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Reducing Defects Number of Ampoule by Considering Expected Failure Cost At Quality Control Department of PT. X

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Abstract

PT. X is producing pharmaceutical packaging that made by glass tube as the raw material of the product; this study took ampoule as the sample. During the production process which is in the quality inspection, the operator found many defect products of ampoule such as crack 32%, glass particle 30%, deformation 14%, scratches 11%, air bubbles 10%, and printing 3%. Multi-Attribute Failure Mode Analysis (MAFMA) is one of them used to eliminate or reduce the causes of failure in order to prevent the repeating failure. The attributes became the criteria level in a hierarchy structure and the potential causes as alternative level. PT. X case study showed on crack failure that weight of severity, occurrence, detectability, and expected cost respectively are 0.3498, 0.0659, 0.1322, 0.4521. The weight of potential failure cause which is the storage room temperature not suitable (Cause A) is 0.2813. After the implementation of defect causes prevention, the percentage of defect reduction is 45% or about 43 units. In the average, the reduction of the defect is 37% or 36 units.

Keywords: Quality Checking, Nonconformity, Defected Products, Failure Mode and Effect Analysis (FMEA), Multi-Attribute Failure Mode Analysis (MAFMA), Analytical Hierarchy Process (AHP).

Abstract

PT. X memproduksi kemasan farmasi yang dibuat dengan tabung gelas sebagai bahan baku produk; penelitian ini mengambil ampul sebagai sampel. Selama proses produksi pada tahap pemeriksaan mutu, operator menemukan banyak produk cacat ampul seperti retak 32%, partikel kaca 30%, deformasi 14%, goresan 11%, gelembung udara 10%, dan pencetakan 3%. Multi Attribute Failure Mode Analysis (MAFMA) adalah salah satunya digunakan untuk menghilangkan atau mengurangi penyebab kegagalan untuk mencegah kegagalan berulang. Atribut ini menjadi level kriteria dalam struktur hierarki dan penyebab potensial sebagai level alternatif. PT. X studi kasus menunjukkan pada kegagalan retak bahwa berat keparahan, kejadian, deteksi, dan biaya yang diharapkan masing-masing adalah 0,3498, 0,0659, 0,1322, 0,4521. Berat potensial penyebab kegagalan yang merupakan suhu ruang penyimpanan tidak sesuai (Penyebab A) adalah 0,2813. Setelah pelaksanaan cacat menyebabkan pencegahan, persentase pengurangan cacat adalah 45% atau sekitar 43 unit. Rata-rata pengurangan cacat adalah 37% atau 36 unit.

Kata kunci: Quality Checking, Nonconformity, Defected Products, Failure Mode and Effect Analysis (FMEA), Multi Attribute Failure Mode Analysis (MAFMA), Analytical Hierarchy Process (AHP).

1. Introduction

PT. X is producing pharmaceutical packaging, made by glass tube which is the raw material of the product. They have three kinds of pharmaceutical packaging product, like Ampoule, Vial, and Horizontal (as known Pipette). They also produce a complete product such as pipette with the cap, called merchandise product. This research only concerned with ampoule. The ampoule is a small sealed vial which has been used to contain and preserve a solid sample or liquid sample. General speaking, Ampoule is made of glass, although it could also be applied to plastic. As the biggest pharmaceutical packaging in Indonesia, PT. X has to maintain the product quality, even thought there is no competitor in the same industry categories. The customers of this company are the pharmaceutical industry and medical department. They used modern machines and tool during the

production processes. They have a special area, called clear zone to select goods and defect products as well as a pack. The clear zone is to maintain the quality and hygienists of their products. If they cannot maintain the hygienists of the product, there will be a big problem for the first line customer as well as landline customer.

In quality management department, there are several sub-divisions, such as quality control, quality assurance, quality system and quality engineering. The quality checks process of production this case is that ampoule has done by quality control division along with tray or storage. There is also an examination of the sample product. Sometimes, quality control needs to compare the product quality by giving samples to the quality management section. The goal is to see the materials in usage, learn to improve the product quality and to ensure that the sample had good quality either.

