# An analysis of rejection rate of a blood bag manufacturing firm with a six sigma perspective

**Dinu Raj S , Snehya A V**

*Abstract***:** *Six Sigma is one of the methods in TQM which has been adopted by several industries to reduce the number of defects (DPMO). This work tries to analyses the DMAIC (Define-Measure-Analyse- Improve-Control) methodology in the existing system of manufacturing of blood bags in a medical device manufacturing firm at Thiruvananthapuram. The overall rejection rate of the blood bags has been analyzed to identify the organization's status in terms of the process sigma level and the corresponding DPMO (Defects Per million Opportunity). The study revealed that the organization is running at a process sigma level of 3.8 which is slightly less than best-in-class. A pareto analysis was carried out to identify the vital problem causing elements followed by a root cause analysis.*

*Index Terms***:** *Blood Bag, DMAIC,DPMO,TQM*

## I. INTRODUCTION

Variation and product rejection are one of the major issues faced by the quality control people in any manufacturing firm. It is a fact that manufacturing two products exactly alike in all characteristics is not possible. Most of the times the extend of variations will be negligibly small and will be coming under the tolerance limits set by the concerned organization. But when these variations exceed the limits of tolerance of conformation, it results in either rejection or rework. This will add cost to the company. These defects are quantified in terms of Defects per Million Opportunities (DPMO). The present study was performed to analyze the rejection level of a blood bag manufacturing firm at Thiruvananthapuram, Kerala and to calculate the DPMO and corresponding Process Sigma Level. It identifies the key causes that contribute to the major share of the problem by root cause analysis

## II. LITERATURE REVIEW

The possibilities of implementation of six sigma in a blood manufacturing firm and the application of seven quality control tools was analysed by a researcher [3]. Similar studies in adoption of Six Sigma DMAIC methodology to reduce the cost of poor quality in a repair division of a company dealing in helicopter [1]. Six sigma tools was reviewed as the major tools that can be used in six sigma implementations. The

methodology, tools and future of six sigma investigated by some reserachers. [6, 8]. The  literature review about the emerging trends and issues in Six Sigma applications [7]. However, in the present study discuss about weighted average methodology which helps to calculate the process sigma level of a blood bag production unit.

## III. RESEARCH METHODOLOGY

Rejections are one of the key non-value adding components of any manufacturing industry. The issue becomes more critical when the scope of rework on the rejected materials is limited and for products like blood bags, the reworks are not possible Six Sigma DMAIC methodology which consist of five phases namely Define-Measure-Analyze-Improve and Control were used to carry out the research work which is explained as follows.

Define     : Define the problem.  .
Measure : Measurement of existing data
Analyze  : Measured data is analyzed
Improve : After analysis suggested actions are implemented for improvement.
Control  : Controling the improvement process.

 The present study emphasis on the Analysis Phase of the DMAIC methodology.

### 3.1. Sampling
Total population sampling which comes under purposive sampling technique has been used because DPMO calculation deals with the entire population and corresponding rejections.

### 3.2. Research Design
Descriptive research design is planned for the work based on the present production status without altering or experimenting with the process.

### 3.3. Sources of data
Secondary sources of data, which include the annual internal inspection-rejection analysis report; and the daily internal inspection records.

### 3.3. Tools for analysis
Tools for the analysis of data include Pareto chart which gives the major causes that contribute to the major portion of the problem. The other tool being used is the Fish bone diagram which gives the root cause analysis. The analysis also includes the process sigma calculation.

## IV. DATA ANALYSIS

The monthly wise rejection data concerned with the blood bag manufacturing were collected .The data include different types of defects and there corresponding numbers which caused the final rejection. Based on this data the following analysis were carried out.

### 4.1. DPMO and Process Sigma

From the production data for, the DPMO, yield and process sigma were calculated and shown in table 1.

### 4.1.1 Interpretations

The company is running at a production target of almost 1million blood bag units per month and this will be getting increased in the coming years due to growing market demand. Table 1 shows the production per month and corresponding rejections.

The present DPMO and the corresponding process sigma of the organization are 8448 and 3.80 respectively. Majority of the Global blood manufacturing companies are running at a process sigma of 4 with DPMO of less than 6100. So the organization is almost matching the standards of global competitors. Implementing six sigma projects in the major defective areas can reduce the rejection rates drastically.

The organization can benchmark a particular DPMO which can be similar to the major global manufacturers so that continuous improvement can be made on a periodic basis to achieve the benchmarked value. The organizations should find out the key areas which requires immediate attention and it can be identified using management tools like Pareto Chart which monitors the key problem creating areas.

