

A REVIEW OF SIX SIGMA: A QUALITY MANAGEMENT TOOL IN THE PHARMA INDUSTRY

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ABSTRACT

Six Sigma is a quality management approach that helps improve process, performance, cut down defects, and boost customer satisfaction across various industries. This review covers the history, key principles, and practical uses of Six Sigma in the pharmaceutical and manufacturing fields. The method is focused on minimizing variation in processes to achieve high-quality results, with a target of just 3.4 defects per million opportunities. It explores important concepts like DMAIC, Lean Six Sigma, SIPOC, VOC, CTQ, SPC, DOE, and process capability. The review also outlines the different levels of Six Sigma skills and includes case studies from the pharmaceutical industry that demonstrate improvements in productivity, process control, and product quality. In general, Six Sigma assists organizations in enhancing efficiency, lowering costs, improving product quality, and supporting continuous improvement, which leads to better business performance and greater customer satisfaction.

KEYWORDS: DMAIC, DFSS, SPC & DOE.

INTRODUCTION

Six Sigma is a statistical approach that provides easy-to-implement adjustments, tools for evaluating and detecting influential elements, and a methodical explanation of problems. Since Motorola implemented it in the mid-1980s, it has evolved into a useful leadership tool with the objective of reaching a quality level of 99.99996%. A vision, a philosophy, a symbol, a statistic, a goal, or a methodology can all be represented by the quality management tool. It only refers to a high standard of quality that aims for near perfection.^[1]

Six Sigma is recognized as a TQM implementation methodology. Six Sigma is a TQM technique and an inventive approach to continuous process improvement.

Integrating a Six Sigma program into the company's current business system covers nearly all of the components of Total Quality Management (TQM), since

improving quality is the main component of TQM. Compared to TQM, Six Sigma has expanded considerably.^[2]

The Six Sigma methodology places a great deal of attention on a very important improvement where customer preferences are converted into activities that increase the company's quality. The company's goal is to achieve 3.4 flaws per million potential difficulties. Through this method, the quality standard can be progressively raised to zero faults and zero failure rates. It is a highly organized process that focuses on creating Near Perfect products and services. It is based on the three ideas of process administration, process design and redesign, and analyse improvement.^[5]

1. Historical Development of Six Sigma The Quality Revolution and TQM

Folaron (2003) provided a comprehensive view of Six Sigma within the historical context of the development of industry and the associated impact on the quality of processes and products.

In particular, since 1980, there has been a profound growth in the use of statistical methods for quality and overall business improvement in the United States and throughout the world. This has been motivated, in part, by the widespread loss of business and markets suffered by many US. companies that began during the 1970s.

For example, the US automobile industry was nearly destroyed by international competition during this period. One US automobile company estimated its operating losses at nearly \$1 million per hour in 1980. The adoption and use of statistical methods have played a central role in the renewed competitiveness of US industry with respect to quality.

Various management systems have also emerged as frameworks in which to implement quality improvement. One of these is total quality management (TQM), which is a strategy for implementing and managing quality improvement activities on an organisation-wide basis. TQM began in the early 1980s, influenced by the philosophies of W. Edwards Deming, Joseph Juran, and others. It evolved into a broader spectrum of concepts and ideas, involving participative organizations and work culture, customer focus, supplier quality improvement, and many other activities to focus all elements of the organisation around the quality improvement goal. Typically, organizations that have implemented TQM employ quality councils or high-level teams that deal with strategic quality initiatives, workforce-level teams that focus on routine production or business activities, and cross-functional teams that address specific quality improvement issues.

Some general reasons that are cited for the lack of conspicuous success of TQM include:

- (i) lack of top-down, high level management commitment and involvement;
- (ii) inadequate use of statistical methods and insufficient recognition of variability reduction as a prime objective;
- (iii) general, as opposed to specific, business-results-oriented objectives; and

Generally, Six Sigma has been far more successful than TQM was. There are several reasons for this, principal among them being the strong focus on projects that positively impact business financial performance. When

quality improvement projects result in real savings, expanded sales opportunities, or documented improvements in customer satisfaction, upper management pays attention. Then business leaders are more likely to be fully involved, to commit the resources needed to train personnel, and to make Six Sigma positions full-time, using these positions as stepping stones to higher positions of responsibility in the organization. The level of technical training in Six Sigma is generally deeper and more extensive than in the typical TQM programmes of the 1980s. And, because the training is project-oriented, it is much more likely that the techniques will actually be used.

Origin of Six Sigma

Bill Smith, a Motorola engineer, developed the Six Sigma programme in 1986 as a response to the necessity for improving quality and reducing defects in their products. The CEO, Bob Galvin, was impressed by the early successes, and under his leadership, Motorola began to apply Six Sigma across the organization, focusing on manufacturing processes and systems. Godfrey (2002) interviewed Bob Galvin on these early days of Six Sigma.

Motorola established Six Sigma as both an objective for the corporation and as a focal point for process and product quality improvement efforts. The Six Sigma concept was tremendously successful at Motorola. It has been estimated that they reduced defects on semiconductor devices by 94% between 1987 and 1993. In recent years, Six Sigma has spread beyond Motorola and has become a programme for improving corporate business performance by both improving quality, reducing costs and expanding markets for products and services. Six Sigma, in some form, has been adopted by thousands of companies both large and small.

The Evolution of Six Sigma

Six Sigma has been implemented in three generations since its inception. Defect removal and basic variability reduction were the main goals of Generation I Six Sigma, especially in manufacturing. One of the best examples of Generation I Six Sigma is Motorola.