The ampoule is one of the products of PT. X, but during the production process in the quality inspection, the operator finds many defect products of the ampoule , like crack 32%, glass particle 30%, deformation 14%, scratches 11%, air bubbles 10%, and printing 3%. It is the big problem for this company. The products have to sterile. If the packaging is contaminated or damaged, the medicine will fill or inject to the packaging as well as contaminate. It can be dangerous to the medicine operator. To make an improvement for this company, this research proposes the MAFMA method to identify the defect causes to improve product quality by reducing the number of defects.

2. Method

2.1 Failure Mode and Effect Analysis

Failure Mode and Effect Analysis is a technique that serves to identify; first, the potential failure modes of a product during its life cycle; secondly, the effects of this failure; and third, the level of criticality of the effects of these failures in the use of the product. Failure Mode and Effect Analysis or generally known as FMEA is a risk assessment tool which is used to identify the possible ways in which a product or a process might fail with the main purpose of improving the existing product or process and preventing the reoccurrence of the failures (Nurkertamanda, 2009).

Failure Mode and Effect Analysis (FMEA) is used to identify the sources and root cause of a quality problem. FMEA is a structured procedure to identify and prevent as much as possible modes of failure (failure mode). Some mode of failure is what is included in disability, conditions beyond specifications set, or changes in the product that causes the disruption of the function of the product (Gaspersz, 2002). The steps of FMEA itself are as follows (McDermott; Milkulak; Beauregard, 2009). These steps are explained in detail following the FMEA worksheet section and are illustrated in a case study.

Step 1 Review the process or product.
Step 2 Brainstorm potential failure modes.
Step 3 List potential effects of each failure mode.
Step 4 Assign a severity ranking for each effect.
Step 5 Assign an occurrence ranking for each failure mode.
Step 6 Assign a detection ranking for each failure mode and/or effect.
Step 7 Calculate the risk priority number for each effect.
Step 8 Prioritize the failure modes for action.
Step 9 Take action to eliminate or reduce high-risk failure modes.
Step 10 Calculate the resulting RPN as the failure modes are reduced or eliminated.

2.2. Multi-Attribute Failure Mode Analysis

Multi Attribute Failure Mode Analysis (MAFMA) is a method that integrating Failure Mode and Effect Analysis (FMEA) conventional considering the economic aspects (Braglia, 2000). In the conventional FMEA only considered some of the attributes of a failure without considering the vitally important namely economic factors.

In MAFMA method, determining potential causes of failure is determined based on the highest weight value. MAFMA method does the calculations by integrating FMEA four factors on the chance of failure (occurrence) change of non-detection, severity, and expected cost. Costs due to the failure are calculated by qualitative comparison (qualitative pairwise comparison). Costs due to this

failure cannot appear when it is not there is a failure or defect in the resulting product. Such costs include, costs due to scrap the product cannot be repaired, costs for reworking (rework), charges for failure analysis, re-inspection and other costs - other costs due to product defects.

2.3. Analytical Hierarchy Process

AHP assists in determining the priority of multiple criteria to perform an analysis of the pairwise comparisons each criterion. In the performance management system is meant by criteria is KPI. In the application of the Analytical Hierarchy Process (AHP) to decisions by many criteria that are subjective, often decision makers are faced with a difficult problem in the weighting each criterion.

The first AHP model was developed by Thomas L. Saaty (1990) is a weighted additive AHP, called additive because of an arithmetic operation to obtain the total weight is the sum. For more details, the additive Saaty AHP model can be seen in Saaty (1990).

2.3.1 Key Priority Index (KPI)

One of the difficulties at the beginning of the implementation of the performance management system determines the weight of each KPI. To perform weighting can be done with two ways, namely by weighting directly (direct weighting) or using methods Analytic Hierarchy Process (AHP).

Weighting rules state that:
1. Value KPI weights ranging between 0-1 or between 0% - 100% if we use percentage.
2. The amount of the total weight of all the KPI should be worth 1 (100%).
3. No weight is negative (-).

