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Review Article

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Six Sigma: An Emerging Approach in Pharma Industry

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ABSTRACT

Six Sigma as a powerful business strategy has been well recognised as an imperative for achieving and sustaining operational and service excellence. Six sigma has made a huge impact on industry but still the academic community lags behind in its understanding of this powerful strategy. In other words, six sigma lacks a theoretical understanding and hence it is our responsibility as academicians to bridge the gap between the theory and practice of six sigma. Six sigma methodology utilises the tools and techniques for fixing problems in business processes in a sequential and disciplined fashion. Each tool and technique within the six sigma methodology has a role to play and when, where, why and how these tools or techniques should be applied is the difference between success and failure of a six sigma project. Six sigma utilises the concept of statistical thinking and encourages the application of well-proven statistical tools and techniques for defect reduction through process variability reduction methods.

Key words-*Six Sigma, DPMO, DMAIC Methodology, DMADV Methodology, Process Management.*

HISTORY:[3]

Six Sigma is a set of tools and techniques/strategies for process improvement originally developed by Motorola in 1981, credit for coining term "Six Sigma" is given to Bill Smith a Motorola engineer (Summers 2006). In the early and mid-1980s, Motorola engineers decided that the traditional quality levels for measuring defects in thousands of opportunities didn't provide enough information. A new standard of measuring the defects per million opportunities was developed and thus created the methodology and needed cultural change associated with it. Six Sigma became well known after Jack Welch made it a central focus of his business strategy at General Electric in 1995. The Six Sigma program was center around manufacturing and operational productivity gains. Honeywell's Six Sigma model had been modified and expanded to be used for the market place and business .Six Sigma today has been used in different sectors of industry.

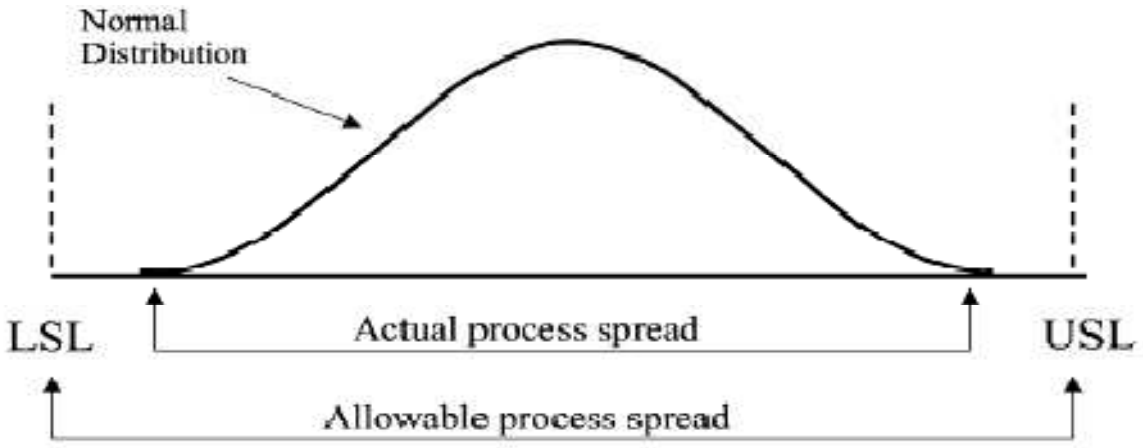
INTRODUCTION:[4]

Today pharmaceutical companies are faced with demanding tasks such as adjustment to the unstable and turbulent market in times of economic crisis, as well as aiming to meet the needs of their users in maintaining their health. In order to meet all requests and requirements and respond to the challenges these companies are struggling to find ways to reduce internal costs and cycle times by providing high quality services to users, through innovative design and efficient response to the unexpected increase in demand for certain products. However, balancing between the desire to reduce costs, on one side and innovative design, on the other is very difficult. Six Sigma was developed based on preceding Quality Management concepts such as Total Quality Improvement, Quality Control and Zero Defects.The methodology measures a process in terms of defects, uses statistical tools to identify the vital factors that matter most for improving the quality of the process and attempts to eliminate defects.

