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RECENT ADVANCES IN PHARMACY: SIX SIGMA APPROACH

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ABSTRACT

We provide an introductory overview of the Six Sigma development and improvement processes. A historical perspective is provided. Six sigma is a statistical concept which helps us to define the problems systematically, provides tools to measure and analyze the influential factors, identifies the improvements that can be implemented easily and ensure that the changes which have been made, are kept alive through a control process and maintains the gains over the time. Six Sigma have been utilized by manufacturing industries to decrease cost and improve quality and productivity by reducing variation and production defects. To achieve six sigma quality, a process must produce not more than 3.4 defects per million opportunities if the output is normally distributed. There are two six-sigma sub methods namely DMAIC and DMADV. Enhancing the quality and operational aspect of the manufacturing process is key and thus, many companies are integrating traditional six sigma. 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.

KEYWORDS: Six sigma, Sigma level, DMAIC, DMADV, Training.

INTRODUCTION

Process improvement initiatives have been in existence for quite some time and include Continuous Quality Improvement (CQI), Process Improvement (PI), Quality Assurance (QA), Quality Management (QM) and Re-engineering. In the mid-1900s, the term Six sigma was coined by a Motorola Engineer, Bill Smith, to describe a new quality control process that merged from the Total Quality Management (TQM) strategy and was very successful in improving profits. 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 and Lean Six Sigma, which is based on the processes and ways to increase their efficiency. Lean and Six Sigma as methodologies can be used independently or together. Today, many companies in different industries, both large and small, adopt Six Sigma and Lean as a regular way to improve the efficiency of design, manufacturing, business processes and intellectual property while reducing costs. Both concepts can be successfully applied in the pharmaceutical and medical device industry, in order to resolve the issue of unnecessary costs that limit profitable innovation.[1]

Six Sigma methods and techniques are applied in business & IT projects for product (Goods and Services) & process design (Define, Measure, Analyze, Design and Verify or DMADV) and improvements (Define, Measure, Analyze, Improve and Control or DMAIC). Six sigma methodologies have been applied within the IT Service Management disciplines primarily for Service and Process Improvement and Optimization.[2]

The six sigma wave has spread from the US to the European Union, Japan, Canada and is gradually becoming popular in India and other less developed countries in Asia, Middle East and Latin America.[3]

Concept of Six Sigma

Sigma is a term use in statistics to represent standard deviation, an indicator of the degree of variation in a set of measurements or a process or a product.

Six sigma is often defined as

Six sigma is a statistical concept or a quality management approach that measures a process or a product in terms of defects at the six sigma level and offers a way to focus on developing and delivering perfect products and services.[4]

This has a number of different meanings and interpretations (Henderson and Evans, 2000). From a business perspective, six sigma may be defined as:

1. A business strategy used to improve business profitability, to improve the effectiveness and efficiency of all operations to meet or exceed customer needs and expectations (Kwak and Anbari, 2006).

Various other definitions include

1. Six sigma is a formal methodology for measuring, analyzing, 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 opportunities (DPMO) to a six sigma level of less than 4.0 DPMO (Bolze, 1998).
2. 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).
3. 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).
4. Minitab describes six sigma as an information-driven methodology for reducing waste, increasing customer satisfaction, and improving processes, with a focus on financially measurable results.[12]

Table-1. Probability of defects and yield of different sigma levels[5]

Sigma Level (Process Capability)	Defects per Million Opportunities	Yield
2	308,537	69.20%
3	66,807	93.32%
4	6210	99.38%
5	233	99.98%
6	3.4	99.99%

Six sigma is a new, emerging, approach to quality assurance and quality management with emphasis on continuous quality improvements. The main goal of this approach is reaching level of quality and reliability that will satisfy and even exceed demands and expectations of today's demanding customer. Six sigma is a well-structured, data driven methodology for eliminating defects, waste or quality control problems of all kinds in manufacturing, service delivery, management and other business activities. It is a systematic methodology for continuous process of quality improvement and continuous process of achieving operational excellence. Six sigma is an approach to upgrade the organizations performance, improving quality and productivity. The basic goal of six sigma approach is to reduce variation within

the tolerance or specification limits of a service performance characteristic. The proper implementation of six sigma will improve customer satisfaction. Six sigma offering a means for measuring improvement. Standard deviation measures the variation or amount of spread about the process average. According to the Six Sigma approach, for a stable process the distance from the process mean to the nearest tolerance limit should be at least six times the standard deviation σ of the process output. To achieve six sigma quality, a process must produce not more than 3.4 defects per million opportunities if the output is normally distributed. A defect can be any type of product or service that does not conform to a standard inspection unit or satisfy the customer. In addition a defect can be an error in a product or service. The term "opportunity" is defined as a chance for non-conformance, or not meeting the required specifications.[6]

Fig.1- Lean Six Sigma

Objectives of Six Sigma

The key objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of various Six Sigma methodologies including the key processes like DMAIC and DMADV.