Here are the steps used to determine the weight of the KPI using AHP:

Determining the priority KPI value, usually the easier to say that KPI A is more important than KPI B, B is less important KPI compared with KPI C, etc., but had difficulty mentioning how important KPI A than KPI B or how less importance compared with KPI B and KPI C. For that we need to create table's conversion of a statement of priority into figures. Examples of priority KPI value scale table as in Table 1.

Definition of middle value is a value if KPI A slightly more important than KPI B and then it should give a value of 3, but if the value 3 is deemed to be too large and value of 1 is too small then the value 2 should it gives to the priority between KPI A with KPI B.

Table 1. Scale Table of KPI Value

Value	Priority Level
1	KPI A is as important as KPI B
3	KPI A is important than KPI B
5	KPI A is more important than KPI B
7	KPI A very important than KPI B
9	KPI A extremely important that KPI B
2,4,6,8	KPI A is slightly more important than KPI B (Median)

The process of the most decisive in determining the weight of the KPI by using AHP is determining the priorities among KPI. Because it often happens discussion tough among the team members the implementation of the performance management system regarding the issue. This is because each team member has their own perception of priorities each KPI.

2.3.2 Consistency of Matrix

As priorities make sense only if derived from consistent or near consistent matrices, a consistency check must be applied. Saaty (1990) has proposed a Consistency Index (CI), which is related to the eigenvalue method:

$$\mathrm{CI} = \frac{\mathrm{x_{max}} - \mathrm{n}}{n-1} \quad (1)$$

Where n = dimension of the matrix
x_{max} = maximal eigen-value

The Consistency Ratio (CR), the ratio of CI and RI, is given by:

$$\mathrm{CR} = \frac{\mathrm{CI}}{\mathrm{RI}} \quad (2)$$

where RI is the Random Index (the average CI of 500 randomly filled matrices).
If CR is less than 10%, then the matrix can be considered as having an acceptable consistency.
Saaty (1990) calculated the random indices shown in Table 2.

Table 2 Random indices

N	3	4	5	6	7	8	9	10
RI	0.85	0.9	1.12	1.24	2.23	1.41	1.45	1.49

2.4. Analysis of Variance

Frequently, scientists are concerned with detecting differences in means (averages) between various levels of a factor, or between different groups. What follows is an example of the ANOVA (Analysis of Variance) procedure using the popular statistical software package, Minitab.

ANOVA was developed by the English statistician, Fisher. Though initially dealing with agricultural data, this methodology has been applied to a vast array of other fields for data analysis. Despite its widespread use, some practitioners fail to recognize the need to check the validity of several key assumptions before applying an ANOVA to their data. It is the hope that this article may provide certain useful guidelines for performing basic analysis using such a software package. Use Main Effects Plot to create a main effects plot and use One-Way or One-Way to perform the one-way ANOVA *F* test.

3. Result and Discussion

3.1 Current Condition

There are many type of defect, but then it is chosen 6 types of defect which is very often appear during the production and from the customer complaint, the six types of them already classify into Crack, Glass Particle, Deformed, Scratches, Air Bubbles, and printing that have number of defect of each is 1829, 1725, 775, 618, 579 and 176 products of ampoules. After the calculation the defect percentage come out with the number 4,43% more bigger than the Acceptance Quality Level (AQL) number is 4%, which is the defect already out of the AQL as shown in the Figure 1.

Table 3. Summary Defect List of Ampoules (April 1th – June 28th 2014)

Defect Classification	Crack	Glass Particle	Deformation	Scratches	Air bubbles	Printing
Number of Defect	1829	1725	775	618	579	176
Unit Percentage	32%	30%	14%	11%	10%	3%
Commulated Percentage	32%	62%	76%	87%	97%	100%

