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IMPLEMENTATION OF SIX SIGMA METHODOLOGY IN A BLOOD BAG MANUFACTURING COMPANY

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ABSTRACT

This paper describes the analysis part of the implementation of Six Sigma methodology in the existing system of manufacturing of blood bag in M/S HLL LIFECARE LTD, Aakulam,Thiruvananthapuram.
As blood bags are the important integral part of medical field the quality assurance and quality control of each components at each stages of production is very important as it is the matter of human life. When it comes to the matter of Quality, medical related equipments should stand at the zenith in quality ranking. In the analysis phase different measurement systems existing in the company are noted and also the specification limits for the product. A thorough analysis of the different processes is also to be performed and study different critical processes of manufacturing and quality checking systems in the company. Also possible causes for process deviations are analyzed during the course of project period. According to the collected data from the manufacturing plant and quality control laboratory a detailed study on CTQs and critical components are noted. Also with the current rejection rate and defects the yield % and sigma level is also found out. At the final phase of the project the new improved sigma level is found out.

Keywords: Six Sigma Methodology, rejection rate, CTQ etc.

1. BLOOD BAGS

Blood bag systems are the fundamentals for worldwide blood supply by standard blood donation. More than 90 percent of all blood donations are processed in these systems that have up to six different bags with variable functions. A combination of PVC bags with retractable needles, pre-donation sampling pouches and different filtration devices form the basis for highly professional whole blood collection systems.. As blood bags are the important integral part of medical field the quality assurance and quality control of each components at each stages of production is very important as it is the matter of human life. When it comes to the matter of Quality, medical related equipments should stand at the zenith in quality ranking. Each point of improvement in any stages of production is a boom for this field.

1.1Objective of Quality Assurance of Blood Bag

As blood bags are the important integral part of medical field the quality assurance and quality control of each components at each stages of production is very important as it is the matter of human life. When it comes to the matter of Quality, medical related equipments should stand at the zenith in quality ranking. Each point of improvement in any stages of production is a boom for this field.

1.2 Objective & Scope

To make a quality control analysis part and to study different critical processes of manufacturing and quality checking systems in the company. Also to check the possibility of modification of existing measurement systems.

With thorough analysis and conclusions made from that it is possible to create innovative solutions using technology and eliminate the sources of variation. Also if the sigma level is low we can attain Six Sigma Level in Manufacturing and Quality Control.

2. QUALITY CONTROL

"Quality is a dynamic state associated with products, services, processes, people and environment that meets or exceeds expectation and helps produce superior value." [1].

If we are concerned with providing 'value' to the customers we must consider how we can improve customer value. There are number of principles which are central to the practice of Quality Management:

- Customer Focus
- Strategic Focus
- Leadership Focus
- Process Focus
- People Focus
- Scientific Focus
- Continual Improvement, Innovation and Learning
- Systems Thinking

In today's international environment, Statistical Process Control(SPC) is a fundamental element of any organization's quality master plan. Quality can mean different things for different people and can be interpreted in a variety of ways by an individual. Quality may be thought to have two main divisions. The quality of a manufactured product and quality of service received. From the manufacturing stand point quality is simply conformance to specification. The ultimate customer could define the quality as fitness to use.

Statistical process control is a procedure in which data is collected, organized, analyzed and interpreted so that a process can be maintained at its present level of quality or improved to a higher level of quality.

The methods in Statistical Process Control (SPC) are collection of data, Organization of data, Analysis of data and Interpretation of data. SPC can be employed wherever the work is being done. SPC involves the use of statistical signals to identify source of variations, to improve performance and to maintain control of process at higher levels. The SPC is a system which emphasis on the prevention of failure. The basic tools of SPC are **:**

1. **Flow Chart:** The entire process is diagrammed from the start to finish with each step of the process clearly indicated.

2. **Pareto Chart:** The number of occurrence or the costs of occurance of specific problem are charted on a bar graph. The largest bars indicate the major problem and are used for determining the priorities for problem solving.

