Article

THE IMPORTANT ROLE OF SIX SIGMA IN PHARMACEUTICAL INDUSTRY – A REVIEW

Shyam Shivling Mahajan[1] , Nikita Savita[2]* , Shubham Kumar[3]

[1] Department of Quality Assurance, DIPSAR, New Delhi-17; [2] Department of Pharmacognosy and Phytochemistry, DPSRU, New Delhi-17;

[3]Department of Pharmaceutical Analysis, DIPSAR, New Delhi-17

Corresponding Author*: Nikita Savita, Department of Pharmacognosy and Phytochemistry, DPSRU

Email ID: nikitanims21@gmail.com

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Abstract:

The purpose of this review article is to discuss in detail Six Sigma in the pharmaceutical industry. This article highlights the history, benefits, characteristics, implementation, methodology, organization, Certifications, and Applications of Six Sigma. The goal of this technique is to decrease unnecessary expenses, improving customer loyalty by offering exactly what the user wants. This process involves a systematic approach and assigns participants specific tasks. It is an approach for Improving Processes, Reducing Process Uncertainty, and Reducing Defects that are driven by business. It is a process improvement strategy used in the pharmaceutical industry to reduce waste, enhance profitability, and enhance product standards and user needs.

Key Words: Six Sigma, Process Capability, DMAIC, DMADV, Benefits of Six Sigma.

Introduction:

It is a tool for improving strategic initiatives and designing sustainable business models that utilize statistical and scientific methods to reduce customer-defined defect rates significantly. It is a continuous improvement approach that uses the Define-Measure-Analyze-Improve-Control (DMAIC) model to reduce defects. It is further developed by Design for Six Sigma, which is focused on developing a durable design that meets customer's needs. It is a tool for systematically assessing, reviewing, improving, and finally monitoring or locking in procedures. This statistical technique eliminates defect frequency from a three-sigma level (66 800 defects per million) to a Six Sigma level (less than four defects per million) using a statistical approach (Bolze, 1998). It is a statistically driven approach for improving business technological innovations. (Paul, 1999). This is a method of data collection and data analysis that is based on a systematic methodology. Study to find out where errors are coming from and how to fix them (Harry and Schroeder, 1999). It is a data-driven approach for eliminating waste, growing customer loyalty, and optimizing procedures, with an emphasis on observable financial outcomes (As defined by Minitab in Goh, 2002).[1]

The main objective of this technique is to reduce process variation such that nearly all items meet customer demands. This is described as having a defect rate of only 3.4 per million events .this technique involves a disciplined approach to developing and delivering products and services near perfection. Six Sigma understands the

importance of the customer. It eliminates process and product defects. It is a tool for measuring the efficiency of our processes to consumer.

HISTORY [4]

Carl Frederick Gauss (1777-1855) is known for inventing Six Sigma as a measurement standard. He was the first to propose the concept of the normal curve. Six Sigma as a product variation measurement standard relates to the 1920s when Walter Shewhart demonstrated that three sigma from the mean is the point where the method needs correction.
Many measurement criteria (Cpk, Zero Defects, etc.) followed, but a Motorola engineer named Bill Smith is credited with coining the word "Six Sigma" in 1986. [4]

Motorola engineers felt that traditional quality standards — assessing defects in thousands of opportunities – didn't provide enough granularity in the early and mid-1980s when Chairman Bob Galvin was at the helm. They inquired how many defects there were per million opportunities. Motorola established this benchmark, as well as the methods and cultural shifts needed to implement it. Motorola produced a tremendous bottom-line performance as a result of our Six Sigma efforts, with savings totalling more than $16 billion. Since then, tens of thousands of businesses all over the world have implemented Six Sigma as a business strategy.

