

Quality in the Pharmaceutical Industries

Vithya Ilarraza Marzán Master's in Manufacturing Competitiveness Jose A. Morales, PhD Industrial and Systems Engineering Department Polytechnic University of Puerto Rico



Abstract

Abstract - There are various techniques to measure the productivity of a certain economic activity, which is one that generates a profit from three phases: production, distribution, and consumption. One restriction in choosing the ideal method is the availability of statistical information. In some localities, there is still insufficient data to measure total factor productivity systematically and periodically. However, there is information that allows calculating productivity for the labor factor in economic activities, notably the pharmaceutical industry. The simplest measurement of labor productivity occurs when there is a company or an industry with a single product. In this case, labor productivity is expressed in units of that single product, either per man hours or per worker. This is an exceptional situation, since it is usually necessary to measure the productivity of a company, or a sector of activity where different products are produced or where the labor platform in the production lines.

KeyTerms – DMAIC, Methodology, SMED, SIPOC.

Introduction

We can define quality as compliance with established specifications to guarantee suitability for use. The quality of a drug is determined by its identity, purity, content, or potency and any other chemical, physical, biological, or manufacturing process properties that influence its ability to produce the effect for which it is intended.

Quality means all the features and characteristics that influence the ability of a device to satisfy the requirement of fitness for use, including safety and performance aspects. Quality is not achieved

As a result of a good implementation of a quality program within the pharmaceutical industry, it is possible to obtain a set of guidelines and interrelated activities, aimed at ensuring that the pharmaceutical products produced have and maintain the identity, purity, concentration, potency, and safety, required for use. The benefits, then, are reflected in the positive results in the medium and long term in a company.

At the beginning of the project implementation, it was observed that the levels of customer satisfaction, documentation, and inventory errors were increasing since they were at an unacceptable level for a company.

While the level of complaints by customers was decreasing, it may be noticed that after the project is implemented, all these goals were in a considerable increase and improvements for company.

Background

Quality control consists of making measurements of product parameters, determining if the values obtained are in accordance with established specifications. In most cases, this quality control is applied to the products produced. The responsibilities of quality have been distributed among several specialized groups. In other times, the head of the laboratory and the engineer were solely responsible for the quality of the product; now the marketing, due to its function of planting the product, must establish the requirements of this. Quality of service, even after the product has reached the consumer's hands, has become an important part of the "product package." This has increased the burden placed on top management particularly in view of the ever-increasing difficulty of locating accountability for deviating from quality standards.

Problem

Poor quality or not having a good quality system costs a company or business too much money while good quality saves your company or organization money. A poor quality system reduces the productivity of the company, mainly due to noncompliance with the requirements established by the different regulatory agencies. Machinery downtime, manufacturing errors, poor plant layout, contract errors, poor telephone image, poor input planning, etc. All these defects are measured and in the end the organization absorbs the cost of its errors and, worse still, points out, fines and until the closure of its operations.

Contribution

The manufacture of medicines implies a great responsibility and a strong commitment of all the employees of the pharmaceutical industry. The reason is obvious: the health and life of consumers depends on the quality of the product. To achieve quality, pharmaceutical companies have implemented a series of actions aimed at obtaining confidence that the processes (operational and administrative) are carried out correctly. They have incorporated a series of preventive measures, control mechanisms and, in general, a set of techniques aimed at permanently increasing their capacity to meet quality requirements.

Methodology

An improvement methodology needs to be used for successfully project. In this case, the DMAIC methodology was selected as tools to achieve the goals of increasing the productivity and quality. **DMAIC**

The tool at Define step was the Project Charter. Project Charter is a statement of the scope, objectives, and participants in a project. Provides a preliminary delineation of roles and responsibilities, outlines the project objectives, identifies the main stakeholders, and defines the authority of the project manager. Serves as a reference of authority for the future of the project.

At the Measure steps the following tools will be used:

The SIPOC diagram - A tool that summarizes the inputs and outputs of one or more processes. The acronym SIPOC stands for Suppliers, Inputs, Process, Outputs, and Customers. The SIPOC diagram helps us to understand the relationship between the supplier and customer, in other words, the input and output variables of the process, and finally the process steps.

Voice of the Customer - A technique that helps to understand in detail the customer needs organized and prioritized. This is showed in hierarchical structure arranged by customer comment, customer needs and customer.

Measure

There are different techniques to measure the productivity of a certain economic activity, which is one that generates a profit from three phases: production, distribution, and consumption. One restriction in choosing the ideal method considering the availability of statistical information.