Pharmaceutical manufacturers are looking in Six sigma principles for significant improvement of operational efficiency and quality, while facilitating compliance. To ensure a strong position in the market and to provide competitive advantage they are looking to increase the efficiency of their operational and manufacturing processes – optimizing resources, improving efficiency, reducing waste and controlling inventory. Current developments in the pharmaceutical industry are in favor that it is now an ideal time to turn to the principles of Six Sigma.

Six sigma: [7, 8, 10]

The term "six sigma process" comes from the notion that if one has six standard deviations between the process mean and the nearest specification limit, practically no items will fail to meet specifications. This is based on the calculation method employed in process capability studies. Capability studies measure the number of standard deviations between the process mean and the nearest specification limit in sigma units, represented by the Greek letter σ (sigma). As process standard deviation goes up, or the mean of the process moves away from the center of the tolerance, fewer standard deviations will fit between the mean and the nearest specification limit, decreasing the sigma number and increasing the likelihood of items outside specification.Six Sigma aims to have processes where the mean is at least 6σ away from the nearest specification limit.



The widely accepted definition of a six sigma process is one that produces 3.4 defective parts per million opportunities (DPMO). A process that is normally distributed will have 3.4 parts per million beyond a point that is 4.5 standard deviations above or below the mean (one-sided Capability Study). This implies that 3.4 DPMO corresponds to 4.5 sigmas, not six as the process name would imply. This can be confirmed by running on Quik Sigma or Minitab a Capability Study on data with a mean of 0, a standard deviation of 1, and an upper specification limit of 4.5. The 1.5 sigmas added to the name Six Sigma are arbitrary and they are called "1.5 sigma shift". The higher sigma level, the smaller probability level of defects occurs in products.

In a Capability Study, sigma refers to the number of standard deviations between the process mean and the nearest specification limit, rather than the standard deviation of the process, which is also measured in "sigmas". As process standard deviation goes up, or the mean of the process moves away from the center of the tolerance, the Process Capability sigma number goes down, because fewer standard deviations will then fit between the mean and the nearest specification limit. [7]

The process capability have bell shape curve, which has higher value at center while lower value at both proximity. The process capability is combined effect of

1. Inadequate process capability.
2. .Inadequate measurement capability.
3. Supplied material variation.
4. Inadequate process control.

When all these four factors combine, effect falls within LSL (Lower Specification Limit) &USL (Upper Specification Limit) the process is said to be capable. When the combine effect of four factors falls below LSL and above causes defect in the process and which is not desirable. When defects are detected in process, there are two options either reject it or rework on it. Both the options are expensive in terms of money& time.

Definitions of six sigma: [1, 2, 9,14]

- Six Sigma is an organized and systematic method for strategic process improvement and new product and service development that relies on statistical methods and the scientific method to make dramatic reductions in customer defined defect rates.[2]
- Six Sigma is a methodology of continuous improvement aimed at reducing defects by using the model Define-Measure-Analyze-Improve-Control (DMAIC), which is further developed through the Design for Six Sigma, which is based on creating a robust design that meets customer requirements.
- Six Sigma is a formal methodology for measuring, analysing, improving, and then controlling or locking-in processes. This statistical approach reduces the occurrence of defects from a three sigma level or 66 800 defects per million to a Six Sigma level or less than four defects per million (Bolze, 1998).
- Six Sigma is a comprehensive, statistics-based methodology that aims to achieve nothing less than perfection in every single company process and product (Paul, 1999).
- Six Sigma is a disciplined method of rigorous data gathering and robust statistical analysis to pinpoint sources of error and ways of eliminating them (Harry and Schroeder, 1999).
- Six Sigma as an information-driven methodology for reducing waste, increasing customer satisfaction, and improving processes, with a focus on financially measurable results (As defined by Minitab in Goh, 2002).

Goals of Six Sigma: [4, 6]

Improving customer satisfaction

- Accelerating process cycle times and time-to market
- Reducing defects
- Controlling variation and improving predictability
- Reducing costs – without "unintended consequences"
- Improving end-to-end process management and measurement
- Offers potential to refine current approaches to supply chain improvement.
- Project-oriented methodology for solving problems using statistical tools; allows to compare different processes according to the sigma levels The quality improvement system, aimed at reducing errors and maintaining them at a low value, "Six sigma", meaning DPMO (DPMO = Defects per Million Opportunities)
- improved effectiveness and efficiency of processes, including e-commerce[17].