### 4.2. Pareto chart

Pareto Chart helps to identify the key causes to the problem. Figure 1 shows the Pareto Chart with causes and corresponding defect percentage.

### 4.2.1 Interpretations

The total rejection causes were thirty eight, out of which nine causes contribute to approximately 84% of the problem. From the Pareto Chart the major causes are identified. This study follows the 80:20 rule and hence the organization can define the CTQ (Critical to Quality) accordingly. The major causes and there corresponding contribution to the problem is shown in Table 2. Among the 20 percent of the key causes, the presence of particulate matter alone contributes to the 21 percent of the problem.
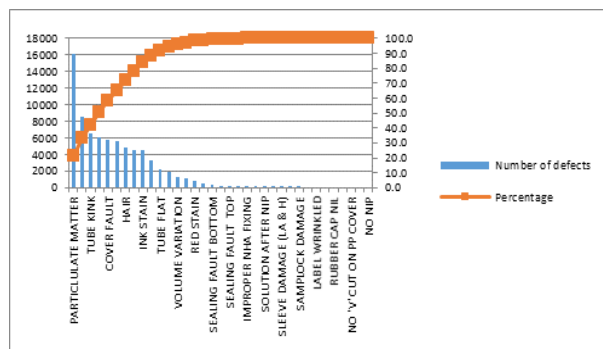


**Fig. 1:** Pareto Chart

| Month | Total production (Nos) | Rejection (Nos) | DPMO | Yield (%) | Process Sigma |
|-------|------|------|------|------|------|
| Apr | 791269 | 9668 | 12250 | 98.78 | 3.75 |
| May | 747106 | 6313 | 8450 | 99.16 | 3.89 |
| Jun | 715719 | 6022 | 8414 | 99.16 | 3.89 |
| Jul | 746122 | 5729 | 7678 | 99.23 | 3.92 |
| Aug | 846146 | 6030 | 7126 | 99.29 | 3.95 |
| Sep | 649208 | 5614 | 8647 | 99.14 | 3.88 |
| Oct | 773791 | 5613 | 7254 | 99.27 | 3.94 |
| Nov | 728411 | 5829 | 8002 | 99.2 | 3.91 |
| Dec | 764190 | 6527 | 8541 | 99.15 | 3.88 |
| Jan | 787632 | 6774 | 8600 | 99.14 | 3.88 |
| Feb | 763243 | 20483 | 26837 | 97.32 | 3.43 |
| Mar | 851055 | 6784 | 7971 | 99.2 | 3.91 |

**Table 1:** DPMO and Process Sigma.

### 4.3. Cause and Effect Analysis

Usually Ishikawa diagram commonly called as the fishbone diagram is used to carry out the Cause and effect analysis. Here a general fishbone diagram with common causes and its effects are illustrated in the figure 2.The sources of major causes are classified as man, method, machine and environment.

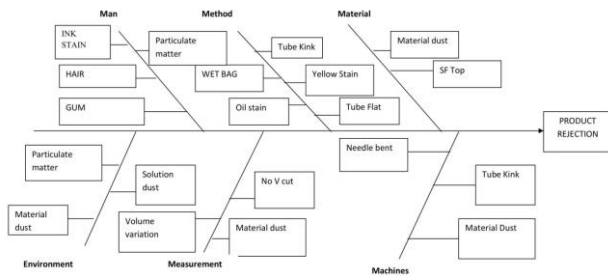| Sl No | Cause | Cause Percentage (%) | Percentage contribution to the problem (%) |
|-------|-------|------|------|
| 1 | Particulate Matter | 2.36 | 21.68 |
| 2 | Oil Stain | 2.36 | 11.50 |
| 3 | Tube Kink | 2.36 | 8.88 |
| 4 | Cpd Stain | 2.36 | 8.21 |
| 5 | Cover Fault | 2.36 | 7.67 |
| 6 | Gum | 2.36 | 7.43 |
| 7 | Hair | 2.36 | 6.53 |
| 8 | Material Dust | 2.36 | 6.14 |
| 9 | Ink Stain | 2.36 | 6.07 |
|  | **TOTAL** | **21.24** | **84.12** |

**Table 2:** Major Causes

**Fig. 2:** Cause-Effect diagram for common causes

### 4.3.1 Interpretations

From the general cause and effect analysis shown in figure2, it was clear that the environment and man were the major sources of causes like particulate matter, material dust, hair etc.

So a well maintained clean room which reduces the particulate matter in the production environment can reduce the overall rejection level drastically as the particulate matter in the product packaging alone contribute to almost 22% of the total rejections annually.