The other objectives of Six Sigma methodology are as follows

a) To increase customer satisfaction
b) To enhance competitiveness
c) To change organizational culture
d) To make advancements toward formal quality award application.

e) To develop organizational competencies

f) To improve organizational performance.[7]

Possible Areas Where Six Sigma Can Be Implemented Are

a) Research and Development

The Research and Development process is the most important process in pharmaceutical industries and forms a major part of costs. The Six Sigma concept is desirable in this scenario to understand the critical processes to new drug development, band to research and streamline existing ones. It is important to have these objectives to reduce drug failures, effect maximum utilization of resources, and increase productivity and optimum utilization of staff and other resources.

b) Cycle Times

Increased cycle times are major factors affecting the timely manufacture, supply and launch new drugs. The earlier industries can take advantage of this market situation ultimately means the difference between success and failure of the product. Value stream mapping and process modelling concepts of Lean Manufacturing and Six Sigma can help in reducing cycle times and operational costs, in addition to increasing the efficiency of processes as well as staff.

c) Defects

Any defects with respect to drugs would be a big blow to any pharmaceutical industry. Six Sigma concepts can help, as they utilize tested scientific tools and statistical tools that help reduce the cost of human errors. Industries can use advanced tools to conduct quality analysis, yield analysis, cost comparison of jobs, risk assessment and comparison of manufacturing processes at different sites. Six Sigma is ideal for the pharmaceutical industry. This position does not exclude lean manufacturing or PAT systems of management, but instead recommends Six Sigma as the initial system of practice. Why? For starters, Six Sigma ideals are based on intense statistical analysis and serious data collection, and the pharmaceutical industry just happens to have huge amounts of data and documentation. This data and documentation, with the appropriate amount of time, could be analyzed according to Six Sigma methods and then used to adjust less than- stellar aspects of the quality system.

The Six Sigma system also focuses on the near obliteration of deviation or non-conformance events, which for pharmaceutical industries falls exactly into line with regulatory standards and quality management goals.[4]

d) In Pharmacy

Many pharmaceutical companies are aiming to transform their business in order to maximize their profits. Enhancing the quality and operational aspect of the manufacturing process is key, and thus, many companies are integrating traditional Six Sigma and Lean Manufacturing. Both methodologies have had successful effects in the surrounding markets like the auto and electronics sectors. Lean Manufacturing is centred on eliminating waste and defects within the manufacturing process which is a prime focus for the pharmaceutical industry. Six sigma alternately concentrates on the actual business processes. Using both methodologies has successfully raised profits within different sectors and has helped to bring about effective changes within the industry. Pharmaceutical companies that implement these concepts are able to successfully improve the quality, productivity, cost, speed, and compliance of their products which ultimately. In order for pharmaceutical companies to implement Six Sigma, there are three levels which have to be affected and changed. These levels are the mindset and behaviors of individuals within the company, the management systems, and the operating system.[7]

Six Sigma Methodologies

Six Sigma projects follow two project methodologies inspired by Deming's Plan-Do-Check Act Cycle. These methodologies, composed of five phases each, bear the acronyms DMAIC and DMADV.

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

2) DMADV (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. In addition to these processes, an increasing number of manufacturers are using DMAICR (Define, Measure, Analyze, Improve, Control, Realise) process.[4,8]

DMAIC refers to a data-driven quality strategy for improving processes, and is an integral part of the company's Six Sigma Quality Initiative. DMAIC, an acronym for Define, Measure, Analyze, Improve, and Control, is a structured problem-solving procedure widely used in quality and process improvement. Almost all implementations of Six Sigma employ DMAIC for project management and completion of process improvement projects.

However, DMAIC is not necessarily formally tied to Six Sigma, and can be used regardless of an organization's use of Six Sigma. Each step in the cyclical DMAIC Process is required to ensure the best possible results.[4,9] Essentials of Six Sigma methodology uses statistical tools to identify the vital few factors, the ones that matter most for improving quality of processes and generating bottom-line results. It has different phases as D M A I C.