Six Sigma Methodologies: [5]

Six Sigma has two key methodologies: **DMAIC** and **DMADV**. DMAIC is used to improve an existing business process. DMADV is used to create new product designs or process designs in such a way that it results in a more predictable, mature and defect free performance.

DMAIC Methodology: [13]

DMAIC is a closed-loop process that eliminates unproductive steps, often focuses on new measurements, and applies technology for continuous improvement.

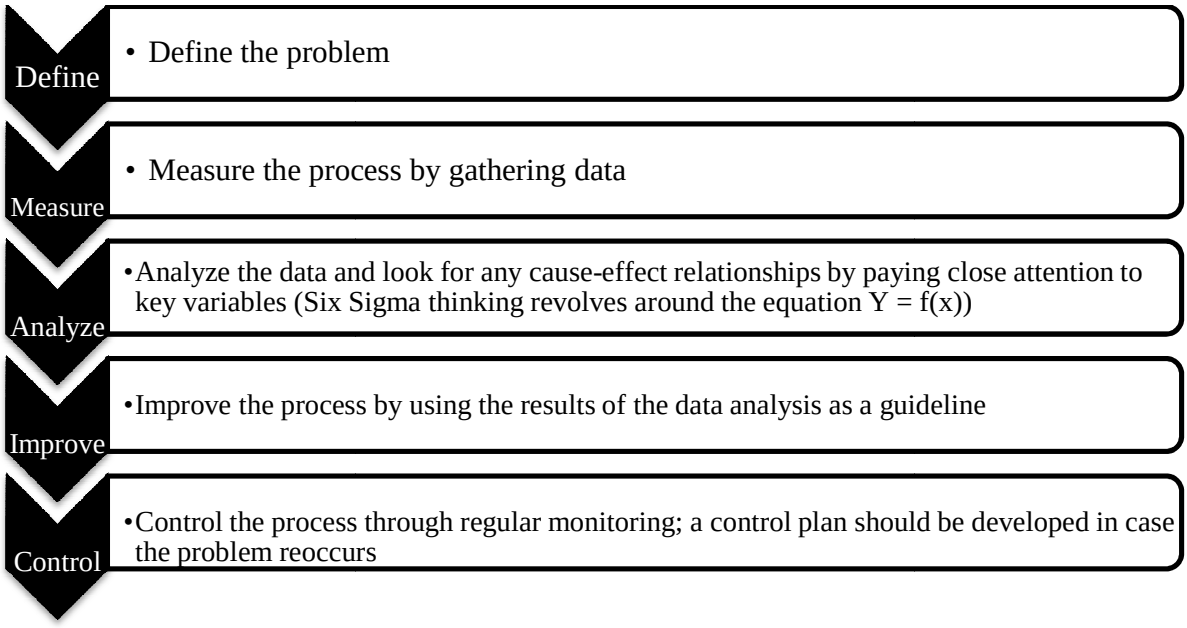
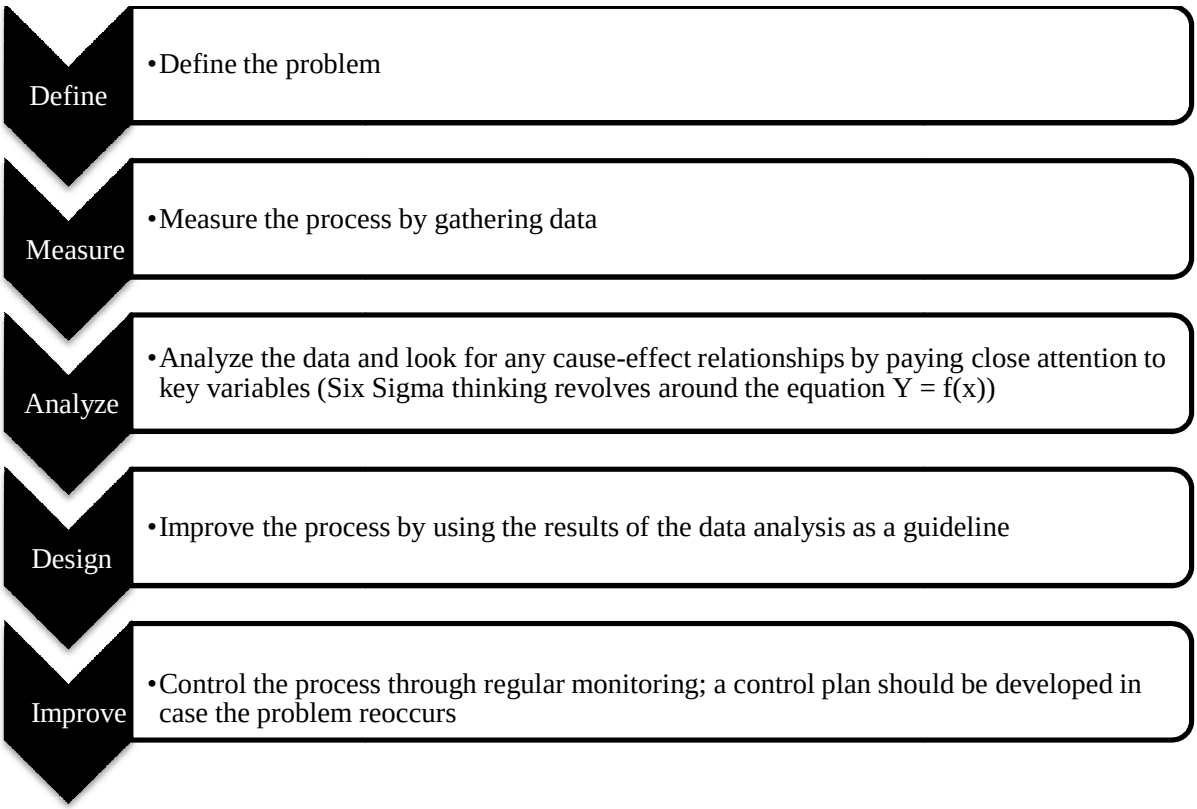