BENEFITS OF SIX SIGMA [5, 6, 7, 8]

1. Ensures long-term success

2. Establishes success targets for everyone

3. Increases consumer value

4. Increases the pace of progress

5. It promotes learning and cross-pollination. Reforms the strategy plan.

6. In the manufacturing process, the number of flaws is reduced.

7. Process Variability is Reduced

8. Increases revenue and customer loyalty [5]

9. In the pharmaceutical sector, this approach is used to minimize waste, make effective adjustments in the manufacturing process to improve operating performance, and improve quality of service and customer satisfaction. [6]

CHARACTERISTICS OF SIX SIGMA [13]

1. Statistical quality control

Six Sigma is a term derived from the Greek letter **σ** (Sigma) from the Greek alphabet, which is used in statistics to represent standard deviation. The term "standard deviation" is used to describe variance, which is a significant technique for evaluating non-conformance in terms of production quality.

2. Methodological approach

Two methodologies are used in six sigma. 1 DMAIC 2 DMADV. DMADV is the acronym for Define, Measure, Analyze, Design, and Verify. DMAIC stands for Define, Measure, Analyze, Design, and Verify.

3. Facts and Data-based approach

Six sigma uses facts and scientific data to improve the output of the process.

4. The Customer focus

Improving the customer focus begins with a better understanding of what it means to be customer-focused and developing a successful customer focus plan**.** Since it's your commitment to your customers that you'll put them first, customer focus is the cornerstone of customer loyalty.

5. Total Quality Management

Six Sigma involves the use of Total Quality Management for enhancing the output of the process and to reduce defects. Total Quality Management (TQM) is a comprehensive approach to the continuous improvement of all organizational processes with the involvement of all employees, resulting in high-quality products and services that satisfy customers. The philosophy behind it is "do the right thing the first time, every time." TQM is a relatively new concept of quality control. It is basically, a management function involving the direction of top management and coordination of all quality-related activities throughout the company to achieve Zero defects and customer satisfaction. [13]

METHODOLOGY FOR SIX SIGMA [5, 6]

There are two methodologies used in the six sigma project. DMAIC and DMADV. DMAIC is a method for improving current business operations. DMADV is a technique for developing a new product or process design that results in more predictable, mature, and defect-free efficiency.

1. DMAIC (Define, Measure, Analyze, Improve, and Control) is a systematic improvement framework for current processes that aren't meeting specifications. This approach is applied to existing business processes to enhance them.

Each level is defined in brief.

A. Define (D) Define the problems in the process and set the project goals to enhance customer satisfaction and process outcomes.

B. Measure (M) Measure your current business processes. Make reports on the existing processes and use them as a benchmark for analysis in the future.

C. Analyze (A) Analyze your relationship in terms of the process. It is essential to consider the relationship to identify factors that will encourage you to keep your firm's strategy in line with customer needs.

D. Improve (I) Improve the process. Using review and other approaches, it is necessary to consistently upgrade and optimize the process.

E. Control (C) Control the process. It is important to make sure you can track and fix any defects to prevent costly errors and a drop in quality.

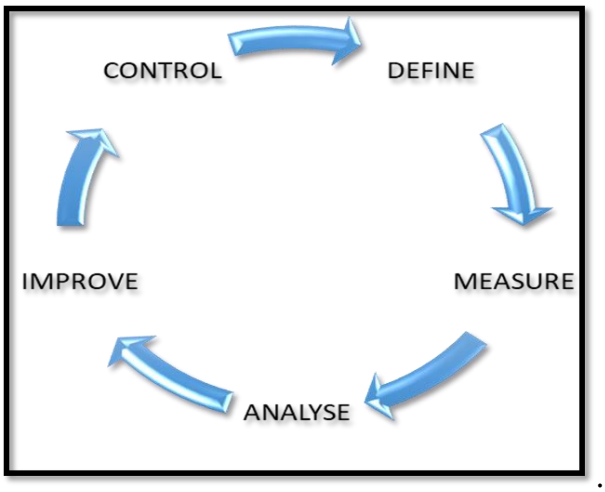

Fig 1 DMAIC Cycle

2. DMADV (Define, Measure, Analyze, Design, and Verify) is a Six Sigma quality management approach for building new processes or products. If a current procedure needs more than gradual enhancement, it can also be incorporated. This approach is used to design new products or processes in such a way that their performance is more consistent, effective, and defect-free.

A. Define (D) Define the problems in the process and set the project goals to enhance customer satisfaction and process outcomes.