The focus on defect elimination and variability reduction persisted in Generation II Six Sigma, but there was now a significant attempt to link these initiatives to projects and activities that enhanced company performance through better product design and cost savings. General Electric is frequently credited with spearheading Six Sigma's Generation II phase. Creating value for the organization as a whole and for its stakeholders (owners) is another emphasis of Generation III Six Sigma.

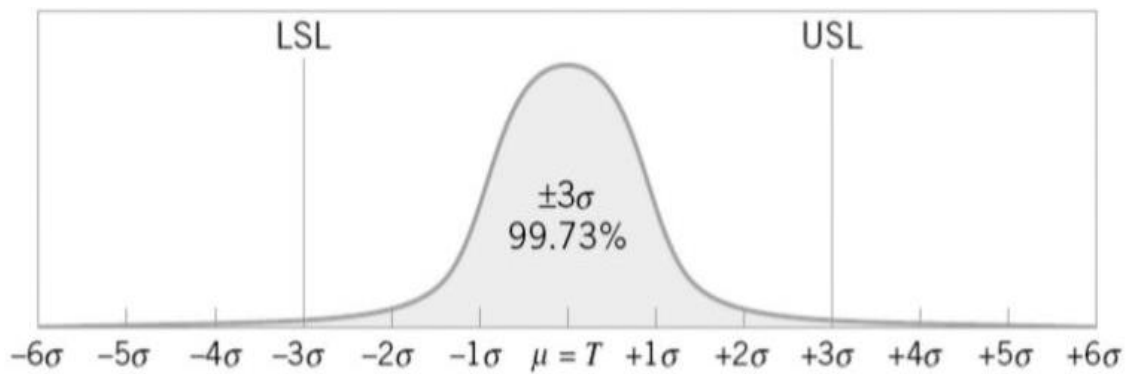


Figure 1: normal distribution at the target.

Table 1: Motorola Six Sigma Concept Normal Distribution.

Spec limit.	Percentage inside spec	Ppm defective
±1 sigma	68.27%	317300
±2 sigma	95.45%	45500
±3 sigma	99.73%	2700
±4 sigma	99.9937%	63
±5 sigma	99.999943%	0.57
±6 sigma	99.9999998%	0.002

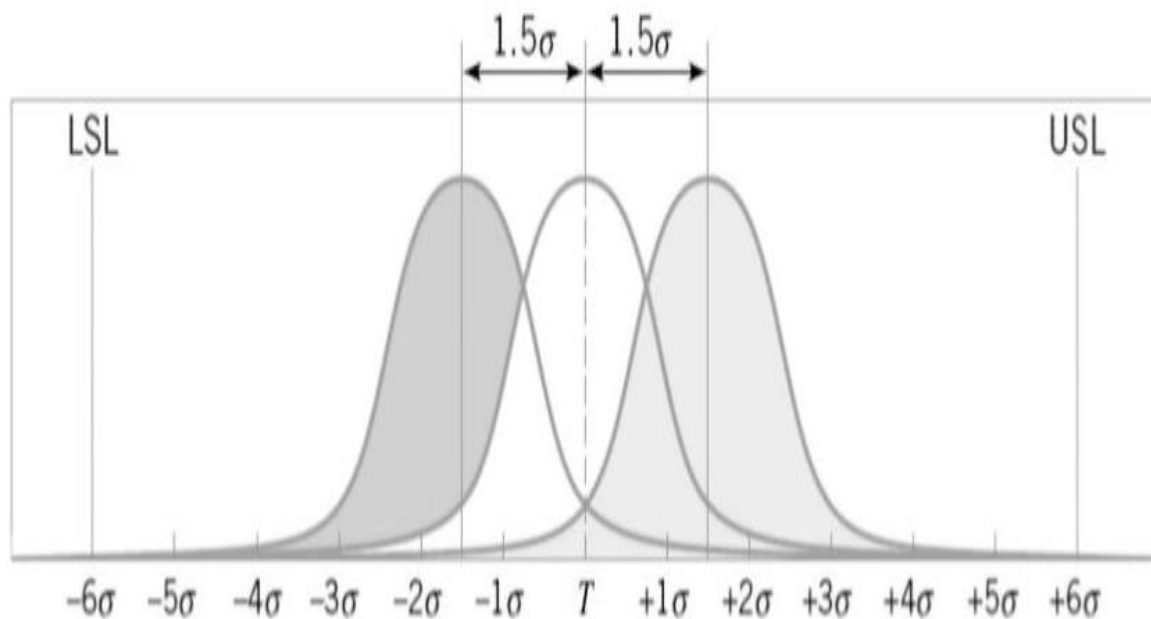


Figure 2: normal distribution with ± 1.5 sigma target.

Table 2: Motorola Six Sigma Concept Normal Distribution With The Shift By ±1.5 Sigma From The Target.

Spec limit.	Percentage inside spec	Ppm defective
±1 sigma	30.23%	6,97,700.0
±2 sigma	69.13%	6,08,700.0
±3 sigma	93.32%	66,810.0
±4 sigma	99.3790%	6,210.0
±5 sigma	99.97670%	233.0
±6 sigma	99.999660%	3.4

(Worker, clients, vendors, and the general public). Raising the price of shares and dividends, preserving or growing employment, expanding markets for company

goods and services, creating new goods and services that reach new and wider markets, and raising customer satisfaction levels across the board (possibly by cutting

cycle time or boosting throughput) are just a few ways to create value.

2. Aim of Six Sigma

Increasing consumer contentment
Improving process cycle times and timeliness.
market Eliminating imperfections
Controlling and enhancing the predictability of variation

Cutting expenses without "unintended consequences"
Enhancing process management and measurement from start to finish

3. How Does SIX SIGMA Work?

Six Sigma consists of three basic elements:
Each of the preceding three factors is discussed in greater detail below.