The simplest measurement of labor productivity is when there is a company or an industry with a single product. In this case, labor productivity is expressed in units of that single product, either per man hour or per worker.

This is an exceptional situation, since it is usually necessary to measure the productivity of a company, or a sector of activity where heterogeneous products are produced or where the workforce participates in several production lines. When that is the situation, a unit of measurement is required that allows standardizing the quantities of various goods produced.

The SIPOC diagram is made up of the indices that express the variations in percentage over time, referred to a base year, which represents the index for the period of analysis. Production indices are compared with labor input indices to measure labor productivity.

The labor productivity indices report the variations in production in relation to the labor factor. However, by themselves they do not allow us to know to what extent the improvement in labor productivity is determined by the greater efficiency of the labor factor, or by physical capital and technology.

The importance of measuring labor productivity lies in the possibility of knowing the performance of workers, with all that this implies for the profitability of a company. It also allows knowing the room for maneuver to increase wages without exerting pressure on prices.

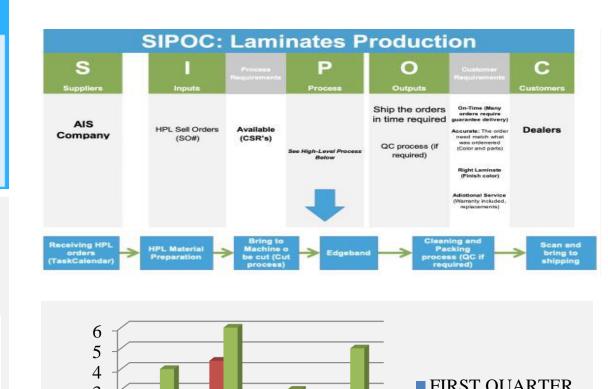
Results and Discussion

An improvement methodology needs to be used for successfully project. In this case, the DMAIC methodology was selected as tools to achieve the goals of increasing the productivity and quality.