B. Measure (M) Measure your current business processes. Make reports on the existing processes and use them as a benchmark for analysis in the future

C. Analyze (A) Analyze your relationship in terms of the process. It's necessary to evaluate the relationship to recognize factors that will motivate you to keep your company's approach aligned with customer demands.

D. Design (I) Design the process. Using review and other approaches, it is necessary to consistently upgrade and optimize the process

E. Verify (V) Verify the design performance and ability to meet customer needs [5, 10]

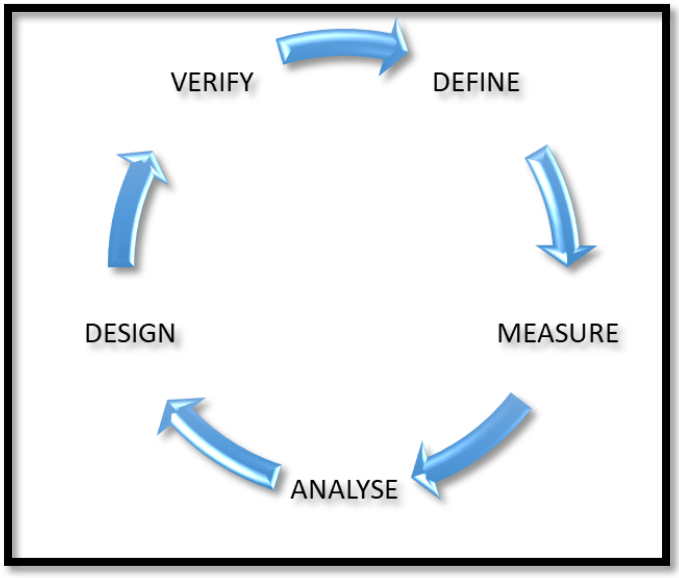

Fig 2 DMADV Cycle

Six Sigma Implementation: [1, 2]

Six Sigma is made up of three essential components:

- Process Improvement
- Process Development
- Process management

The following sections go into each of the three elements in greater detail.

Process improvement

Process improvement aims to remove the root causes of performance flaws in existing processes in an organization. These performance flaws may be creating serious problems for the company or stopping it from running as effectively as it could.

Process Development

A successful process development must consider the process's suitability for the organization's ultimate goal. Process design requires a broad perspective of the whole organization.

Process management

Process management is a method of analyzing and managing the processes that exist in a company. It's a good strategy to employ during a crisis to ensure that processes are productive and consistent since this can lead to a more efficient and cost-effective organization.

In general, process management entails Defining procedures, identifying key customer requirements, and identifying process "owners." Customer criteria and primary performance metrics are used to evaluate performance. Analyzing data to improve measures and neat process management systems. Controlling process efficiency by controlling process inputs, activity, and outputs, as well as reacting quickly to problems and process variation [1, 2]

ORGANIZATION OF SIX SIGMA [11]

A Six Sigma program assigns particular positions and titles to members of an organization. To incorporate Six Sigma throughout the organization, need a highly organized format.

A. Leadership

The Leadership team sets the aim and objective of the six sigma project. The main functions of leadership include

The goal of the Six Sigma project is defined by the leadership team

Describes how the outcome will favor the customer.

Establishes a work schedule as well as provisional deadlines.

Creates a system for inspection and oversight.

Team members should be supported, and proven positions should be defended.

B. Sponsor

The sponsor is responsible for solving problems in the current Six Sigma projects. Six Sigma sponsors are high-ranking individuals who are well-versed in the Six Sigma methodology and committed to its success. In the current Six Sigma project, the sponsor is in charge of resolving issues. Six Sigma is normally overseen by a full-time, high-level champion, such as an Executive Vice President. Sponsors are process and system owners who assist in initiating and coordinating Six Sigma implementation projects in their areas of responsibility.

C. Implementation Leader

The Implementation Leader is the person in charge of supervising the Six Sigma team endeavor and assisting the leadership council by ensuring that the team's stuff is finished in the desired manner.

D. Coach

A coach is a Six Sigma specialist or consultant who creates a plan, determines project outcomes, and mediates disagreement or deals with program resistance.