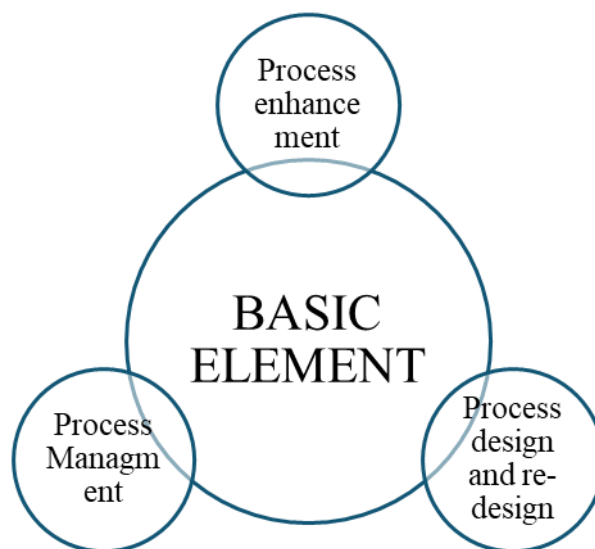


Figure 3: Elements Of Six Sigma.

Process improvement

The goal of process improvement is to identify and eradicate the root causes of performance shortcomings in existing processes within the company. These performance inadequacies may be generating genuine problems for the business or preventing it from operating as efficiently and effectively as possible.

Process design and redesign

Sometimes simply enhancing current processes is insufficient, and new processes or existing processes must be redesigned. There are various reasons why this may be necessary:

Organizations may choose to replace rather than fix essential processes.

During an improvement project, an organization realizes that simply upgrading an existing process is insufficient to meet customer quality expectations.

An organization recognizes a chance to launch a new product or service. Increase

Management of processes

Process management is sometimes the most difficult and time-consuming aspect of Six Sigma since it necessitates a fundamental shift in how a business is organized and run.

Generally speaking, process management includes:

Outlining procedures, important client needs, and process "owners."

Comparing performance to key performance indicators and client expectations.

Data analysis to improve metrics and improve process management systems.

Managing the performance of a process by keeping an eye on its inputs, operations, and outputs and reacting promptly to issues and changes in the process.

4. Variability along with processing capability

The process capability curve is bell-shaped, with a larger value at the middle and lower values at both ends proximity.

1. Process capacity is the combined effect of
2. Insufficient process capabilities.
3. Inadequate measurement capability.
4. Variation in supplied materials.
5. Inadequate process control.

When all four elements fall inside the LSL and USL limits, the process is considered competent. When the aggregate effect of four factors goes below LSL and higher, it leads to process defects, which are undesirable.

When errors are found during the process, there are two options: reject or rework. Both solutions need significant financial and time investment.

The Effects of Process Variability
 An increase in the number of defects
 Decrease in Yield
 A higher cost of production
 A greater cycle time

5. Six Sigma Lean

Lean and Six Sigma (6 s), two essential business techniques for improving an organization's standards and output, work together to form LSS. By concentrating on procedure execution elements that are genuinely essential, LSS is a basic method utilized to find and remove mistakes and malfunctions within an organization.

Like Six Sigma, lean is a method used by commercial organizations to streamline manufacturing and production operations. Eliminating unneeded and inconvenient processes from the production process is a key component of lean manufacturing, which focuses solely on those that directly improve the final product.

Lean offers methods for improving value, reducing waste, and improving flow in order to increase efficiency.

Evaluates value from the consumer's perspective. Lean places a strong emphasis on overall improvement.

Decreases inventory, lead times, and space needs.

6. Comparison of lean and 6 sigma^[7,23]

Table 2: Comparison Of The Most Important Attributes Of Lean And Six Sigma.

feature	lean	Six sigma
Main Emphasis	reducing waste and increasing the effectiveness of the organization.	Removing flaws and decreasing process variance
Strategy.	employs defined procedures and tools and include everyone in the process of performance improvement	data-driven approach with a statistical dependability focus.
Techniques.	system for improving performance	heavily dependent on accurate and trustworthy data
Relationship.	parallel methods with similar Japanese inspirations.	Lean Six Sigma is frequently created by combining Lean
Optimal Use Case.	eliminating processes that don't offer value to improve flow and speed.	addressing the underlying causes of discrepancies and quality problems

7. Six sigma methodology^[11,23,39]

To improve processes, the DMAIC (Define, Measure, Analyze, Improve, and Control) system is utilized. The DMAIC process, which stands for define, measure,

analyze, improve, and control, includes recognizing the challenge you decided to resolve, assessing current approaches, selecting and putting into effect a solution, and maintaining that solution carrying forward.^[8]