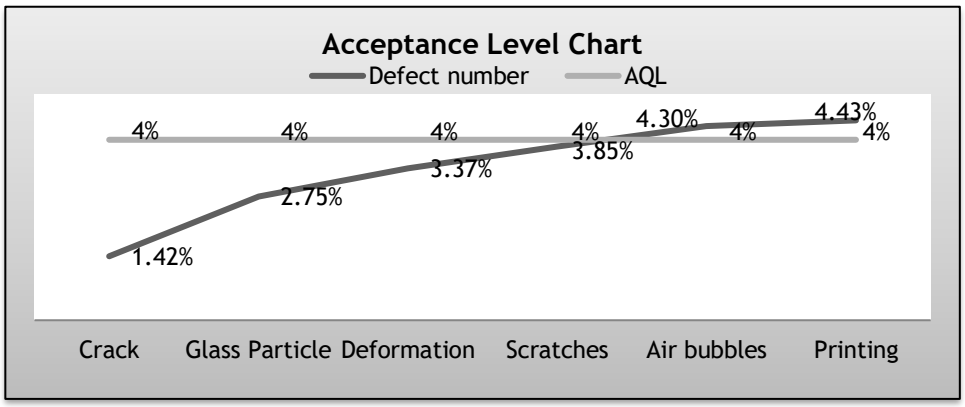

Figure 1. Acceptance Level Chart

Pair Comparison among Criteria and Alternative

Pair comparison among criteria and alternative can be shown in Table 4.

Table 4. Importance Level Table of Criteria (Numeric)

Criteria	Severity	Occurrence	Detectability	Expected Cost
Severity	1	8	3	½
Occurrence	1/8	1	1/3	¼
Detectability	1/3	3	1	¼
Expected Cost	2	4	4	1
Total	3.46	16	8.3333	2

The next step is normalizing the matrix by divide each row with the total of each column. The weight value of each row will be got by divided the row sum with the total of row sum.

Table 5. Normalization Table of Criteria Pair Comparison

Criteria	Severity	Occurrence	Detectability	Expected Cost	Total	Weigh
Severity	0.2892	0.5	0.36	0.25	1.3992	0.3498
Occurrence	0.0361	0.0625	0.04	0.125	0.2636	0.0659
Detectability	0.0964	0.1875	0.12	0.125	0.5289	0.1322
Expected Cost	0.5783	0.25	0.48	0.5	1.8083	0.4521
Total					4.0	1.0

Based on the Table 5, each criterion have different value, which is severity has 0.3544, occurrence has 0.0665, detectability has 0.1177, and the expected cost has 0.4613. It is clearly shown by the weight value that the biggest value is expected cost. So, in the next stage of the pair comparison of each alternative will be related by the expected cost criteria.

The next step is calculating the Consistency Ratio (CR). Steps to get the CR value are:

- Multiply the initial matrix with weight value of each criterion to get the result.

$$\begin{bmatrix} 1 & 8 & 3 & 1/2 \\ 1/8 & 1 & 1/3 & 1/4 \\ 1/3 & 3 & 1 & 1/4 \\ 2 & 4 & 4 & 1 \end{bmatrix} \times \begin{bmatrix} 0.3498 \\ 0.0659 \\ 0.1322 \\ 0.4521 \end{bmatrix} = \begin{bmatrix} 1.4998 \\ 0.2667 \\ 0.5596 \\ 1.9442 \end{bmatrix}$$

- Divide the result with weight value of each criterion to get the final matrix.

$$\begin{bmatrix} 1.4998 \\ 0.2667 \\ 0.5596 \\ 1.9442 \end{bmatrix} \div \begin{bmatrix} 0.3498 \\ 0.0659 \\ 0.1322 \\ 0.4521 \end{bmatrix} = \begin{bmatrix} 4.2877 \\ 4.0468 \\ 4.2321 \\ 4.3006 \end{bmatrix}$$

- The next step, summed up all the number in final matrix and divided with total row of matrix to get the average value (x_{max})

  Total = 4.2877 + 4.0468 + 4.2321 + 4.3006 = 16.8671

  Average = 16.8671/ 4 = 4.2168

- To calculate the CI and CR value has been mentioned in Formula 1 and 2. Also for RI number is shown in Table 2, if the n is 4, so RI should be 0.9.