Lean Six Sigma **DMAIC** ■FIRST QUARTER

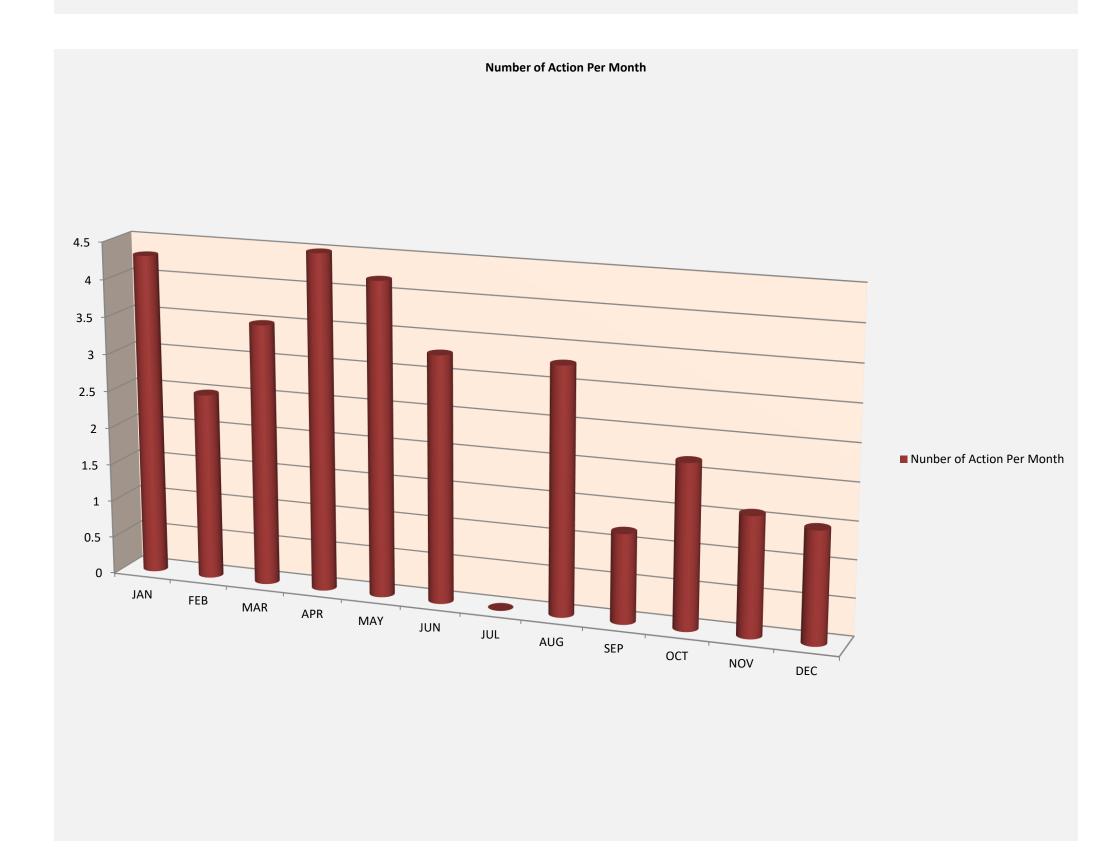
■ THIRD QUARTE

The SIPOC analysis helped to identify the relationship of the process from the suppliers to the customers. The process plays an important role between the suppliers and materials until the The customer improve the delivery time of the product, product quality, and lead time.

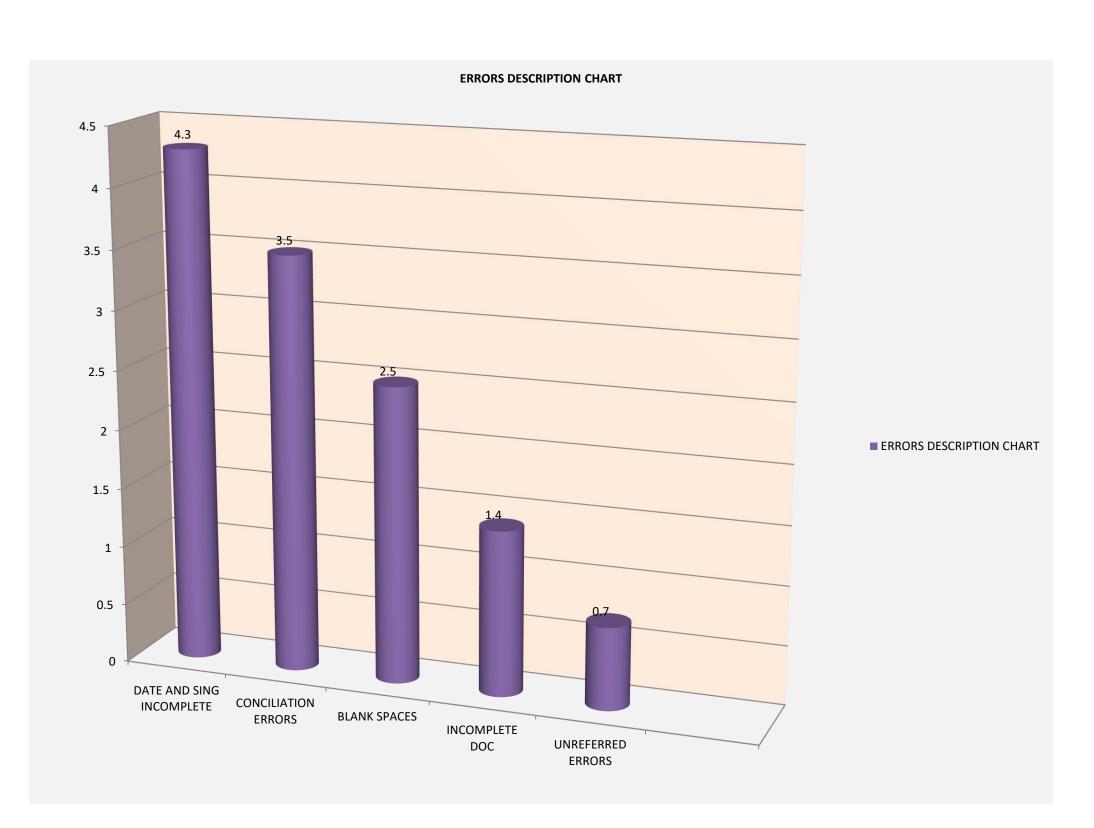


Results and Discussion Con't

Corrective actions are monitored based on how long they are on the list and the number of actions taken. One way to graph the "status" of problem solving through corrective actions is by graphing the months of the year against the actions carried out during those months.



With the following graph, it can be clearly seen that the three main problems for which there are too many errors and the factors to attack are firstly the incomplete signatures or dates, followed by the errors in reconciliation, and then the blank spaces.



