RESEARCH PAPER

FROM VARIABILITY TO VALUE: SIX SIGMA TRANSFORMING PHARMACEUTICAL QUALITY

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ABSTRACT
The main purpose of this article paper is to discuss the six sigma and its tools for identifying the root cause of defects and to improve the standard of quality in pharmaceutical industry. The name "six sigma" comes from statistics, where sigma represents standard deviation operating at six sigma quality means extremely low defects rates. The main objective of six sigma is to decrease unnecessary defects and improving customer satisfaction by providing excellent products as per their requirements. Six Sigma uses structured methodology approaches like DMAIC and DMADV tool for systematically assessing, reviewing, and improving the process.

KEYWORDS: Six sigma, defects, DMAIC and DMADV cycle
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Introduction

Quality improvement has grown crucial across industries due to increased regulatory obligations, market competition, and customer needs. Six Sigma, established by Motorola in the 1980s, stands as one of the most effective quality management systems. (1)

Six Sigma is a systematic, data-driven approach to defect reduction and variability in processes to achieve near perfect quality. This statistical technique lowers the defect frequency from a three-sigma level (66,800 flaws per million) to a Six Sigma level (less than four defects per million). It is a technique for assessing how well our procedures serve customers. (2)

In the pharmaceutical and biotechnology industries, where product quality, patient safety, and regulatory compliance are extremely important, Six Sigma plays a vital role in optimizing manufacturing processes, minimizing errors, and improving overall operating efficiency. Also Six Sigma enhances other quality methodologies like Lean manufacturing, Good Manufacturing Practices (GMP), and Quality by Design (QbD) (3)

ADVANTAGES

- ✓ Ensures long-term success
- ✓ Increases consumer value
- ✓ By getting rid of waste and avoiding issues rather than resolving them after they arise, it reduces operating costs.
- ✓ By streamlining processes and removing waste, organizations can become more efficient and productive

DISADVANTAGES

- ✓ Six Sigma deployment is expensive since it necessitates additional resources because of sophisticated technologies and testing techniques. A significant disadvantage is that it also requires highly qualified, certified workers and intensive training for current employees.

HISTORY

The Motorola Innovation: In the 1980s, Bill Smith and Mikel Harry at Motorola applied these ideas, defining Six Sigma goal that significantly reduces errors by aiming for six standard deviations from the mean, or 3.4 defects per million opportunities (DPMO). (4)

In essence: Gauss provided the math, while Motorola engineers created the system and the name (Six Sigma) to leverage that math for world-class quality. (5)

CHARACTERISTICS OF SIX SIGMA (14)

Customer focused approach

Understanding customer needs through the recognition of Critical-to-Quality (CTQ) attributes is a key component of Six Sigma. Improving customer satisfaction and fulfilling customer expectations serve as the foundation for the overall improvement process. (6-7)

Data driven decision making

Instead of focusing completely on inference, all Six Sigma decisions heavily rely on statistical information and analysis. Tools such as hypothesis testing, regression, capability analysis, and SPC are

used to ensure accuracy and objectivity in problem-solving. (8)

Structured methodology

Six Sigma uses structured approaches like DMAIC for enhancing existing processes and DMADV for creating new procedures. These phased methods enable systematic analysis, improvement, and control of processes, ensuring consistent outcomes. (9)

Reduction of process variation

A core aim of Six Sigma is minimizing process variation and achieving near-perfect quality, quantified as 3.4 flaws for every million opportunities. This variance reduction enhances reliability and process stability across industries. (10)

Strong leadership and trained role

Successful Six Sigma deployment requires trained professionals like Project Champions, Black Belts, Master Black Belts, and Green Belts. These roles ensure disciplined execution and sustain the culture of continuous improvement. (11)

Financial Impact Orientation

Six Sigma projects are selected based on measurable financial benefits such as reduced operational costs, improved cycle time, and enhanced productivity. The approach ensures that every improvement links directly to business goals. (12)

Continuous improvement culture

Using techniques like statistical monitoring, FMEA, Pareto analysis, and root cause analysis, Six Sigma promotes continuous improvement. This encourages teams to continuously strive for process optimization and defect reduction. (13)

Cross functional team work

Projects involve people from different levels and functions, supported by a "belt" structure (Green Belt, Black Belt, etc.). (14)

METHODOLOGY

The six sigma project employs two approaches

- DMAIC
- DMADV

DMAIC

D ⟶ Define

M ⟶ Measure

A ⟶ Analyze

I ⟶ Improve

C ⟶ Control

DMAIC (Define, Measure, Analyse, Improve, and Control) was a systematic improvement framework for current work. This approach is used to enhance existing business processes.(15)

Define: Identify the issues within the procedure and establish project objectives to improve client contentment and overall process performance.