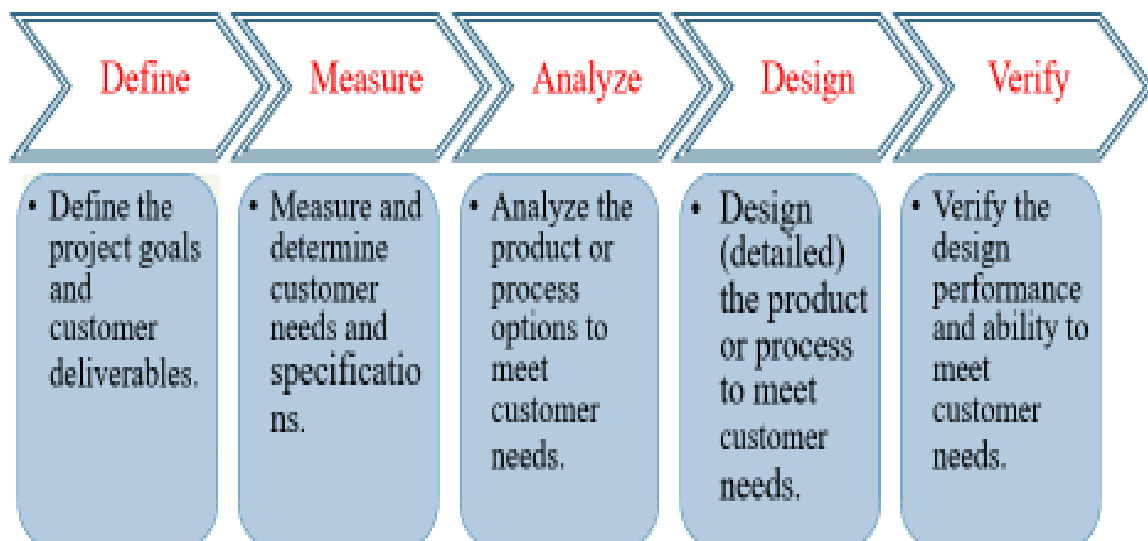


Figure 4: Dmadv Methodology.

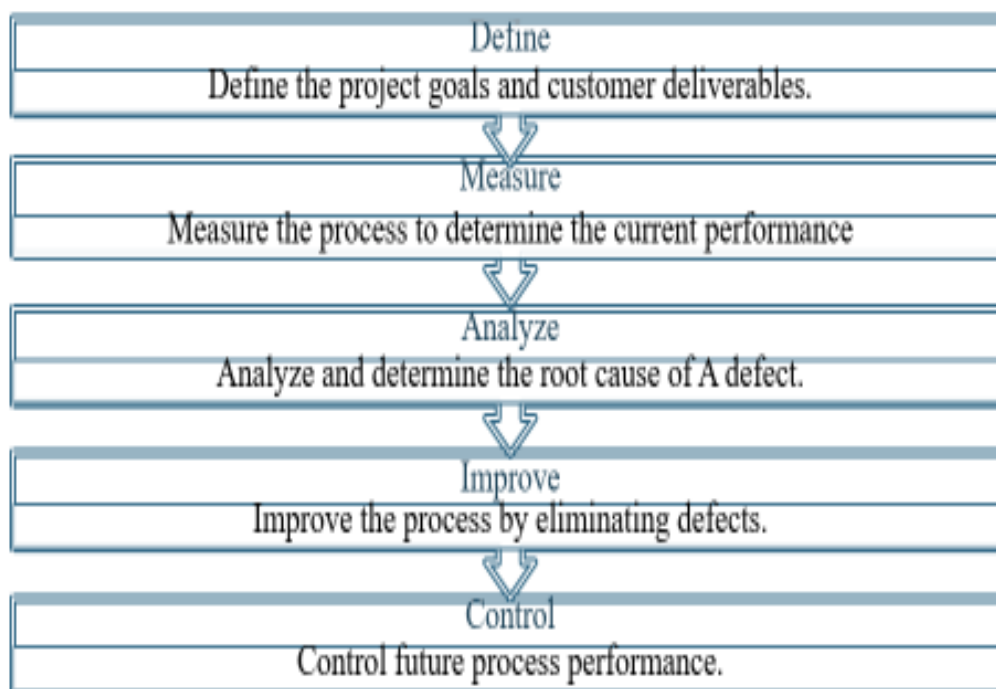


Figure 5: DMAIC Methodology.

8. Six sigma tools

CRITICAL-TO-QUALITY (CTQ) AND VOICE OF CUSTOMER (VOC)^[25,12]

At the beginning of the defined phase, Voice of Customer (VOC) is collected to define requirements, Expectations, comments, preferences of the customer for the Product or service before actually starting of Implementing The idea. Different methods are used to

collect VOCs. Special Teams like marketing, IT, etc. Are used to collect and file VOCs.^[25]

CTQ's are known as critical-to-quality which shows the need of the customer regarding different measurements. CTQ's are the part of VOC where a chart is made regarding different Needs of the customer and what are the required inputs to be Given to get desired outputs. Let us understand CTQ and VOC with an easy example.

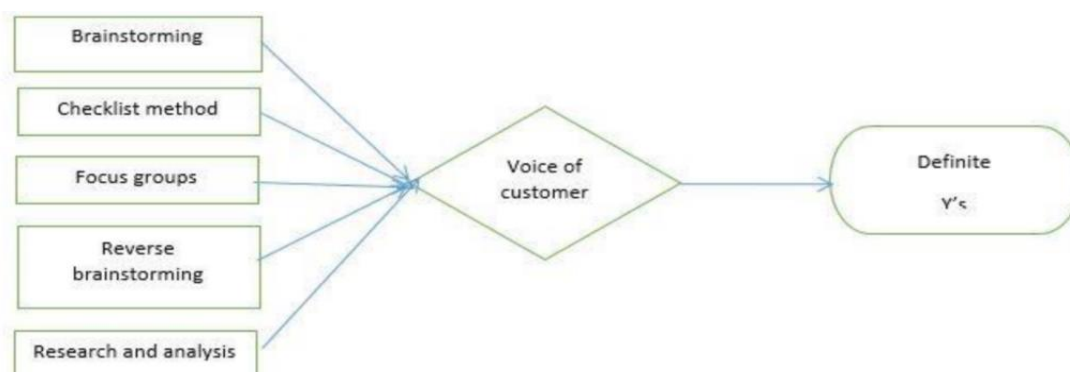


Figure 5: Voice of Customer.