  CI = $\frac{4.0808-4}{4-1}$ = 0. 0269 CR = $\frac{0.0723}{0.9}$ = 0.0803

As mentioned in part 2.3.2, if $CR_{calculate}$ (0.08) < $CR_{standard}$ (0.1), so the matrix is consistent.

Based on the calculation, it gets the value of logical consistency or consistency ratio is 0.08 whereas the standard value of consistency ratio is 0.1. It appears that the logical consistency value is smaller than the standard value, so it proves that the respondent is consistent in doing pair comparison between criteria. In hence, the data is valid.

Table 6. Order of Weight Value of Cause Alternatives

Causes	Cause A	Cause G	Cause C	Cause B	Cause D	Cause E	Cause F
Weight	0.2813	0.2105	0.2074	0.1931	0.0399	0.0393	0.0284

Based on Table 6, Cause A has the highest value followed by G and C.

3.2 Improvement Process

After the critical or potential failure appeared, then it is continued with the improvement phase, which is by implementing the prevention on the production floor. The improvement has been implemented since January 1st until March 28th 2015. There are five failure processes, but they have seven causes. Those causes also have seven preventions that implemented since the first day of implementation of improvement. It is focused on Cause A, because it was the most potential failure causes, the prevention of cause A is fixed the temperature standard in Standard Work Instruction (SWI) for storage room, so uncontrolled dilatability is not occurred anymore. The improvement is done by installing the temperature controller in the storage room. If the temperature is not stable or steady, the alarm of controller will be on. It was to remind the operator that temperature is not stable or steady.

The second action was conducted monthly training about material handling and loading to the machine. This action was conducted to prevent the material damage that caused by human error (the operator was not handling the material rightly). The next, the operator did double inspection of tubing glasses before mass production in the material lock to prevent the foreign particle stick inside or outside tubing glass. It also could be effected the product damage. The next action was the setup man always has to make sure that temperature is set based on the SOP. This action was applied to prevent improper process that caused by the temperature was not standard as SOP. The other action was the operator has to control the temperature of lehr once hour. It prevented the improper process that caused by the temperature was not stable and steady during the annealing process. Next, the action was the operator did the on line inspection and confirm the SOP to prevent the quality control failure that caused by inspection process was not suitable as SOP. The last action was conducted monthly training about packaging method, including pre-packaging process. It prevented the product damage for example funnel crack that caused by lack of the packer skill in packaging process.

In doing this research, the installment of digital controller temperature that has been done by spending cost IDR. 114,400,000 for Controller Device and then IDR. 10,000,000 for installment cost. The total of investment cost in order to fix the problem of Cause A is IDR. 124,000,000. It can say the investment for the failure Cause A is feasible because the total cost investment that have been done is still less than the total failure of cause A which is IDR. 270,900,000.

The defect number of cause A based on current data is 301, while the defect number of cause A after implementation is 243 and the defect reduced by 58 items which is 19%.

ANOVA

Table 7. Observation Data of Temperature Treatment

Temperature	Total Defect					
	Observation 1	Observation 2	Observation 3	Observation 4	Observation 5	Observation 6
26° C	1	2	1	1	2	1
30° C	1	0	2	1	0	1
34° C	2	2	1	3	3	2

The analysis and corresponding results are presented in the following points:

- Regarding the quantity of total defects and to determine the influence upon the temperature, this research applied an ANOVA with 3 temperatures each under 6 observations, as shown in Table 7.
- In relation to the total failure of cause A by differentiating the temperature for 26, 30, and 34 degree celsius, we do 6 observations that expect to know if there is a relation of the temperature with the defect. The hypothesis are:

  Null hypothesis All means are equal
  H_0 : The defect number is not influenced of the temperature level

  Alternative hypothesis At least one mean is different
  H_1 : The defect number is influenced of the temperature level