3. **Check Sheets:** A data gathering sheet is prepared that categorize problems or defects. Check sheets information may be put on a Pareto chart.

4. **Cause and Effect Diagram:** A problem is systematically tacked back to possible cause. The diagram organizes the search for the root cause of the problem. The similar diagram can be used to systematically search solutions to a problem.

5. **Histogram:** A bar chart showing the comparative frequency of specific measurements. The shape of the histogram can indicate that a problem exist at a specific point in a process.

6. **Control Chart:** One of the main tools of SPC is the control chart. Originally introduced by Dr. Walter Shewart in 1920's has revolutionized the way companies in both manufacturing and service industries monitor quality. Broken line graphs illustrate how a process or a point in a process behaves over time. Samples are periodically taken checked or measured and the result plotted on the chart. Control chart are used to find source f special cause variation to measure the extend the common cause variation and to maintain control of a process that is operating efficiently.

2.1 Quality Improvement

 The factors affecting the quality are as follows:

- **1. Machine:** Improve the machinery to be able to produce consistent quality products.
- **2. Material:** Establish partnership with the supplier. Gather data and provide feedback to supplier about the quality.
- **3. Manpower:** Train your personnel to take responsibility for the process. Give
- responsibility to the process owner.
- **4. Method:** Gather data from the process. Use even quality tools to analyze data. Develop
- better methods to meet the requirements.
- **5. Environment:** Make visible control possible. Improve working condition for the operator. Improve layout constantly.

3. SIX SIGMA AND ITS METHODOLOGY

Six Sigma, the quality improvement methodology made famous by Motorola in the 1980s, has generated a multitude of articles and hundreds of books by many authors for good reason: It has produced significant cost savings and reductions in waste for the organizations that have embraced it. Although its roots are in manufacturing, and it continues strong within that industry, it has expanded into such non-manufacturing industries as financial services, healthcare and food processing. Even the public sector is embracing the methodology because of its proven track record in private industry.

Six Sigma is a revolutionary business process designed to significantly reduce organizational inefficiencies thereby increasing bottom- line profits.[2] The concept is to eliminate defects that take time and effort to repair, not to mention make customers unhappy. It is a management philosophy that eliminates defects by emphasizing understanding, measuring and improving processes. The statistical

concept of the term six sigma means that processes are working nearly perfectly, delivering only 3.4 defects per million opportunities (DPMO). Sigma (the Greek letter) is a statistical term that measures standard deviation and represents a measure of variation, in other words, the distribution around the mean of any process or procedure. For management, this term is used to measure defects in the outputs of a process and show how far the process deviates from perfection.

3.1 Design for Six Sigma

The Design for Six Sigma (DFSS) is used to design or redesign a product or service from the ground up. It is based on the idea that when Six Sigma quality is designed correctly into the product at the outset, life cycle costs are dramatically reduced and product reliability greatly enhanced. DFSS augments an organization's current product development process; it is not a replacement. When the essentials of Six Sigma have been mastered, organizations are certainly ready to carry that improvement into the development and design of new products. Like its parent Six Sigma, DFSS uses a disciplined set of tools to bring high quality to product launches. It begins with an analysis of an entire product development system to find gaps in the processes that are negatively affecting new product performance. It also addresses customer requirements that drive new product development. After gap analysis is completed and customer requirements identified DFSS kicks in with its own version of Six Sigma's DMAIC. One popular DFSS is called DMADV (Define, Measure, Analyze, Design and Verify).

The general procedure for the methodology[3] is as follows:

• Customer requirements are gathered.
- These requirements are analyzed and prioritized.

• A design is developed.
• The requirements flow down from the system level to subsystems, components and processes.
• The product or service capability, including process capability, is tracked step-by-step and gaps between capabilities and requirements are identified to generate action items.
• A control plan is established.