CTQ Tree

VOC: "I have to wait for 1.5 hrs. For my pizza to Arrive"
 CTQ name: - Delivery time
 CTQ measure: - Hours and Minutes (HH: MM)
 CTQ requirements: - less than 45 minutes to deliver Pizza
 Defect: - 5 pizza delivery per hour
 Unit: -pizza
 Opportunity: - decrease preparation time, increase Oven temperature, take a shorter route, decrease baking Time

A. SIPOC DIAGRAM^[12,17]

SIPOC is not just an arrangement of letters but it is the Process that is done initially to give formal and legal Information to the person unfamiliar with the process. SIPOC Diagram is an overview of the whole system from the supplier to the consumer; this helps in getting the idea of the Company's interaction outside the premises. This is the eagle's Eye view of the company's interaction and relation with Suppliers and consumers.

SIPOC diagram consists of 5 elements as the name suggests That is Supplier, Input, Process, Output, Consumer.

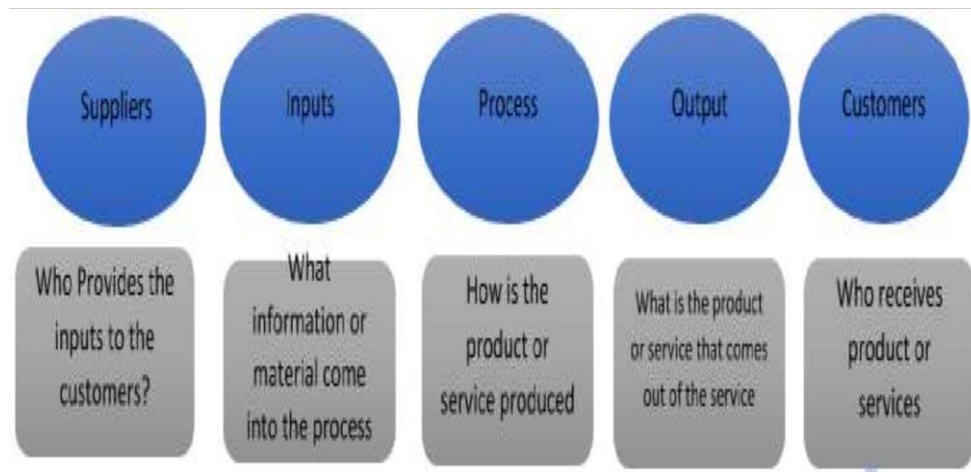


Figure 6: SIPOC Diagram.

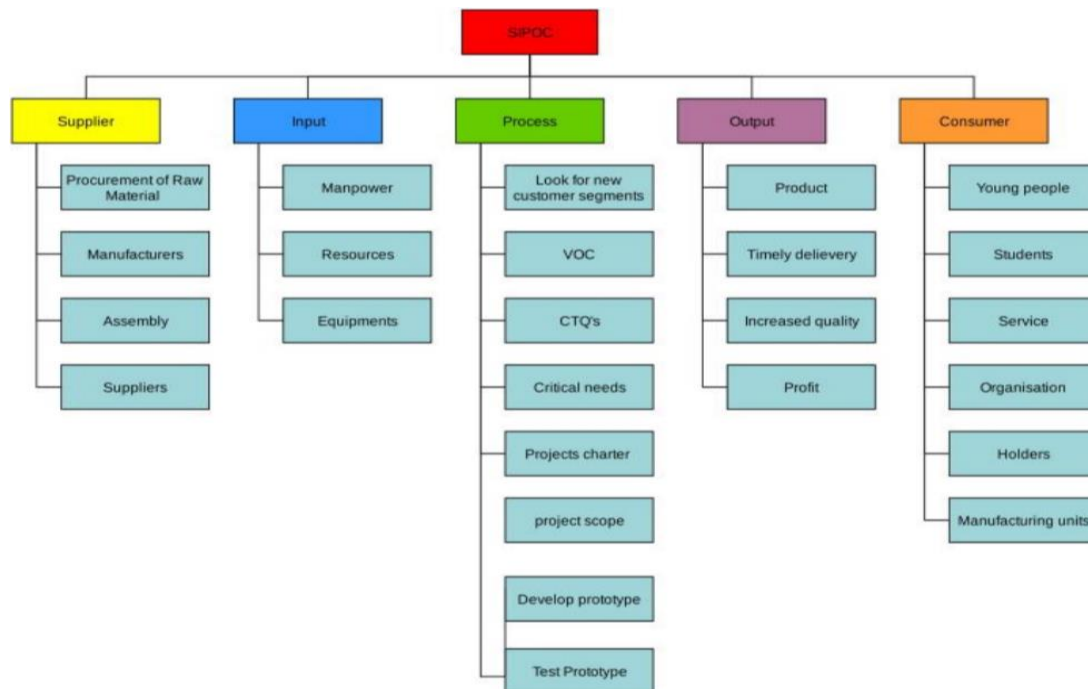


Figure 7: SIPOC Diagram Components.

MEASUREMENT SYSTEM ANALYSIS (MSA)^[11,17]

During the measurement phase, not only taking the measurements, is important but it is mandatory for the system to be Accurate throughout the process. This accurate reading will directly affect the Improve and Control phase. To ensure the Consistency and accuracy of data, different charts are used by inserting and running different data using software like Minitab.

Different terminologies used in MSA are:

Discrimination- Minimum incremental difference between two measured values.

Accuracy: Difference between baseline value and observed value.

Stability- The observed value of at least 2 Measurements by two operators should be the same.

MSA plays a very important role in six sigma. It helps in Determining the variance by using the mathematical and Theoretical analysis by software to determine the amount of Error in comparison to baseline.