- Define your clientele, their needs for products and services, as well as their expectation
- Mapping the process flow will help you define the process that needs to be improved.

Measure: Measure your present company procedures. Create reports on the current procedures and utilize them as a standard for future analysis.

- To find the gap, compare the findings of the customer survey.

Analyze: From the information collected identify areas for improvement and the underlying causes of problems.

Determine the sources of variance and the gaps between current and objective performance.

Improve: Improve the procedure. It is essential for continuous upgrade and optimize the process by review and any other methods.

- Develop creative solutions with discipline and technology.
- Create and apply an implementation strategy.

Control: Maintain the process on the new path by controlling the improvements. Avoid going back to the "old way."(16)

DMADV

D ⟶ Define

M ⟶ Measure

A ⟶ Analyze

D ⟶ Design

V ⟶ Verify

DMADV is a Six Sigma quality management approach for building new processes or products.

Define: Specify the goals of the project and the deliverables for both internal and external clients.

Measure: Assess and verify the requirements and needs of the client.

Analyze: Examine the available processes to satisfy the needs of the client**.**

Design: Create a method. So the process must be continuously improved and optimized via review and other methods**.**

Verify: Check if the design performs well and can satisfy the needs of the client (17)

SIX SIGMA CERTIFICATION PROCESS (18)

- Establishing A plan for implementing Six Sigma is mostly the responsibility of Executive Leadership, which includes the CEO and other key members of the management team. Additionally, they give other function holders the flexibility and means to investigate fresh concepts for efficiency and quality enhancements.
- Champions are primarily in charge of implementing Six Sigma. They are typically chosen from upper management by the organization's executive leadership in a united manner. Additionally, they serve as black belts' mentors.

- Champion-identified Master Black Belts serve as the organization's internal Six sigma specialists. They dedicate all of their time to Six Sigma and make sure that it is implemented in an integrated manner.
- Black Belts use the Six Sigma methodology on specific projects under the direction of Master Black Belts. Masters and Champions While Black Belts focus on executing Six Sigma projects, Black Belts choose projects or tasks for Six Sigma.
- Employees that adopt Six Sigma implementation in addition to their regular work duties are known as Green Belts. They work under the direction of Black Belts and assist them in reaching the final outcomes.
- Employees that are part of a corporate-wide initiative and possess a rudimentary understanding of Six Sigma methodologies are known as Yellow Belts. Unlike Green or Black Belts, Yellow Belts do not oversee projects independently.

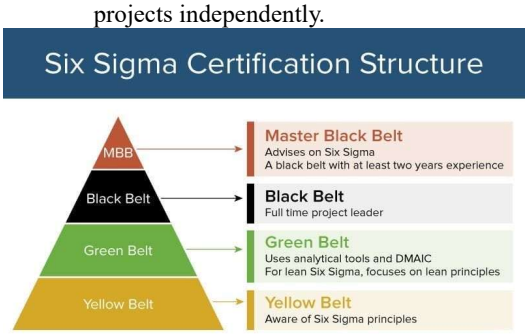

Figure 1

APPLICATIONS

Pharmaceutical industry

This method is utilized in the pharmaceutical business to reduce waste, modify manufacturing procedures when necessary, and boost productivity—all of which contribute to higher-quality products and improved client support. The ability of a process to satisfy the intended requirements and specifications of a good or service is referred to as process capability. The process capacity index measures a procedure's ability to produce consistent results under specified limits. The letter Cpk stands for (process capability index). In nearby businesses like the automotive and electronics sectors, both approaches have produced favorable outcomes. Reducing waste and manufacturing process faults is a top objective for the pharmaceutical business. (19)

Research and development

In the pharmaceutical sector, research and development is the most important stage and contributes significantly to costs. In this situation, it is preferable to use the Six Sigma principle to examine and optimize current processes as well as to take into account the crucial ones in the creation of new drugs. These objectives are required to reduce drug failures, improve staff and other resource use, and increase efficiency. (20)

