



Review Article

Six Sigma: A novel approach to pharmaceutical industry

M. S. Charde*, R. T. Bande, A. S. Welankiwar, J. Kumar and R. D. Chakole

Government College of Pharmacy, Kathora Naka, Amravati-444604, (M.S.) India – 444604

*Correspondence Info:

Government College of Pharmacy,
Amravati, MS India 444604
Email : Jite1511@gmail.com

Keywords:

Six sigma,
DMAIC,
DMADV,
DPMO.

Abstract

The statistical concept, six sigma is used to define problems systematically, provides tools to measure and influential factors and identifies the improvements that can be implemented easily. It is quality management tool which can be considered as a vision, a philosophy, a symbol, a metric, a goal, a methodology. It simply means a measure of quality that struggle for near perfection. It is a highly disciplined process that focuses on developing & delivering Near perfect product & services It is based on three element Process improvement, Process Design/re-design and Process management. When we use this technique for a process then process variation reduced to 3.4 DPMO (Defects per million Opportunities). Six sigma is divided in two sub methods DMAIC (Define, Measure, Analyze, Improve and Control) is improvement system for existing processes that doesn't meet specification. DMADV (Define, Measure, Analyze, Design, Verify) is used to develop new processes at six sigma level.

1. Introduction

Sigma is a term used in statistics to represent standard deviation, an indicator of degree of variation in a set of measurements or a process or a product. Six sigma is a statistical concept or a quality management approach that measures a process or a product in terms of defect at six sigma level and offers a way to focus on developing and delivering perfect products and services¹. The term 'Six Sigma' was coined by Motorola engineer named Bill Smith. Incidentally, 'Six Sigma' is a federally registered trademark of Motorola². It is a known fact that in a process with six sigma capability, process variation is not reduces more than 3.4 defects per million opportunities. Six sigma as a problem solving approach has been used in various fields to provide the fundamentals of variation management and reduction in order to assist in transforming established methodologies in to new and efficient techniques. It can be seen as: a vision; a philosophy; a symbol; a metric; a goal; a methodology⁵. It simply means a measure of quality that strives for near perfection. It is a disciplined, data-driven approach and methodology for eliminating defects (driving towards six standard deviations between the mean and the nearest specification limit).

2. Objectives^{3,4}:

- Reducing defects
- Controlling variation and improving predictability
- Reducing costs – without "unintended consequences"
- Improving end-to-end process management and measurement
- To increase customer satisfaction
- To enhance competitiveness
- To change organizational culture
- To make advancements toward formal quality award application
- To develop organizational competencies
- To improve organizational performance

3. Six Sigma Methods

DMAIC process (Define, Measure, Analyze, Improve, Control) is an improvement system for existing processes falling below specification and looking for incremental improvement.

DMADV process (Define, Measure, Analyze, Design, Verify) is an improvement process used to develop new processes or products at Six Sigma quality levels. It can also be implemented if a current process requires more than just incremental improvement.

1. DMAIC Process:

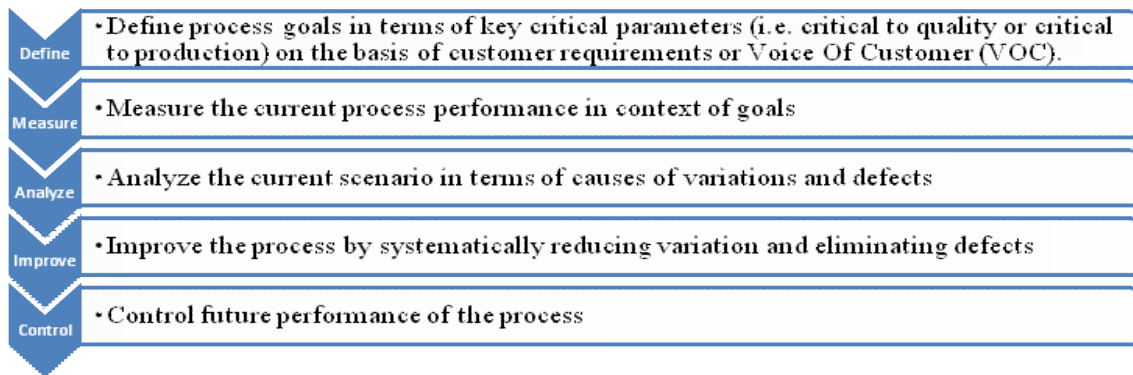
D - Define goals to improve the overall process between your company strategy and your customer's demands.

M - Measure your current processes. Collect relevant data on your current processes and then use this data as a baseline for future comparisons.

A - Analyze your relationship within the process. It is important to understand the relationship to determine factors that can ensure you keep your companies strategy in line with your customers demands.

I - Improve the process. It is important to constantly improve and optimize the process, using analysis and other techniques. One technique that is often used is Design of Experiments. (This is a technique that can help to test a hypothesis, using acceptable experimental design)

C - Control. It is important ensure that you can control and correct any variances avoiding possibly costly defects and loss of quality.