There are 5 types of Parameters to observe: -

1. Reproducibility
2. Stability
3. Linearity
4. Repeatability
5. Bias

The error to be detected depends on two things.

- 1) The instrument used for measurement. (repeatability)
- 2) The person operating the instrument. (Reproducibility)

How much error is acceptable in MSA?

Less than 10% is considered as accurate

10% to 30% is considered acceptable after studying the importance of the project, cost, use, etc.

More than 30% is rejected and the error must be Corrected before applying.

The only purpose to use MSA in six sigma is to get Accuracy, precision, and stability in the process to match the Sigma level DPMO.

B. DESIGN OF EXPERIMENTS (DOE)^[17]

Design of experiments (DOE) is the six-sigma tool used in Analyze phase. The main objective of DOE is to

observe and modify the input variable by monitoring the change in output.

DOE give the exact change in the final product by changing the input.

The process of DOE is simple and visual hence it is easy to Decode. The process consists of 3 major steps such as

Factors-Factors are the change in input which is Decided by project team during the brainstorming Session.

Levels-Levels are just the number of factors that can Affect the process success. They are the settings at Which the experiments are to be carried out.

Response-The final step is to evaluate the output of DOE and discussion with the respective department Regarding improvements of the process and choosing the best response to eliminate the error.



Figure 8: Design of Experiment.

C. STATISTICAL PROCESS CHART (SPC)

After completion of all the phase in DMAIC the final process and continuous process will be construction and monitoring of statistical process control charts (SPC charts). Control Phase according to theory is the easiest phase, while it is most Difficult phase in six sigma methodology. Constant Monitoring and data are done using the time frame. Each Constraint is measure with respect to time. After collection of Data there are numerous control charts to select and use.

Construction of control charts include one mid line, one Bottom line and one top line. The top line is called upper Control limit (UCL) and the bottom line is known is lower Control line (LCL). Both the UCL and LCL can be derived from the previous data.

Plotting of data in control charts are simple

- 1) Open software for producing control charts
- 2) Input UCL and LCL for the chart
- 3) Input data recorded
- 4) Select okay and plot the chart.

There are certain conditions that can be observed in the Charts which will prove the uncertainty of the process.

- 9 points in a row on the same side.
- 6 points in a row all increasing or decreasing.
- 14 points in a row fluctuating up and down on the Same side.
- 2 out of 3 points having more than 2 standard Deviations from centre.
- 4 out of 5 points more than 1 standard deviation from centre.

9. Designing of six sigma: ICOV approach

The four main steps of the Designing for Six Sigma methodology we employ at the micro level are referred to as ICOV tool

1. Identify.
2. Characterize.
3. Optimize.
4. Validate.

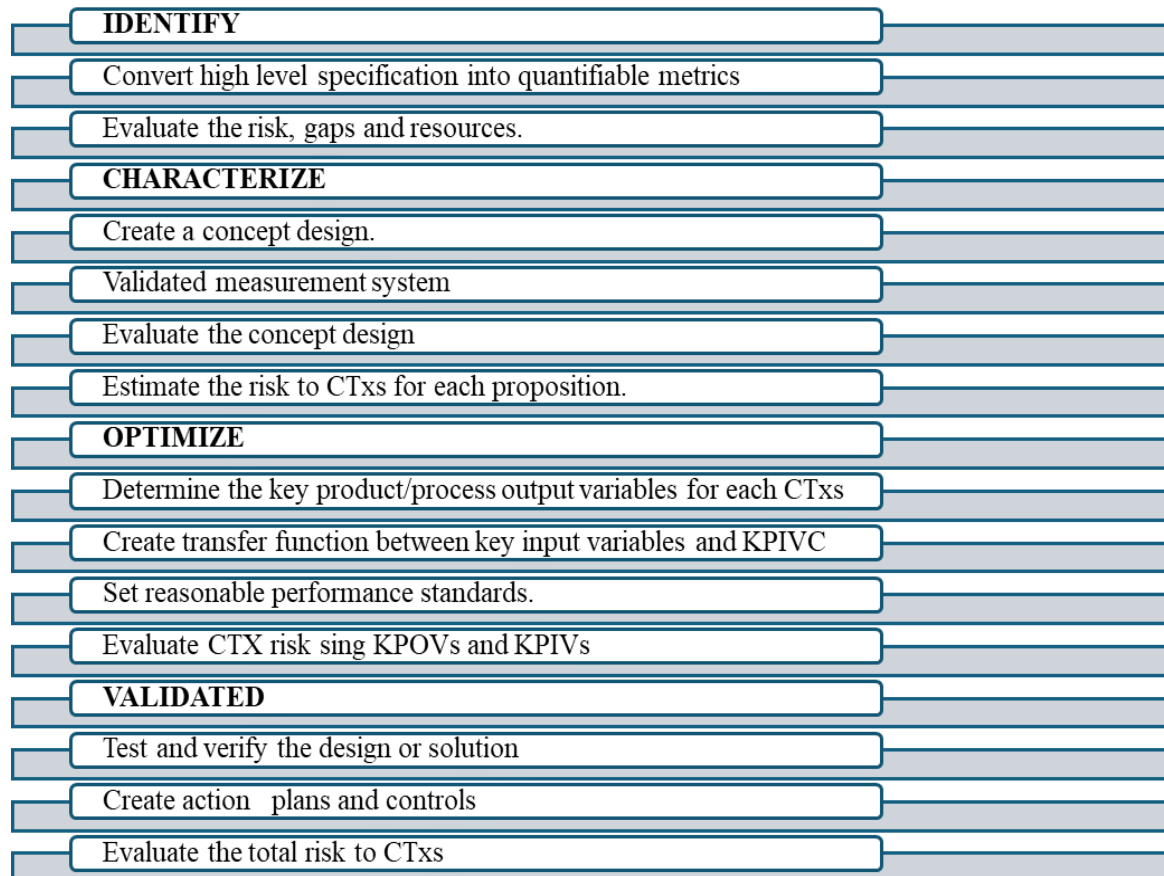


Figure 9: IVOC TOOL.