  Significance level $\alpha = 0,05$

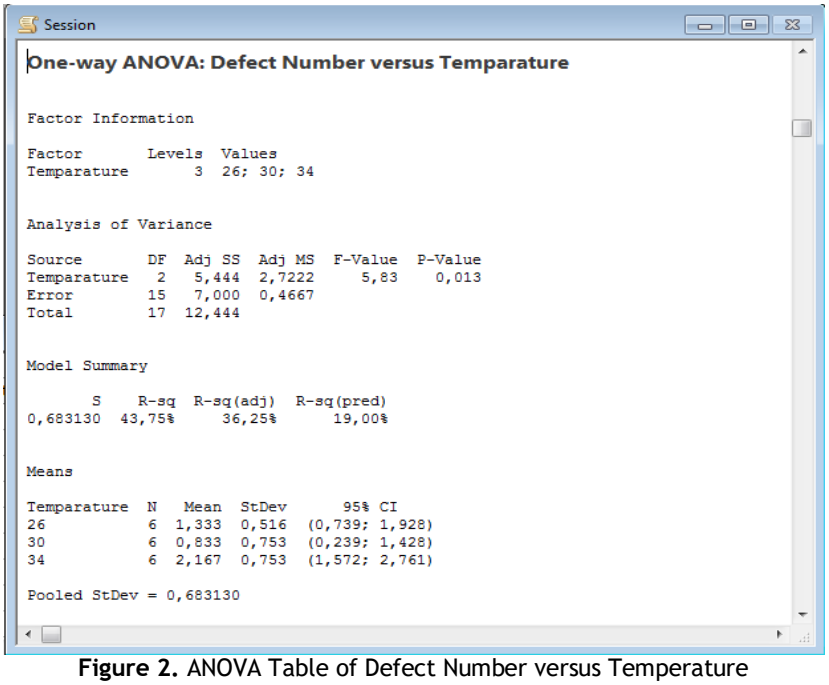

Figure 2. ANOVA Table of Defect Number versus Temperature

The data shown in Figure 2 indicates that there was a difference between the levels, as the p-value is 0.013. Only the level of 0 micron is different from the rest of the half and that the other three levels fall within its three different confidence intervals. The implement of digital temperature controller improved the ampoule quality by reducing the defect number up to 58 units.

Because the three lots that were selected randomly contain differently amounts of temperature, the experiment was an unbalance design. Each batch contains 65 tubing glasses, which in turn about 1350 units of ampoule that are selected by inspector. The data was tested for normality before test the hypothesis by means in Figure 2, indicating that there was no difference in total of ampoule defect number.

The ANOVA table shows that the power level has statistically significant effect on the each defect number. The effect of the factor (temperature level) can be displayed using the boxplot as shown in Figure 3. The boxplot shows that the defect number increase as the temperature level increase.

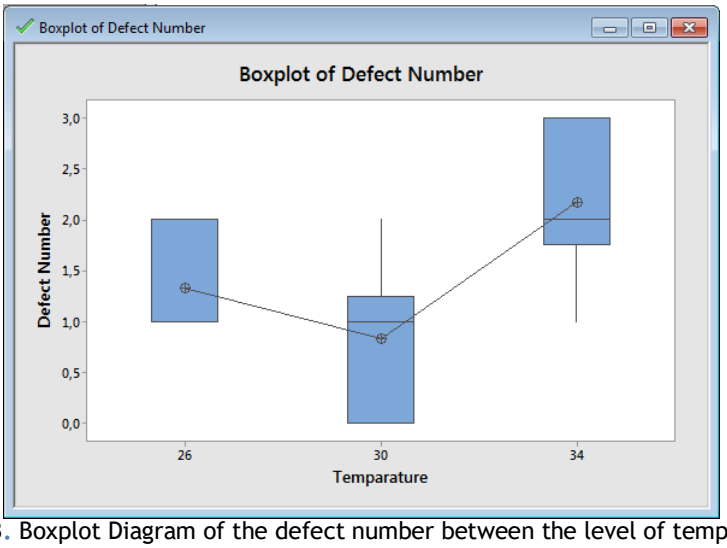

Figure 3. Boxplot Diagram of the defect number between the level of temperature

Since the p-value (0.01) is smaller than the significance level (α = 0.05), so it can conclude that rejected H_0. The defect number is influenced of the temperature level.