3.2 Five Phases of Six Sigma Methodology

The Six Sigma methodology is universally recognized and defined as comprising the following five phases: Define, Measure, Analyze, Improve and Control (DMAIC). In some organizations only four phases are used: Measure, Analyze, Improve and Control (MAIC). In this case, the Define deliverables are considered pre-work for a project or are included within the Measure phase. The DMAIC methodology breaks down as follows:

Define: Define the project goals and customer (internal/external) deliverables.
Measure: Measure the process to determine current performance.
Analyze: Analyze and determine the root causes of any defects.
Improve: Improve the process by eliminating defect root causes.
Control: Control future process performance.

3.2 Fish Bone Diagram

The Fishbone Diagram is a tool for analyzing process dispersion. It is also referred to as the "Ishikawa diagram," because Kaoru Ishikawa developed it, and the "fishbone diagram," because the complete diagram resembles a fish skeleton. The diagram illustrates the main causes and sub causes leading to an effect (symptom). It is a team brainstorming tool used to identify potential root causes to problems. Because of its function it may be referred to as a cause-and-effect diagram. In a typical Fishbone diagram, the effect is usually a problem needs to be resolved, and is placed at the "fish head". The causes of the effect are then laid out along the "bones", and classified into different types along the branches. Further

causes can be laid out alongside further side branches. So the general structure of a fishbone diagram is presented below.[4]

Causes in the diagram are often based on a certain set of causes, such as the 6 M's, described below. Cause-and-effect diagrams can reveal key relationships among various variables, and the possible causes provide additional insight into process behavior. Causes in a typical diagram are normally grouped into categories, the main ones of which are:

- The 6 Ms: Men/people, machines, methods, materials, measures, mother nature
- 4 Ps – Places, Procedures, People, Politics
- 4 Ss – Surroundings, Suppliers, Systems, Skills

Causes should be derived from brainstorming sessions. Then causes should be sorted through affinity-grouping to collect similar ideas together. These groups should then be labeled as categories of the fishbone. They will typically be one of the traditional categories mentioned above but may be something unique to our application of this tool. Causes should be specific, measurable, and controllable.

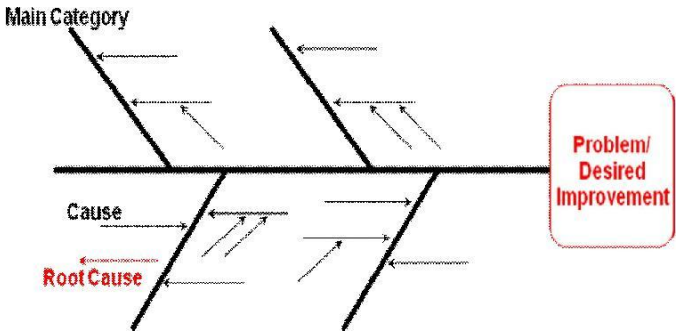

FIGURE.1 FISH BONE DIAGRAM

The Fishbone diagram could be applied when it is wanted to:

- Focus attention on one specific issue or problem.
- Focus the team on the causes, not the symptoms.
- Organize and display graphically the various theories about what the root causes of a problem may be.
- Show the relationship of various factors influencing a problem.
- Reveal important relationships among various variables and possible causes.
- Provide additional insight into process behaviors.

The main goal of the Fishbone diagram is to illustrate in a graphical way the relationship between a given outcome and all the factors that influence this outcome. The main objectives of this tool are:

- Determining the root causes of a problem.
- Focusing on a specific issue without resorting to complaints and irrelevant discussion.
- Identifying areas where there is a lack of data.
-

4. COMPANY PROFILE: HLL LIFECARE LTD

HLL Lifecare Limited (formerly Hindustan Latex Limited) (HLL) is an Indian healthcare products

manufacturing company based in Thiruvananthapuram, Kerala, India. A Government of India -owned corporation (Public-sector undertaking), it produces health care products, including condoms, Surgical Sutures, Hydrocephalus Shunts, Tissue Expanders, blood bags, and contraceptive pills. Two most modern Plants were added, one at Thiruvananthapuram and the other at Belgaum in 1985. Another Plant was added in the early nineties at Aakkulam in Thiruvananthapuram for the production of Blood Transfusion Bags, Copper T IUD's, Surgical Sutures and Hydrocephalus Shunt.