E. Team Member

A person who works on a Six Sigma project and is assigned specific responsibilities and deadlines to achieve the project's goals.

F. Process Owner

The individual who takes on responsibility for a process after a Six Sigma team has completed its work. [11]

CERTIFICATION IN SIX SIGMA [4, 10, 12]

The criteria for Six Sigma certification differ from one company to another. It's a fine decision to have procedures in place for certifying a Six Sigma professional's ability to use the methodology and for certifying projects. Effective completion of training and one or more assignments are usually part of the qualification criteria. Six Sigma approaches are used in pharma companies to decrease the number of defects. Six Sigma is a problem-solving methodology based on a data-driven, systemic approach with an emphasis on consumer effect. [4]

The method also involves the use of statistical methods and analysis.

All Six Sigma practitioners, including Master Black Belts, Black Belts, and Green Belts, must be trained in quality tools and the financial aspects of the discipline.

Champion

Champion training lasts between one and four days. Champion training should be sufficient enough to give champions an overview of the Six Sigma problem-solving processes and to prepare them for their roles as guides, instructors, and facilitators for Black and Green Belts. Champion training usually takes place previous to Black and Green Belt training.

Green Belt

Green Belt preparation should focus on day-to-day process flow improvement problems. Green Belt training will take anywhere from one to three weeks.

Black Belt

Before handling a Six Sigma project, Black Belts must master the topics covered in Black Belt training. It is built on the DMAIC methodology, as well as the Six Sigma techniques and skills that help it.

Master Black Belt

To improve their project and coaching skills, Master Black Belts usually undergo additional training outside the Black Belt program.