3.3. Cost Analysis

The failure cost of cause A is obtained by multiplying defect number with the price per item. The total failure cost of cause A shown in Table 8.

Table 8. Failure cost of Cause A

	Defect Number in 1000	Price/ Item	Total Failure Cost
Cause A	301	Rp700	Rp270.900.000

In Table 9 shown that investment is contain with the price of controller device and also the installment cost. The total of investment cost is obtained by summing up those two expenses. The price of controller device is 114,400,000 with the lifetime 10 years and the installment is 10,000,000, so the total of investment cost is 124,000,000.

Table 9. Investment Cost

Investment Cost	
Controller Machine	Rp114.400.000
Intallment	Rp10.000.000
Total	Rp124.400.000

Table 10 has shown that the expenses for maintenance and electricity are categorized in direct cost. The total of direct cost is obtained by summing up those two expenses.

Table 10. Direct Cost

Direct Cost	Cost/ month	Period	Total cost
Maintanace	Rp5.000.000	3	Rp15.000.000
Electricity	Rp1.500.000	3	Rp4.500.000
Total			Rp19.500.000

The failure cost of cause A based on current data is 270,900,000. While the failure cost of cause A based on data after implementation process is 218,700,000.

By assuming defect numbers of cause A in 3 months period for 10 years is constant. It can be obtained the reduction cost by multiplying the current failure cost of defect number of cause A, which is 270,900,000 multiply with 40 months period with the result is 10,836,000,000. Then, failure cost of defect number of cause A after implementation for 10 years is 8,748,000,000. The reduction of failure cost was obtained by calculating failure cost before minus failure after and the result is 2,088,000,000. The company can save money 1,183,600,000 by installing the digital

temperature controller for 10 years. Its value is obtained by calculating the direct cost also for 10 year which is 780,000,000 and sum up with installment cost 10,000,000 and the result is 904,400,000. So, the company can save money by calculating the reduction cost minus with the total installation cost and direct cost for 10 years, which is 2.088,000,000 minus 904,400,000 and the value is 1,183,600,000.

In the improvement stage, it has been done the prevention for those failure causes, but it is more focused on the potential failure cause which is causes A. Table 11 shows that cause A defect number reduced from 301 to 243 that has reduction 58 units which is 19%. The reduction percentage is obtained by dividing reduction number with defect number of current data (data before implementation). While the other causes did not have significant reduction because it is only focused to reduce defect number of cause A.

Table 11. Result Table (Before and After Summary Data)

Causes	Before		After		Reduction	Reduction Percentage
	Defect Number	Defect Percentage	Defect Number	Defect Percentage		
Cause A	301	16%	243	14%	58	19%
Cause B	223	12%	212	13%	11	5%
Cause C	277	15%	253	15%	24	9%
Cause D	348	19%	336	20%	12	3%
Cause E	339	19%	317	19%	22	6%
Cause F	172	9%	164	10%	8	5%
Cause G	169	9%	159	9%	10	6%
Total Defect	**1829**		**1684**		**145**	

4. Conclusion

The results obtained from the conventional FMEA table that shows the potential cause of the cracks ampoule is the temperature is not standard (cause D), because it has the highest RPN value that is 216. However, it is different from the results indicated by the method MAFMA, wherein the MAFMA method results that led to the failure of most potential is cause A (storage room temperature) with the highest weight value is 0.2813.

Differences in results caused that MAFMA method considering the economic aspects that were not considered in the method of the FMEA. Although, the FMEA explained that the cause A is not often occurred as failure causes, but in the method MAFMA, it calculates the amount of costs to be incurred by cause A larger than other causes.

Therefore, the quality improvement process implemented based on the priorities of the potential failure to consider the economic aspects. So it is clear that significant results on the cause A, the defect number reduced from 301 to 243 that have reduction 58 units which is 19%. The reduction percentage is obtained by dividing reduction number with defect number of current data (data before implementation). While the other causes did not have significant reduction because it is only focused to reduce defect number of cause A.

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