4.1 Blood Bag Manufacturing

Types of Blood Bags manufactured in the plant:

Single Blood Bag: For whole blood collection. The bag contains CPDA solution.
Double Blood Bag: For whole blood collection and separation of 2 different blood components (red blood cells, and plasma) obtained through the process of centrifugation and extraction.

Triple Blood Bag: Triple Blood Bag with SAGM, for whole blood collection and separation of 3 different blood components (red blood cells, plasma and platelets). The primary bag contains CPD and one satellite bag contains SAGM.

Quadruple Blood bag: Quadruple blood bags with SAGM for whole blood collection and separation for different blood components (red blood cells, plasma and platelets) through the buffy coat method. The primary bag contains CPD solution and has 3 satellite bags. One satellite bag is of 100 ml capacity to prepare platelets through the buffy coat method.

Cord blood collection bag: HLL manufactures an umbilical cord blood collection bag of 150 ml capacity with 22 ml of CPD solution. Each bag comes with a second layer of packing of aluminum foil for the convenience of cord blood collection centers.

Top and Bottom Bag: Top and Bottom Quadruple blood bags are for whole blood collection and separation of three different blood components (red blood cells, plasma and platelets). The primary bag contains CPD solution and one satellite bag comes with SAGM solution for red cell preservation.
Top and Bottom Blood Bag with Leukocyte filter for CRC: Top and Bottom penta blood bag with a CRC filter for whole blood collection and separation of 3 different blood components (leukodepleted red blood cells, plasma and platelets).The primary bag contains CPD solution and one satellite bag is attached to a CRC filter which comes with SAGM solution for red cell preservation.

5. CSE STUDY

Here as we discussed before we are applying the Six Sigma Methodology (DMAIC). According to this methodology each phase are clearly described with sufficient data and its analytical steps.

5.1 Define Study

This phase of the DMAIC methodology aims to define the scope and goals of the improvement project in terms of customer requirements and to develop a process that delivers these requirements. The first step towards solving any problem in the Six Sigma methodology is by formulating a team of people associated with the process. Then here Critical to Quality (CTQ) was decided. It was decided to consider the rejection percentage of blood bag during welding process as the Critical to Quality (CTQ) characteristic for this project. The goal statement was defined as the reduction in rejection in rejection of blood bag from the existing level, which should result in large cost saving for the company in terms of customer satisfaction and scrap cost. Reduction in rejection will lead to increased output to meet the market demand and thereby increase in turnover and reduction in operational expenses [6]. It also improves on time delivery with 100% quality products. Also a detailed specific Project Charter has been prepared

which is presented in Appendix 1.

5.2 Measure Phase

The Objective of the measure phase is to understand and establish the baseline performance of the process in terms of process capability or sigma rating. The CTQ considered in this case was the rejection percentage of blood bag during welding process. These rejections are due to various types of types of defects. Certain processes are automatic and the defects happening in that processes are discarded automatically, but others are through visual inspection. Master samples are provided for identifying the defects through visual inspections. In the measure phase Defects per million Opportunities (DPMO) is calculated and current yield and Sigma level for different processes are also calculated using Sigma Confidence Calculator which is created using Microsoft Excel.

Rejections at Bag welding

Colpit Semi Auto H.F Welding Machine: 85 to 90 rejections for a Batch size of 3500. Port welding- 24 rejections

Second Welding- 40 rejections

Rejection in Visual Inspection- 40 to 50 for a batch size of 3500.