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

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

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

I (Improve) - 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) – Control the process. It is important ensure that you can control and correct any variances avoiding possibly costly defects and loss of quality.[11]

We can say that, the Define phase sets the targets for the Six Sigma project, the Measure and Analyze phases characterize the process, and the Improve and Control phases optimize the process and then maintain it.[5]

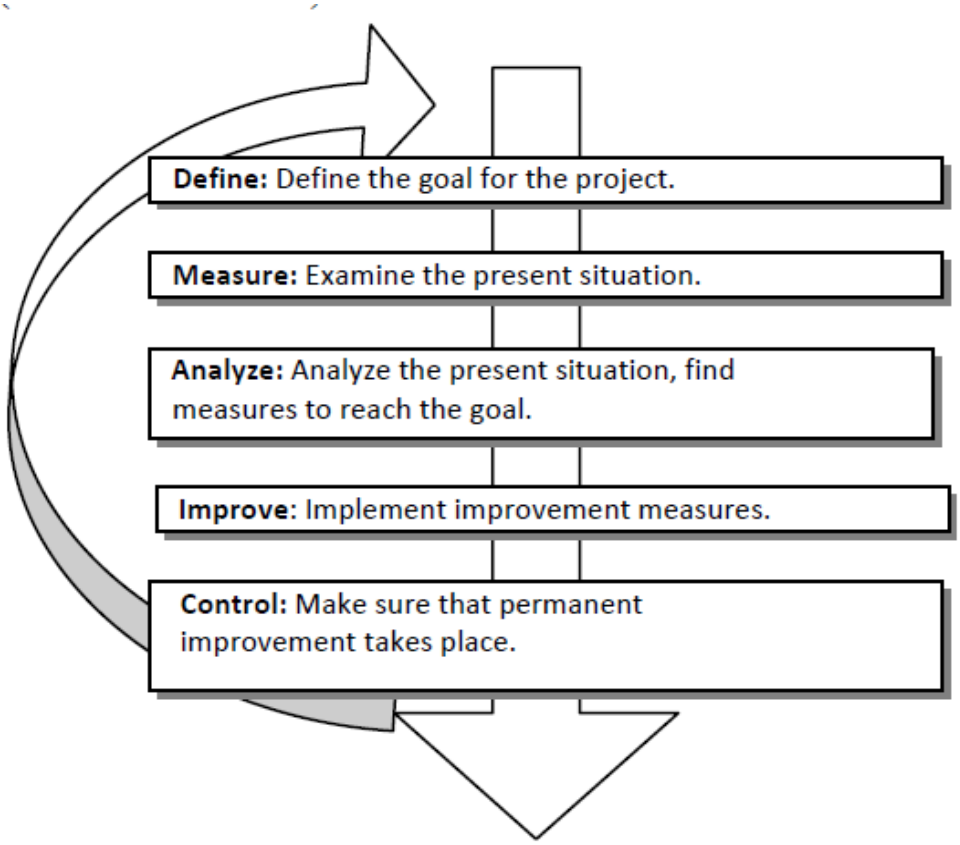

Fig. 2 The DMAIC methodology[10]

DMADV

DMADV (Define, Measure, Analyze, Design and Verify) is an improvement system used to develop new processes or products at six sigma quality levels.[4]

Define: Define the project goals and customer (internal and external) deliverables.

Measure: Measure and determine customer needs and specifications.

Analyze: Analyze the process options to meet the customer needs.

Design: Design (detailed) the process to meet the customer needs.

Verify: Verify the design performance and ability to meet customer needs.[7]

Similarities of DMAIC and DMADV

Let's first look at the DMAIC and DMADV methodologies and talk about how they're alike. DMAIC and DMADV are both:

1) Six Sigma methodologies used to drive defects to less than 3.4 per million opportunities.

2) Data intensive solution approaches, Intuition has no place in Six Sigma - only cold, hard facts.
3) Implemented by Green Belts, Black Belts and Master Black Belts.
4) Ways to help meet the business/financial bottom-line numbers.
5) Implemented with the support of a champion and process owner.[4]

Differences of DMAIC and DMADV

DMAIC and DMADV sound very similar, don't they? The acronyms even share the first three letters. But that's about where the similarities stop.