10. SIX SIGMA SKILL LEVELS

The belts were modified to identify the various six sigma proficiency levels. Let's examine the many belt types, the kinds of training that each belt has undergone, and how each belt contributes to the application of six sigma. In order of expertise, the belts are:

1. **White belt**
2. **Yellow belt**
3. **Green belt**
4. **Black belt**
5. **Master black belt**

Let's now examine each belt in more depth.

White belt

The fundamental six sigma principles, such as quality and process thinking, are introduced during white belt training.

Knowledge-based certification is what white belt training involves.

During white belt training, an overview of six sigma is provided.

White belt training stimulates curiosity and comprehension of six sigma.

Yellow belt

The DMAIC approach is introduced during yellow belt training.

The straightforward procedure and high-quality equipment are explained. For instance, the idea of variety, process mapping, voice-of-customer analysis, and brainstorming for root cause analysis.

Yellow belts receive training on how to use these tools to conduct and assist improvement sessions.

They participate in a green belt DMAIC program as team members.

Green belt

Participants in green belt training go through every stage of DMAIC.

Data analysis using statistics is taught in addition to process and quality tools.

Green belt participants are already assigned the DMAIC project when they arrive for training. During training sessions, they will incorporate what they have learned into their work.

Green belt members receive training to oversee and manage DMAIC projects on a part-time basis.

Black belt

Black belts are experts in six sigma who work full-time.

The upper management assigns them complicated tasks, which they oversee and complete.

They receive instruction in sophisticated statistical and quality methods used in six sigma. For instance,

experiment design, inferential statistics, and process capacity (DOE).

Master black belt

training in advanced statistical analysis, project management, process simulation, and change management is provided to master black belts.

11. Case study

Aim: -Implementing 6 sigma in a Functional Organization to Address Tablet Breakage Complaints.

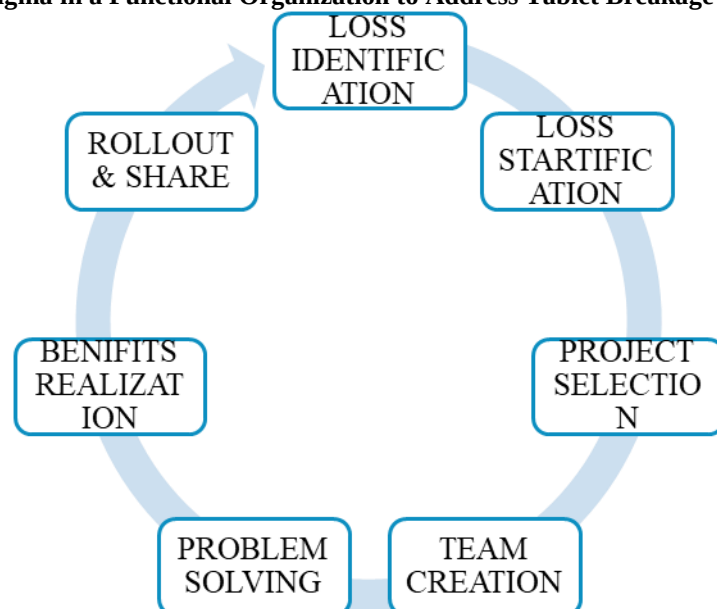


Figure 10: DMAIC Framework.

A seven-step internal resolving issues framework based on the D, M, A, I, and C approach that incorporates Lean & Six Sigma techniques.

Loss Identification: Since the packing department was identified as a bottleneck, there are 11.6 days of work in progress.

Due to their frequent occurrence and effect on production line delay, short pauses brought on by sensor triggers or product entrapment are classified as chronic stops.

These issues lead to a backlog of work in the packaging department, a high rate of repeats, and delayed production. The crew still doesn't know what is generating these issues, though.

The team's KPIs are quality, performance, and availability. The packaging division usually produces 5.4 million blisters per week, which is 1.1 million fewer than what the buyer requests.

Loss Stratification: Three packaging lines did not exhibit the tablet feed issue because of different manufacturing settings and equipment. When shortstops linked to pill feed were observed on each of the six blister lines, they became more apparent. In order to

They coach and train the remaining members of the company in six sigma.^[6]

prevent product delays, it suggests a significant issue that requires prompt action. The lessons learned from fixing a problem on one line can be applied to solve problems on all lines, proving the need to fix problems on all lines.

Project selection: After the problem statement was created and evaluated, it was determined that tablet feed issues were the primary cause of layoffs in the packing area line. Over the course of four months, these issues caused 335 hours of downtime, or an average of 20 hours per week, with packaging line C80/2 accounting for 72 hours of that layoff.

Team creation: The selection of the team for a "Cantered Enhancement" project was based on their subject-matter competence, problem-solving skills, and comprehension. A weekly oversight method was created to keep every participant informed.

Process technicians, specialized engineers, and operating personnel were involved to ensure that production line components and technical assessment were appreciated.

Problem-Solving: During each shift, the study team performed a checklist exercise using product 10C821 according to the C80/2 manufacturing process.

Approach: It was discovered that broken, incomplete pills were the most frequent cause of stoppages. However, if a half table gets into the feeding way, it will likely face longitudinally and spin 90 degrees, blocking the feed chute.