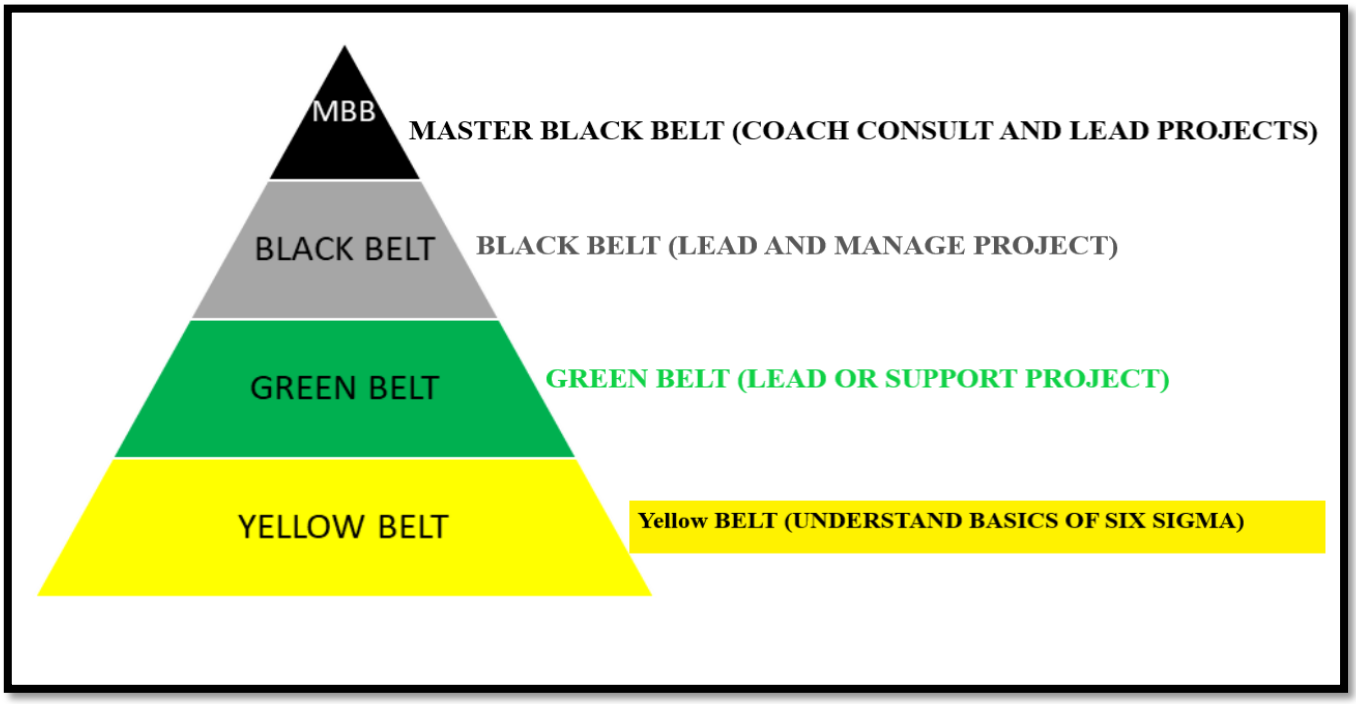

Fig 3 Six Sigma Certifications

APPLICATIONS OF SIX SIGMA [10, 11, 13]

(A) Pharmaceutical Industry

In the pharmaceutical industry, this technique is used to minimize waste, make needed changes in manufacturing processes, and increase efficiency, all of which help to improve product quality and customer service. Process capability refers to the capability of the process to meet the desired specification and requirement of a product or service. The capability of a process to achieve consistent output under defined constraints is measured by its process capability index. The letter Cpk stands for it. [10] In the pharmaceutical industry, several firms are attempting to transform their operations to increase profits. Many businesses are combining conventional Six Sigma and Lean Manufacturing to improve the quality and operational aspects of the manufacturing process. Both methodologies have had positive results in adjacent markets such as the automotive and electronics industries. The pharmaceutical industry places a high priority on reducing waste and defects in the manufacturing process, so Lean Manufacturing is a hot topic that should provide value to customers when involving management at all times.

(B) Research and Development

The most significant phase in the pharmaceutical industry is research and development, which accounts for a large portion of costs. In this case, the Six Sigma principle is desirable to consider the essential processes in new drug production, as well as to study and streamline existing ones. These goals are necessary to minimize drug failures, enhance resource usage, and boost efficiency and staff and other resource usages.

(C) Cycle Times

Increased cycle times are a major factor influencing the manufacture, supply, and launch of new drugs on time. The ability of earlier industries to take

advantage of this business situation inevitably determines whether a product succeeds or fails. Lean Manufacturing and Six Sigma principles such as value stream mapping and process modeling can help reduce cycle times and operating costs while also increasing the reliability of processes and personnel.

(D) Defects

Any drug-related flaws will be a major setback for the pharmaceutical industry. Six Sigma principles can benefit because they rely on scientific and mathematical methods that have been shown to reduce the cost of human errors. The industry may use advanced methods to conduct quality analysis, yield analysis, job cost comparisons, risk analyses, and manufacturing process comparisons across several locations. Six Sigma is extremely beneficial to the pharmaceutical industry. [11]

(E) In Healthcare System

The assessment, evaluation, and knowledge of process variations is required for continuous improvement in healthcare systems. Wherever possible, process variation should be eliminated. Important process variables in healthcare include laboratory turnaround times, patient longer waits, patient satisfaction scores, adverse events (prescription, dispensing, and administration), emergency service response times, infection rates, mortality rates, patient falls, postoperative lengths of hospital stay, “door-to-needle” times, and counts of an adverse event. Monitoring, analyzing, and studying such variables with care can result in significant improvements in healthcare service quality.

Visionary leadership, proper planning, education, and training, the availability of trained staff, productive resources, personnel, and process management, and cooperation and teamwork among service providers can all help to improve healthcare quality. [14]

CONCLUSION

Six Sigma is a systematic approach to data collection and statistical analysis. Study to find out where errors are coming from and how to fix them taking a process to the Six Sigma level guarantees that the product's quality is safeguarded. The primary goal of improved quality is for the organization to earn more profit. Quality is defined as the degree of excellence of a product or service given to a customer in very simple terms. It complies with the requirements of the client. If the consumer is pleased with the product or service, it is of the required standard of quality. Six sigma is used in the pharmaceutical industry to reduce waste, make effective changes in the production process to enhance operating performance, and improve product quality and customer service.

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