Daily Production Report dt. 30/04/2013

(Fully Automatic HF Welding Machine)

Input	Accept	Rejection	Defect Rate
8927	8639	288	3.23

Calculated DPMO: 32261.678
Current Sigma Level: 3.35
Rejection Rates at different processes:

- Tensile Strength(Slit)-
  --Sample Size(N)= 200 ; No: of defects=3
- Centrifugal Test-
  --Sample Size(N)= 200 ; No: of defects=0
- Pressure strength Test-
  --Sample Size(N)= 200 ; No: of defects=2
- Needle Tip Damage-
  --Sample Size(N)= 50 ; No: of defects=3

The component testing is also carried out with a batch size of 200 and for main production process the batch size taken was 3500.Pareto diagram was drawn to show different rejections in different production stages. Figure shows the Pareto diagram.

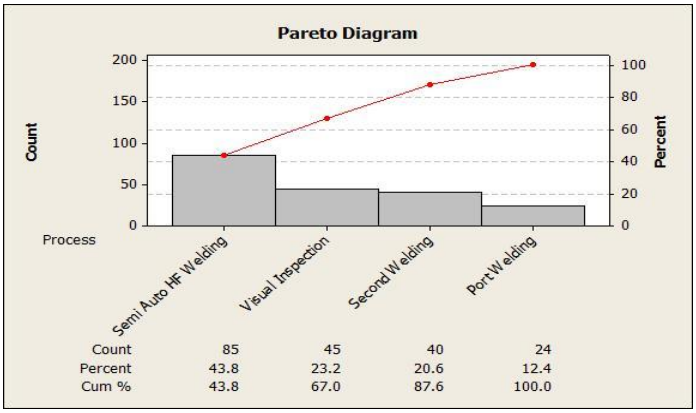

FIGURE 2. PARETO DIAGRAM

5.3 Analyse Phase

After mapping the processes, proceeded to analyse the potential causes of defects. A cause and effect diagram (Fish Bone Diagram) was prepared after conducting a brain storm session. The output of the Cause and Effect diagram depends brain storming session. Figure illustrates the cause and effect analysis prepared.

The next step is in this phase was to gather data from the process in order to get the better picture of the potential causes, so that the root cause/s can be identified. Then had a detailed discussion with the process personnel to identify the possible data that can be collected on the potential causes in the cause and effect diagram. After getting the detailed picture of availability of data on causes, the type of analysis possible on these causes are discussed. Based on this a cause validation plan was prepared to detail the type of data to be collected and the type of analysis possible for each of these causes. Some of the causes like Improper cleaning after each batch production, Small Irregularity in material feeding point, Irregularity in Sheet Separator, Sag of sheets due to offsetting of Dancing Roller, Loading-Unloading System not OK etc have to be validated only by observing the process (GEMBA).

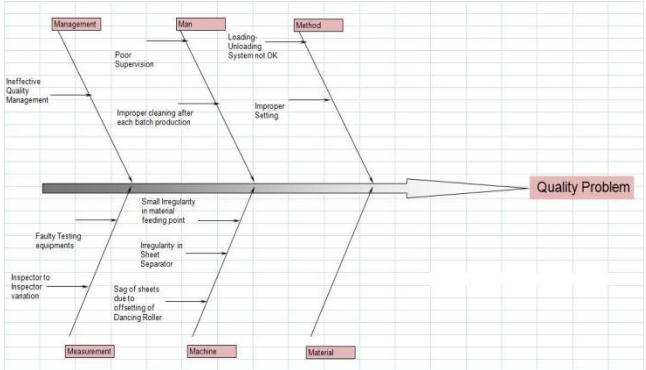

FIGURE 3.FISHBONE DIAGRAM AFTER BRAIN STORM SESSION

Hence for other few causes, detailed data were collected and analyses were planned and for the remaining causes GEMBA was planned to validate the causes. Table 1 summarizes the potential causes and the type of analysis planned and conclusions for each cause.