The packaging section is the last step in the manufacturing process, when the final product is inspected to ensure it meets specifications. 50% of the 751 mistakes that were found originated from the coating

division or happened during transportation to the warehouse.

According to the study, 70% of tablet breakage incidences occurred in nutrient bowl A and top feeder regions during the packaging process.

Improving the strength of tablets is an easy solution to prevent them from breaking, and it aligns with Six Sigma techniques to identify the actual cause of tablet breakage online.

Benefits Realization & results: Following the completion of the root cause process, the following actions were taken:

Table 3: Observation of Six Sigma Approach.

Operation	Causes
Perform distorting Trial on riddle plate.	It is possible to remove 79% of the broken tablets that were found during packing.
Accomplish the maintenance check, install the appropriate platens, and assign storage spaces.	Incorrect-sized platens can't effectively eliminate half-tablet flaws. There is nowhere to store platens to make switching over easier.
To make changing between different-sized tablets easier, allow platens to be stored.	Cross-line plate sharing is an inefficient system. Combining different sets
Maintain consistency in the variables of the manufacturing line transportation system.	There are no set guidelines. Standard optimized settings will reduce setup output variance and improve manufacturing output quality.

Benefits

Product backlog for packing decreased to 84%.
For each batch, 8.3% more cycles had been completed.
The time required to change lines decreased by 25%.
More lines were obtainable by 11%.

Rollout and share

The project's measures are currently being evaluated for implementation throughout the production site in the effervescent department because of the similar procedure.

Implementation of 6 s in European pharmaceutical sector

The use of 6 s in the European pharmaceutical sector entails an organized approach to process improvement, defect reduction, and raising overall pharmaceutical product quality.

The European pharmaceutical business has implemented Six Sigma to comply with legal requirements, promote operational effectiveness, and assure the superior safety and quality of its products. Guidelines for pharmaceutical quality, safety, and efficacy are determined by the European Medicines Agency. To achieve conformity Six Sigma implementation should follow these recommendations 30,31

Case Study: An International Pharmaceutical Firm with a significant share of the market in Europe, Astra Zeneca, started a Six Sigma journey to improve its production methods and provide the greatest possible quality of the product.

Define Phase: Astra Zeneca started by noticing a crucial problem with tablet coating, one of their production processes. High tablet weight fluctuation was the problem, which might raise issues with quality and regulation. Defining the issue and how it affects product quality was the goal of this phase.

Measure Phase: The company gathered a lot of information on tablet coating procedures, including information on variations in tablet weight, equipment settings, external factors, and operator behaviour. This stage intended to precisely determine the problem's scope.

Analyze Phase: AstraZeneca discovered the underlying reasons for variations in tablet weight using statistical methods. It was found that operators used various ways to modify parameters and that the equipment's specifications were not adjusted. The issue was additionally triggered by variations in the surrounding environment.

Improve Phase: The business made adjustments in response to its findings. It established specific operational processes, standardized equipment settings, and operated under tighter control over the environment. The aim was to lower the range of tablet weights. Following the modifications, AstraZeneca maintained a close watch on the tablet coating procedure to make sure the modifications were persistent.

Control Phase: In order to avoid the issue occurring again, control charts and proceeding measuring methods were also built.

Current scenario of 6 s in Uk pharmaceutical industry

Manufacturers in the pharmaceutical sector implement 6 s or lean Six Sigma to save operating costs, improve processes, and guarantee they deliver excellent customer service.

Case Study: How GlaxoSmithKline Reduced Manufacturing Time By Implementing the Six Sigma Strategy.

The second-largest pharmaceutical firm in the world, Glaxo Smith Kline, with headquarters in the UK, uses 6 s as one of its methods to a wide range of various jobs in a number of divisions to enhance operational effectiveness.^[29]

Businesses, like GSK, may implement process improvement strategies that concentrate on producing almost perfect goods and processes by minimizing defects according to the Lean Six Sigma approach. Lean Six Sigma, for instance, may enhance research and development activities, shorten cycle times (reduce manufacturing time for a certain product from 120 days to 30 days), boost sales and marketing campaigns, and lower manufacturing costs and procedures while maintaining profitability in the pharmaceutical industry.^[29]

At GSK, all three studies were employed simultaneously:

- Lean Six Sigma was producing significant, measurable improvements to the company in GMS (Global manufacturing and supply); In the consumer healthcare sector, project management was significantly enhancing the project performance; and
- Throughout the Organization, (Organizational Development) teams were promoting increased degrees of participation and successful initiatives for change.^[34]
- None of the three subjects, however, were adequate to carry out GSK's strong ambition on their own. Lean Six Sigma, for instance, was capable of delivering savings and efficiency but struggled to change the general mindset via training alone. However, a strictly OD strategy carried the potential of neglecting direct, observable business indicators and outcomes in favor of building skill and behaviors.^[9]

12. CONCLUSION

Six Sigma is a well-organized, statistical method aimed at achieving almost perfect results by minimizing variations in processes and removing defects. It was first created by Motorola and later improved by General Electric. This method uses the DMAIC framework—Define, Measure, Analyze, Improve, and Control—to bring about clear financial and operational improvements. The text explains how organizations combine Lean principles with Six Sigma to increase efficiency and deliver value to stakeholders while

keeping high quality standards. The success of this approach is backed by various specific tools, such as SIPOC diagrams and Measurement System Analysis, along with a certification system that shows different levels of expertise. In-depth examples from the pharmaceutical industry show how these methods are used to tackle difficult production challenges and meet regulatory requirements. Overall, the text presents Six Sigma as a developing leadership idea that is crucial for modern business performance and ongoing improvement.

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