At each stage of the process, characteristics will be given to the product that is developed. A defect is how it is known to any characteristic that does not comply with the established specifications and that results in customer dissatisfaction. Each stage of the process will be influenced by different types of defects, in an analytical way they can be observed as follows:

Expressed in a mathematical form they can be expressed as follows:

DE = (DC + DI) - DO

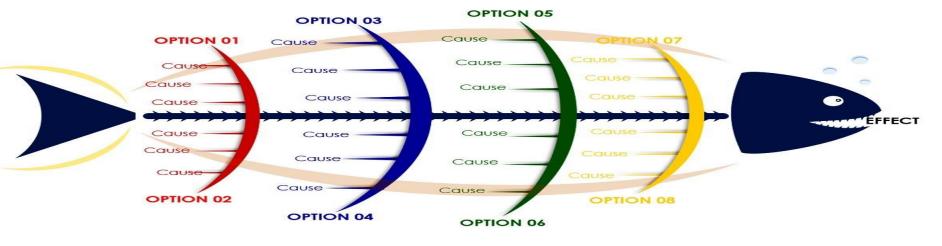
■ THIRD QUARTER

DC= Created Defects

DI= Included Defects **DO**=Observed Defects

Where, **DE**= Escaped Defects

FISHBONE DIAGRAM CAUSE AND EFFECT



A cause and effect diagram, often called a "fishbone" diagram, can help in brainstorming to identify possible causes of a problem and in sorting ideas into useful categories. A fishbone diagram is a visual way to look at cause and effect. It is a more structured approach than some other tools available for brainstorming causes of a problem (e.g., the Five Whys tool). The problem or effect is displayed at the head or mouth of the fish. Possible contributing causes are listed on the smaller "bones" under various cause categories. A fishbone diagram can be helpful in identifying possible causes for a problem that might not otherwise be considered by directing the team to look at the categories and think of alternative causes. Include team members who have personal knowledge of the processes and systems involved in the problem or event to be investigated.

Conclusions

The manufacture of medicines implies a great responsibility and a strong commitment of all the employees of the pharmaceutical industry. The reason is obvious: the health and life of consumers depends on the quality of the product. They have incorporated a series of preventive measures, control mechanisms and, in general, a set of techniques aimed at permanently increasing their capacity to meet quality requirements. Together, all these resources, actions and tools make up the company's Quality System. In its basic essence, a Quality System includes all the necessary tools to achieve and maintain quality, so the quality system requires a constant effort in training and education by and for quality.

Quality policies describe guidelines and management strategies related to quality. On the other hand, quality objectives are the ambitious purposes (in a set time) that seek to achieve all the results related to quality.

References

US Food and Drug Administration, 21.CFR Part 210. Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General. US Food and Drug Administration, Vol 4. Revised as of April 1, 2013. https://www.fda.gov/drugs/development-approval-process- drugs/pharmaceutical-quality-resources [Accessed: April 4, 2021].

Six-Sigma-Material, "Throughput Yield (TPY)," Six-Sigma-Material.com, March 20, 2016. [Online]. Available: http://www.six-sigma- material.com/Throughput-Yield.html.[Accessed: April 8, 2021].

Pan Learn, "DMAIC Approach in Lean Six Sigma", msystraining.com, June 29, 2018. [Online]. Available: https://www.msystraining.com/articles/quality- management/dmaic-approach-in-lean-six-sigma/. [Accessed: April 10, 2021].

GoLeanSixSigma, "DMAIC – The 5 Phases of Lean Six Sigma," GoLeanSixSigma.com, March 7, 2016. [Online]. Available: http://www.goleansixsigma.com/dmaic-five-basic-phases-of-lean-six-sigma/. [Accessed: April 11, 2021].

J. M. Juran and J. A. De Feo, Eds., "Lean Techniques: Improving Process Efficiency," in Juran's Quality Handbook, 6th ed., New York: McGraw Hill, 2010, pp. 327-353.

Admin, "Single Minute Exchange of Die (SMED) Definition and Example", sixsigmadaily.com, April 4, 2018. [Online]. Available: https://www.sixsigmadaily.com/single-minute-exchange-of-die-smeddefinition-example/. [Accessed: April 13, 2021].

US Food and Drug Administration, 21.CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals, US Food and Drug Administration, Vol 4. Revised as of April 1, 2013 https://www.fda.gov/medical-devices/postmarket-requirementsdevices/quality-system-qs-regulationmedical-device-good-manufacturingpractices [Accessed: April 17, 2021].