Another concern is that from the work force. Although they are provided with gloves and other covering materials to prevent direct contact with the products, their negligence creates the problems like hair, ink stain etc.

### 4.4. Root Cause Analysis of major causes

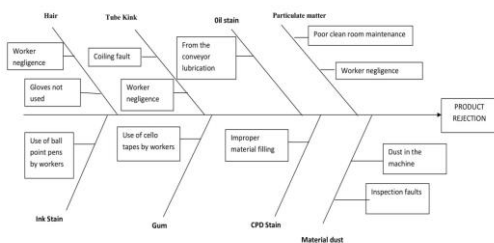Root cause analysis of the major causes were studied and is described in figure 3



**Fig. 3:** Root cause analysis of major causes

### 4.4.1 Interpretation

Here also the major root causes are poor maintenance of the clean room and worker negligence. Organization should take necessary steps to reduce the particulate matter in the environment. Workers needs to be trained and strict instructions should be given to adhere to the standard operating procedures

## V. FINDINGS AND DISCUSSION

The present DPMO and the corresponding process sigma of the organization are 8448 and 3.80 respectively (Table1). Majority of the Global blood manufacturing companies are running at a process sigma of 4 with DPMO of less than 6100. To match with the global standards, the company should benchmark the DPMO at a further lower level less than that of the present DPMO of competitors as they are also in the race of reducing the rejection levels.

Implementing Six Sigma philosophy is a practical aid for attaining the objectives of wastage reduction and thereby reducing the production cost in the long run. For this organizational commitment is the basic requirement. Organization should start with small Six Sigma projects by identifying some of the key areas which need immediate attention. Employees need to be trained and projects should be assigned to them in a participative manner. There should be Six Sigma teams handling individual projects constantly monitored by higher certified authorities.

### 5.1. DPMO and Process Sigma

The present DPMO and the corresponding process sigma of the organization are 8448 and 3.80 respectively, as shown in Table1. Majority of the Global blood manufacturing companies are running at a process sigma of 4 with DPMO of less than 6100. To match with the global standards, the company should benchmark the DPMO at a further lower level less than that of the present DPMO of competitors as they are also in the race of reducing the rejection levels.

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### 5.2. Major Causes

Results of the Pareto chart shown in Figure 1 follows the 80:20 rule. i.e. 20 percent of the causes create 80 percent of the problem. There were totally thirty eight causes of rejection out of which nine contributed to 84 percent of total rejections. The chart also shows that the particulate matter alone contributes to the 22 percent of the major defects. So concentrating on this cause alone can reduce the overall rejection rate exponentially.

These nine causes can be made into nine Six Sigma project problems so that continuous improvement can be made which result in huge cost saving to the company in the long run.

### 5.2. Cause and Effect Analysis

Usually Ishikawa diagram commonly called as the fishbone diagram is used to carry out the Cause and effect analysis. Here a general fishbone

diagram with common causes and its effects are illustrated in the figure 2.

From the general cause and effect analysis, it is clear that the environment and man are the major sources of causes like particulate matter, material dust, hair etc .

So a well maintained clean room which reduces the particulate matter in the production environment can reduce the overall rejection level drastically as the particulate matter in the product packaging alone contribute to almost 22% of the total rejections annually.

Another concern is that from the work force. Although they are provided with gloves and other covering materials to prevent direct contact with the products, their negligence creates the problems like hair, ink stain etc. The results of the cause and effect analysis shows light towards two major concerns such as presence of Particulate matter beyond the specified limits, worker's negligence. Particulate matter needs to be strictly controlled although the production environment is of clean room of specified class. Organization can thik about upgrading the class.

Worker's negligence is another great concern. Eventhough they are provided with gloves to cover their hands, reluctance to wear or improper wearing leads to the entry of particles stuck with their hands and also the hairs of their hands getting trapped inside the packages prior sealing of the covers.

Use of ball point pens leaves inks stains on the product during handling. Use of cellophane tapes for some other purposes also leaves gum stains on the product. These are getting transferred through the hands of workers.

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## VI. CONCLUSION

This study helps to identify the process sigma level as well as its DPMO which can be used as a measure for gap analysis with respect to the global competitors of the firm. Concentrating on the major causes as per the findings of the study, the firm can well advance towards achieving the goal of becoming a world class manufacturer. The study also revealed that the environmental conditions and worker negligence contribute to the major problem. So periodic clean room maintenance and employee training can make visible improvements in the long run. Since the work has been a descriptive and emphasis was given on the analysis part of the

DMAIC methodology, the future scope is in the implementation and control phase. This can be carried out by having individual Six Sigma projects

## ACKNOWLEDGMENT

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