Table 1. Tools and Technique DMAIC Six Sigma

Steps	Key Process	Tools and Technique	Deliverable
Define	Define customer and customer requirements Define the process map and map the process to business plot Define the general problem Define the project timeline	Project charter Cause and effect diagram Process map SIPOC	Project charter General problem Identification Business process and plot Process mapping to business plot
Measure	Create data collection plan Collecting and comparing data to determine problem and process capability	Data collection matrix Measurement system analysis (MSA) Process capability analysis	Data needed Accuracy of measurement system and process Process capability in purpose to meet customer requirement
Analyze	Analyzing data and process to determine process variance Analyzing the root-cause problem Create the priority of root-cause problem as the improvement target	Cause and effect diagram Pareto analysis Control chart (current condition) Scorecard FMEA (current condition)	Root-cause problem Root-cause prioritization
Improve	Create potential alternative solution Select and create prioritization of alternative solution Test the solution Implement the solution	Control chart (current condition) FMEA (after improvement)	Potential risk The cause and effect of risk
Control	Create process control plan Implement the process control plan	Control plan	Stability control and process output

DMADV Methodology:



Implementation Of Six Sigma: [6,19]

There are three basic elements to Six Sigma:

- Process improvement
- Process design/re-design
- Process management

Each of the above three elements is examined in more detail below.

Process improvement

The purpose of process improvement is to eliminate the root causes of performance deficiencies in processes that already exist in the organization . These performance deficiencies may be causing real problems for the organization, or may be preventing it from working as efficiently and effectively as it could.

Process design/re-design:

Sometimes simply improving existing processes is not enough, and, therefore, new processes will need to be designed, or existing processes will need to be redesigned. There are several reasons why this could be necessary:

- An organisation may choose to replace, rather than repair, one or more of its core processes.
- An organisation discovers, during an improvement project, that simply improving an existing process will never deliver the level of quality its customers are demanding.
- An organisation identifies an opportunity to offer an entirely new product or service.

Process management-

Because it requires a fundamental change in the way an organisation is structured and managed, process management is often the most challenging and time consuming part of Six Sigma.

In general, process management consists of:

● Defining processes, key customer requirements, and process "owners".

● Measuring performance against customer requirements and key performance indicators.

● Analysing data to enhance measures and refine the process management mechanisms.

● Controlling process performance by monitoring process inputs, process operation, and process outputs, and responding quickly to problems and process variations.

Application in Pharma Industry:[20]

In the past few years, a few pharmaceutical companies started adopting Six Sigma mainly to reduce cycle time and cost.