Health care system

For healthcare systems to continuously improve, assessment, evaluation, and understanding of process variations are necessary. Process variation should be removed whenever feasible. Laboratory turnaround times, longer wait times for patients satisfaction ratings, adverse events (prescription, dispensing, and administration), response times for emergency services, rates of infection, patient falls, hospital stays, mortality following surgery, and "door-to-needle" times and adverse event counts are all significant process variables in the healthcare industry. The quality of healthcare services can be significantly improved by carefully tracking, evaluating, and researching these factors. (21-22)

Six Sigma Tools

Define phase tools

The following tools are used in the Define phase to precisely define the issue, project scope, goals, and client requirements.

Project Charter SWOT Analysis Voice of Customer (VOC)
Critical to Quality (CTQ) PESTLE Analysis
SIPOC Diagram SWOT analysis
Process Mapping Benchmarking

In the Define phase, tools are employed to clearly identify the complications, project goal, its scope and the needs of the client. Project Charter is used to formalize improvement initiatives by defining goals, timelines, responsibilities, and expected outcomes. Voice of Customer (VOC) and Critical-to-Quality (CTQ) tools help to convert client expectations into measurable outcomes. SIPOC diagrams and process mapping are applied to visualize high-level process flows and interactions between suppliers, inputs, processes, outputs, and customers. Additionally, SWOT analysis, benchmarking, and Pareto analysis assist in prioritizing critical processes and improvement opportunities.

Measure Phase Tools

In the Measure phase, tools are used to collect valid data and quantify current process performance. Process mapping and current-state flow charts help identify critical measurement points and key process variables. Structured data collection methods, such as check sheets, used to make sure consistency and precsion. The accuracy of the measurement system is evaluated using Measurement System Analysis (MSA), including Gauge Repeatability and Reproducibility (Gauge R&R) studies, to minimize measurement error. Additionally, descriptive statistics and process capability analysis (Cpk , Cp) are mostly used to assess process variation and

defect levels, providing a quantitative baseline for subsequent analysis. (23)

Analyze phase tool

The Analyze stage focuses on determining the underlying causes of defects and sources of variation affecting process performance. Pareto analysis is employed to prioritize the most significant factors contributing to defects. Cause-and-effect (Ishikawa) diagrams are used to systematically explore potential causes related to materials, methods, machines, manpower, measurement, and environment. FMEA (Failure Mode Effect Analysis) supports risk-based evaluation of potential failure and prioritization of corrective actions. Statistical tools such as hypothesis testing, regression analysis, and correlation analysis are applied to validate cause-and-effect relationships and confirm statistically significant root causes. (24)

Improve Phase Tools

Solutions are created and put into action to get rid of confirmed root causes during the Improve phase. Alternatives for improvement are produced using structured problem-solving methods and brainstorming. A crucial method for identifying ideal operating conditions and optimizing important process parameters is the Design of Experiments (DOE). To get rid of non-value-added tasks, lean tools and kaizen ideas are frequently combined. By adding fail-safe procedures, Poka-Yoke (mistake-proofing) techniques are used to prevent errors. Before implementing changes on a large scale, pilot testing is done to make sure they are sustainable and effective. (25-26)

Control phase tool

The Control phase makes sure that gains are maintained throughout time. Process stability is tracked and variations are identified using statistical process control (SPC) methods, especially control charts. To standardize enhanced processes, control plans and Standard Operating Procedures (SOPs) are created or revised. Internal audits, performance dashboards, and visual management systems facilitate ongoing compliance and monitoring. To confirm the Six Sigma method's long-term effectiveness program, periodic process capability analysis is also carried out to confirm that the process continues to satisfy customer and regulatory requirements. (27-28)

CONCLUSION

Six Sigma is a methodical technique to statistical analysis and data collection. Investigate to determine the causes of errors and how to resolve them. Reaching the Six Sigma technique ensures that the nature of the final product is protected Thus, the "quality of a product or service" can be defined as the degree to which it incorporates features and characteristics that enable the customer to use it. You are meeting their needs at the same time. The pharmaceutical sector uses six sigma to cut waste, increase customer service and product quality, and make efficient modifications to the production process to improve operating performance.

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