine used during the production process must remain stable so as not to cause a lot of damage

5. Control stage

The control stage for the dry syrup production process includes:

a. Perform regular and sustainable maintenance and repair of factory machines.

b. Supervise raw materials and employees in the production section so that the quality of the goods produced is better.

c. Record all products every day of each type and machine, which is carried out by employees in the production process.
d. Report the results of recording damaged products based on product type. Record the results to the supervisor and the total damaged products within a period of one month are listed in the montly manager.

CONCLUSION

Based on the results of data processing and analysis, the conclusion of this study is to use the six sigma method (DMAIC), it can be seen that there are several causes of defective products that cause defects, namely broken bottles with a defect percentage of 38.72%, then a torn bottle cap of 37.31%, logo printed italicized of 12.69% and dirty bottles of 11.28%. One of the causes in general is from the elements of humans, materials, machines, methods. For human factors, an analysis of the correlation between work factors is successfully carried out, including age, years of service, and work shift with work fatigue, which shows that the age and working period factors have a relationship with work fatigue. Whereas for the work shift, it has no relationship with work fatigue, this is due to the working hours for all shifs which are the same as 8 hours of work, the difference is that for the day work shift and the night work shift, there is no pressure obtained directly from the direct superior. The sigma value in 1 year is obtained at 3.06 with the possibility of defects of 60,264.13 DPMO, so that the company can still reduce the level of defects in the production process, it is necessary to give recommendations for increasing the sigma value for dry syrup production, and proposed improvements in the human, material, method, and machine elements.

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