TABLE 1 CAUSE-VALIDATION-RESULT PLAN

Cause	Plan for validation	Observation/Conclusion
Faulty Testing Equipments	Gauge R & R	Not a Root Cause
Inspector to Inspector Variation	Gauge R & R	Not a Root Cause
Small irregularity in Material feeding point	GEMBA	Root Cause
Sag of sheets due to offsetting of Dancing Roller	GEMBA & Data Analysis	Root Cause

According to this study a fish bone diagram with root causes is prepared. So now we have clear picture of different process variations and its causes. With these data we can prepare various solution procedures for these root causes. The improve phase and control phases are done according to these inference.

5.4 Improve Phase

This phase of the Six Sigma project is aimed at aimed at identifying solutions for all the root causes identified during the Analyse phase, implementing them after studying the risk involved in implementation and observing the results. For improvement we have to document the study and analyse results and should present before the management of the organization. There were isolated efforts in the organization in the past to implement initiatives, such as statistical process control, Kaizen 5S etc. During the implementation of these initiatives, no systematic effort was made to identify the improvement opportunities in line with business priorities or customer requirements. As a result, the impact of these initiatives was not very visible in the organization whereas in Six Sigma, projects were identified with respect to the voice of the business/customer and the problems addressed were of highest priority to the organization. By analyzing the previous years' activity log book it was found that the defect rate was around 4% to 5% which accounts to a very high rejection rate. When the current production is studied it was found to be around 3%. But after the modification it falls up to 1.23%. For successful implementation and monitoring of Six Sigma a core group should be formed with all functional heads of the organization. So it's the tedious work that should be done very carefully and effectively.

5.5 Control Phase

The real challenge of the Six Sigma implementation is the sustainability of the achieved results. Due to variety of reasons, such as people changing the job, promotion/ transfer of persons working on the process, changing focus of the individual to other process related issues elsewhere in the organization and lack of ownership of new people in the process, quite often maintaining the results and controlling the newly implemented ways are extremely difficult. Sustainability of the results requires standardization of the improved methods and introduction of monitoring mechanisms for the key results achieved. It also requires bringing awareness among the personnel performing the activities.

6. CONCLUDING REMARKS

By analyzing the previous years' activity log book of the manufacturing unit of M/S HLL LIFECARE LTD it was found that the defect rate was around 4% to 5% which accounts to a very high rejection rate. When the current production is studied it was found to be around 3%. After all the above mentioned study, analysis and implementing the solution it was found that the rejection rate falls down. After the modification it falls up to 1.23%.

In addition to that like any other initiative, in Six Sigma also there were inherent difficulties in executing this project. Availability of people for attending training during their busy schedule of day-to-day work was very difficult. Getting support of the people at the lower levels in the organization for participating in the implementation of the solutions was not easy. Since the organization did not have any software for capturing data automatically, collection of data from the process during different phases of the Six Sigma project implementation is also very difficult. The team, by involving people at all levels in the organization, achieved the expected results. Finally, the significant achievement of this project will create many followers for Six Sigma in the organization.

APPENDIX 1

Project Title: Analysis Of Different Processes In A Blood Bag Manufacturing Unit For The Purpose Of Implementation Of Six-Sigma Methodology

Background and reasons for selecting the project:
The rejection of blood bag at different level of production was as high as 3.25to 4 % daily. Approximately 8900 units are produced during every shift. The cost of components rejected due to defects was increasing. In addition to this, there was loss associated with machine and man-hour related to rejection.

Aim of the project:
To reduce the rejection, to increase the quality processes and to check whether production meets the 6-sigma level.

Critical to Quality characteristic:

Rejection percentage of blood bags and its components.

Data Sources :	HLL Life care Ltd, Aakulam, Trivandrum
Expected Benefits:	Reduction in rejection will lead to increased output to meet the market demand and thereby increase in turnover and reduction in operational expenses.
Expected customer benefits:	Improving on time delivery with 100% quality products.
Schedule:	Define: 1 Week, Measure: 3 weeks, Analyze: 5 weeks, Improve: 2 weeks, Control: 1 week.

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