2. DMADV Process:

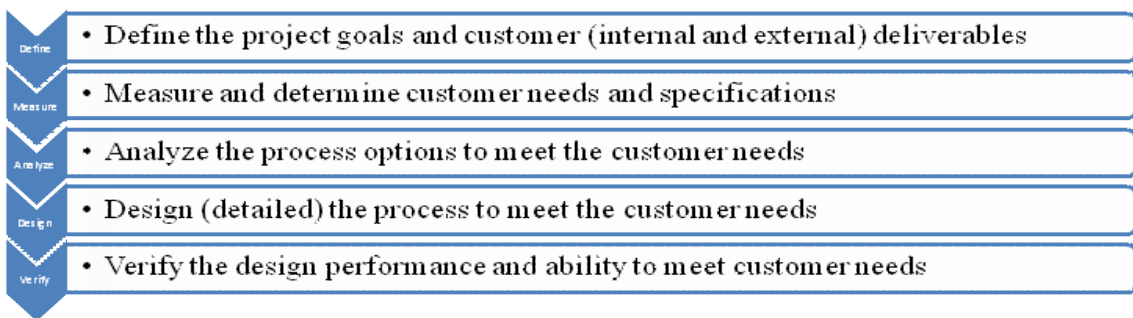
D - Define the project goals to improve the overall process between your company strategy and your customer's demands.

M - Measure your current processes. Collect relevant data on your current processes and then use this data as a baseline for future comparisons.

A - Analyze your relationship within the process. It is important to understand the relationship to determine factors that can ensure you keep your companies strategy in line with your customers demands.

D - Design the detailed process to meet customer needs

V – Verify the design performance and ability to meet customer need.



4. Use of DMAIC & DMADV:

The DMAIC methodology, should be used when a product or process is in existence at your company but is not

meeting customer specification or is not performing adequately. The DMADV methodology, should be used when a product or process is not in existence at your company and one needs to be developed & The existing product or process exists and has been optimized (using either DMAIC or not) and still doesn't meet the level of customer specification or six-sigma level.

Strategies 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

Process Calculation:

Step 1: Define Your Opportunities

An opportunity is the lowest defect noticeable by a customer. Typically, most products (and services) have more than one opportunity of going wrong. For example, it is estimated then in a drug product could have the following opportunities for error wrong API or wrong Excipients.

Step 2: Define Your Defects

Defining what a defect is to your customer is not easy either. You need to first communicate with your customer through focus groups, surveys, or other voice of the customer tools. Defect may be no product of standard quality or customer didn't have product available.

Step 3: Measure Your Opportunities & Defects

Suppose Opportunities (last year): 175,800 products Defects (last year): 400 products.

Step 4: Calculate Your Yield

Subtracting the total number of defects from the total number of opportunities, dividing by the total number of opportunities, and finally multiplying the result by 100 calculate the process yield.

Step 5: Look Up Process Sigma

The final step (if not using the iSixSigma Process Sigma Calculator) is to look up your sigma on a sigma conversion table, using your process yield calculated in Step 4.

Working of Six sigma:

Process improvement

The purpose is to eliminate root cause of defects or deficiencies in processes that already exist in organization. These deficiencies causes real problem for the organization so process improvement is necessary.

Process design/re-design

Sometimes simply improving existing process is not sufficient at that time we have design or re-design the process. The reasons why this is necessary

There are several reasons why this could be

- 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

Process management requires fundamental change in organization structure so it is 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.

Six Sigma and the Pharmaceutical Industry

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

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.

In 2001, the top deficiencies incurred during FDA audits in clinical trials, include the following:

- Non-compliance with protocol, e.g.; inclusion /exclusion criteria not met mistakes on randomization, etc.
- failure to report non-concomitant medications
- failure to maintain drug accountability
- failure to obtain proper informed consent
- failure to maintain adequate data in the CRF
- Source verification document not done properly or missing. These areas evidently need to be given more emphasis and attention. It would be interesting to see how Six Sigma can be applied in clinical trials and attain reduction in these common mistakes.

5. Conclusion

Six sigma being a cornerstone philosophy among world's leading corporation because it has proven itself by generating great business returns. It is one of the most important quality management approach which mainly leads to error minimization when the six sigma technique is applied then defects are minimized to 3.4 DPMO that is the reason why it is one of the best quality improvement method.

References

1. Palkar M, Rajadhyaksha P, Shah M, Shedge A, Goyal G. Application of six sigma in pharmaceutical industries. Presented at 59th Indian Pharmacy congress; 2007 Dec; Varanasi, India.
2. B. Greg *et al.* Six sigma for managers. New York: Mcgraw Hill; 2002
3. www.sixsigmaway.com
4. <http://healthcare.isixsigma.com>
5. Kaur G, Khanna S, Nasa A. Six sigma in Pharmaceutical regulatory affairs. Presented at 59th Indian pharmacy congress; 2007 Dec; Varanasi, India.
6. Deepak Poharkar et al. Six sigma: golden opportunity for pharmaceutical industries, *Int. J. Pharmtech. Res.* 2010. 2(2). 1160-64.
7. Sharma O.P. *et al.* Six sigma in pharmaceutical industry and regulatory affairs, *Journal of Natura Conscientia.* 2011. 2(1). 273-293.
8. Samuel, Philip and Lisa Modesitt. Leveraging next generation Six Sigma : addressing challenges in pharmaceutical industry.
9. Liu, Elliott. Breakthrough : Do clinical research the Six Sigma way.