The following key strategies are suggested to launch a Six Sigma effort within the pharmaceutical industry:

- Begin to change the traditional ways of conducting clinical trials by campaigning for the implementation of needed integration initiatives through the use of Six Sigma with a commitment from top down leadership.
- Focus on the integration of technology and workflow improvement in meeting challenges and extend new ventures not possible using conventional isolated implementation of technology or homegrown process improvement methodologies.
- Provide tested research approaches for the quantitative evaluation of clinical development and process improvement strategies, the integration of which highly correlates with strong financial performance.

One success story is on the supplier and material approval process in a packaging division of one company. The process of identifying and certification of a supplier of packaging materials usually takes 12 months because of the very complex process involved. The Six Sigma team was formed and traced 4 pilot products and focused on the critical paths, analyzed and identified process problems. Using Six Sigma methodology, they were able to streamline the process and were able to reduce the cycle time from twelve to five months and realized significant savings[20].

REFERENCES

1. Chakraborty, A. and Chuan, K. Total Quality Management and Six Sigma, Intech ltd., 2012, 247-286.
2. Linderman, K. Schroeder, R. G. Zaheer, S. and Choo, A.S. Six Sigma: a goal-theoretic perspective, *J Oper Manag,* **21**: 193–203(2003)
3. Henderson, K.M. Evans, J.R. Successful implementation of Six Sigma: benchmarking General Electric Company, *Benchmarking: an International Journal*, **7**: 260-282(2000)
4. Rusko, M. Králiková,R. Application of Six Sigma Method To EMS Design, Faculty of Materials Science and Technology In Trnava, **30**: 39-44(2011)
5. Ratnaningtyasa, D.D. and Surendrob, K. Information Quality Improvement Model on Hospital Information System using Six Sigma, *Procedia Technology,* **9**: 1166 – 1172(2013)
6. Pokharkar, D. Jadhav, V. Gholve S and Kadam V. Six Sigma: Golden Opportunity for Pharmaceutical Industry, *Int J PharmTech Res,* **2**: 1160-1164(2010)
7. Janil, P. Chauhan, S. Patel, G. Sant, L. Patel, D. *et.al.* Sigma six: a quality control tool in pharma industry, *International journal of universal pharmacy and bio sciences,* and **2**: **59**-69 (2013)
8. Antony, J. Banuelas, R. Key ingredients for the effective implementation of Six Sigma program, *Measuring Business Excellence,* **6**: 20-27(2002)
9. Antony, J. Antony, F.J. Kumar, M. Six sigma in service organizations Benefits, challenges and difficulties, common myths, empirical observations and success Factors, *Int J Qual Reliab Manag,* **24**: 294-311(2007)

10. Motwani, J. Kumar, A. Antony, J. A business process change framework for examining the implementation of six sigma: a case study of Dow chemicals, The TQM Magazine, **16**: 273-283 (2004)
11. De Feo, J. Bar-El, Z. Creating strategic change more efficiently with a new Design for Six Sigma process, *J Change Manag*, **3**: 60-80 (2002)
12. www.uwstout.edu/content/lib/thesis/2009/2009faustj.pdf
13. Desai, T.N. Shrivastava, R.L. Six Sigma – A New Direction to Quality and Productivity Management, Proceedings of the World Congress on Engineering and Computer Science, 2008, 1-6.
14. Brady, J.E. Allen, T.T. Six Sigma Literature: A Review and Agenda for Future Research, *Qual. Reliab. Engng. Int.*, **22**: 335–367 (2006)
15. Antony, J. Some pros and cons of six sigma: an academic perspective, *The TQM Magazine*, **16**: 303-306 (2004)
16. Tenera, A. Pinto, L.C. A Lean Six Sigma (LSS) project management improvement model, *Procedia - Social and Behavioral Sciences*, **119**: 912 – 920(2014)
17. OECD, "Improving Value in Health Care: Measuring Quality," Health Policy Studies, 2010.
18. Pande, P. and Holpp, L. What is Six Sigma? McGraw-Hill, 2002, 2-6.
19. http://www.dti.gov.uk/bestpractice
20. Sharma, O.P. Gupta, V. Rathore, G.S. Saini, N.K. Sachdeva, K. Six Sigma in Pharmaceutical industry and Regulatory Affairs: A Review, *Journal of Natura Conscientia*, **22(1)**: 273-293 (2011)