Table-2. Differences Of Dmaic And Dmadv

DMAIC	DMADV
Define - Define the project goals and customer (internal and external) deliverables	**Define** - Define the project goals and customer (internal and external) deliverables
Measure - Measure the process to determine current performance	**Measure** - Measure and determine customer needs and specifications
Analyze - Analyze and determine the root cause(s) of the defects	**Analyze** - Analyze the process options to meet the customer needs
Improve - Improve the process by eliminating defects	**Design** - Design (detailed) the process to meet the customer needs
Control - Control future process Performance	**Verify** - Verify the design performance and ability to meet customer needs

Uses of DMAIC and DMADV

The DMAIC methodology, instead of the DMADV 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, instead of the DMAIC methodology, should be used when:

a) A product or process is not in existence at your company and one needs to be developed,
b) 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.[4]

Formula for Calculation of Sigma

a) Defects Per Million Opportunities (DPMO) = (Total Defects / Total Opportunities) * s1,000,000
b) Defects (%) = (Total Defects / Total Opportunities)* 100%
c) Yield (%) = 100 - %Defects

d) Process Sigma (type this formula into Excel) =NORMSINV (1-(total defects / total opportunities))+1.5

Be sure to include the Equals (=) sign. This will give you your process sigma (or sigma capability) assuming the 1.5 sigma shift.

For example if you type this into Excel, = NORMSINV (1-100/1000000)+1.5 you will get 5.22 for your Process Sigma.[15,16,17]

Training

Training is a very important part of making an organizational culture favourable to Six Sigma and arming the participants with the skills and knowledge which they required to effectively contribute to the initiative. The centre of any Six Sigma training should be the five-phased DMAIC methodology, supplemented by the basics of champion and Belt training.

1. Champion Training

Champion training typically ranges in duration from one to four days. Champion training should be long enough to provide an overview of the Six Sigma problem-solving processes and prepare champions for their role as the Black and Green Belts guide, mentor, and facilitator. Champion training typically occurs before Black and Green Belt training.

2. Six Sigma Practitioners Training

All Six Sigma practitioners—Master Black Belts, Black Belts, and Green Belts—need to receive training on quality tools and the financial aspects of Six Sigma. In general, a training program should focus on helping the participants understand how the tools fit into the overall methodology. The training approach should consist of training intervals followed by time for practical application on actual projects.

3. Green Belt Training

When designing Green Belt training, it is best to include more of the day-to-day process flow improvement issues and overall process measures than the high-level statistical tools that Black Belts need to understand. Training time period for Green Belts varies, sometimes extending to three weeks.

4. Black Belt Training

Black Belt training covers the topics that Black Belts will need to master before managing a Six Sigma project. Its basis is the DMAIC approach and the Six Sigma techniques and skills that support that methodology. Additional training in project management skills, soft skills, the voice of the customer, and lean management will better prepare Black Belts for their leadership role.

5. Master Black Belt Training

Master Black Belts typically receive additional training beyond the Black Belt curriculum in order to improve their project and coaching skills.[13]

Fig.3- Six Sigma Practitioners Belt

Benchmarking For Six Sigma

Benchmarking is a standard by which something can be measured or judged. This term was first used by surveyors. They set a benchmark by marking a point of known vertical elevation. Therefore benchmark becomes a point of reference for a measurement. We have to benchmark every day. We have to compare our performance, lifestyle, or a game of golf with friends and peers.

Benchmarking helps us to

a) Identify Areas for Breakthrough Improvements,
b) Establish Higher Targets, And
c) New Priorities.

Note benchmarking is not simple comparison and subsequent blind copy of what seems to be the best. We must carefully analyze the outcome of benchmarking and focus on what adds maximum value in our business context. There are three types of benchmarking.

a) Internal Benchmarking

It compares (critical-to-business) processes or products across the organization on key critical-to-quality parameters such as turn-around-time or cost.

b) Functional Benchmarking

It compares similar functions or processes with industry leaders in that area.

c) Competitive Benchmarking

It focuses on direct competitors in terms of their products, services, processes, and customers.[7]

CONCLUSION

Implementation of Six sigma has the potential to enhance customer benefits with regards to increased quality and in some cases also by shortening time to market for new products. We wholeheartedly support the process design and improvement principles of Six Sigma, which have been used to great success in improving quality and productivity in applications around the world. 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 product or process is not in existence at your company and one needs to be developed or the existing product or process exists and has been optimized and still doesn't meet the level of customer specification or six-sigma level. Companies that use this overall approach have better opportunities to benefit greatly from the six sigma implementation.

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