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SIX SIGMA IN THE PHARMACEUTICAL INDUSTRY: A RECENT CONCISE REVIEW

PATEL CJ[1], PATEL J[2], PATEL S[3], PATEL T[4], PATEL H[5]

1. Coordinator, Quality Assurance, Meghmani Unichem LLP, Dahej, Gujarat, India.
2. Manager, Quality Assurance, Meghmani Unichem LLP, Dahej, Gujarat, India.
3. Assistant Manager, Quality Assurance, Meghmani Unichem LLP, Dahej, Gujarat, India.
4. Assistant, Quality Assurance, Meghmani Unichem LLP, Dahej, Gujarat, India.
5. Editor In Chief, IJPRBS Journal, Ahmedabad, Gujarat, India.

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Abstract: Sigma is a letter in the Greek alphabet that has become the statistical symbol and metric of process variation. The sigma scale of measure is perfectly correlated to such characteristics as defects-per-unit, parts-per million defective, and the probability of a failure. The word Sigma is a statistical term that measures how far a given process deviates from perfection. Six Sigma is a highly disciplined process that helps us focus on developing and delivering near-perfect products and services. The central idea behind Six Sigma is that if you can measure how many "defects" you have in a process, you can systematically figure out how to eliminate them and get as close to "zero defects" as possible. Six Sigma is a flexible system used to achieve, sustain and maximize business success. The focus of Six Sigma is to enhance customer satisfaction and reduce costs by using facts and statistical analysis to minimize the non-desirable variation in the business processes.

Keywords: Six Sigma, Statistical Symbol, DMAIC, Quality Management, Pharmaceutical Industry

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Corresponding Author: MR. CHIRAG J. PATEL

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INTRODUCTION

Six Sigma was launched by Motorola in 1987. It was the result of a series of changes in the quality area starting in the late 1970s, with ambitious ten-fold improvement drives. The top management with CEO Robert Galvin developed a concept named Six Sigma. Six Sigma was introduced into Korea in 1997, and it is regarded as a fascinating management strategy in many Korean companies. Harry (1998) defines that Six Sigma is "a strategic initiative to boost profitability, increase market share and improve customer satisfaction through statistical tools that can lead to breakthrough quantum gains in quality." Six Sigma is regarded as a fresh quality management strategy which can replace TQC, TQM and others[1].

It is important however to realize that the Six Sigma system is not a statistical system. It uses statistics as tools for the use and interpretation of the data; however the ultimate goal for Six Sigma is to change the entire mindset and culture of the organization to create systems and processes that are as close to perfect as achievable thus ensuring that they are functioning at the best possible performance levels. Six Sigma can be seen as: a vision; a philosophy; a symbol; a metric; a goal; a methodology"[1, 2].

Many pharmaceutical companies are experiencing increased operational and financial pressure caused by several issues such as customer's demand for more innovative products at better prices, expiring patents and insufficient drugs in pipe line. Many of the core businesses and processes in pharmaceutical industries are therefore in great need of change to be better aligned with the changing economic climate[3].

In addition, a survey presented by Lenzer (2004) shows that only 13% of the Americans believe that pharmaceutical companies are "generally honest and trustworthy". This survey also indicates that the public confidence in drug companies has decreased faster than for any other industry[4].

Liu (2005) discusses the fact that only a few pharmaceutical companies are listed among the more than 300 member companies of the International Society for Six Sigma Professionals (ISSSP)[5].

This suggests that there are still much for the pharmaceutical industry to gain from Six Sigma and much to be learnt from other industries. However; there are many pharmaceutical companies that have implemented Six Sigma and are successfully using it to accomplish their corporate strategy. Examples of pharmaceutical companies that have implemented Six Sigma are Baxter, Eli Lilly, Johnson & Johnson and Novartis (Stückrath 2006)[6].

Carleysmith et al. (2009) describes the benefits of the implementation of Six Sigma tools in the R&D Pharmaceutical department of GlaxoSmithKline (GSK) which resulted in increased productivity by eliminating and decreasing time spent on repetitive tasks thereby reducing

cycle times and a better knowledge exchange due to increased teamwork and common best practice procedures[7].

The Pharmaceutical companies that have implemented the strategy were surveyed to investigate how Six Sigma has benefited the customer by improving the Key Performance Indicators identified below.

The following Key Performance Indicators were used to measure customer benefits:

A. Improved quality of product

B. Price reduction of products

C. Shorter delivery times to market

D. Increased financial support to new development projects[3]

REASONS FOR POPULARITY OF SIX SIGMA[8, 9]

There are several reasons for this popularity. First, it is regarded as a fresh quality management strategy which can replace TQC, TQM and others. In a sense, we can view the development process of Six Sigma as shown in Figure 1. Many companies which were not quite successful in implementing the previous management strategies such as TQC and TQM, are eager to introduce Six Sigma.

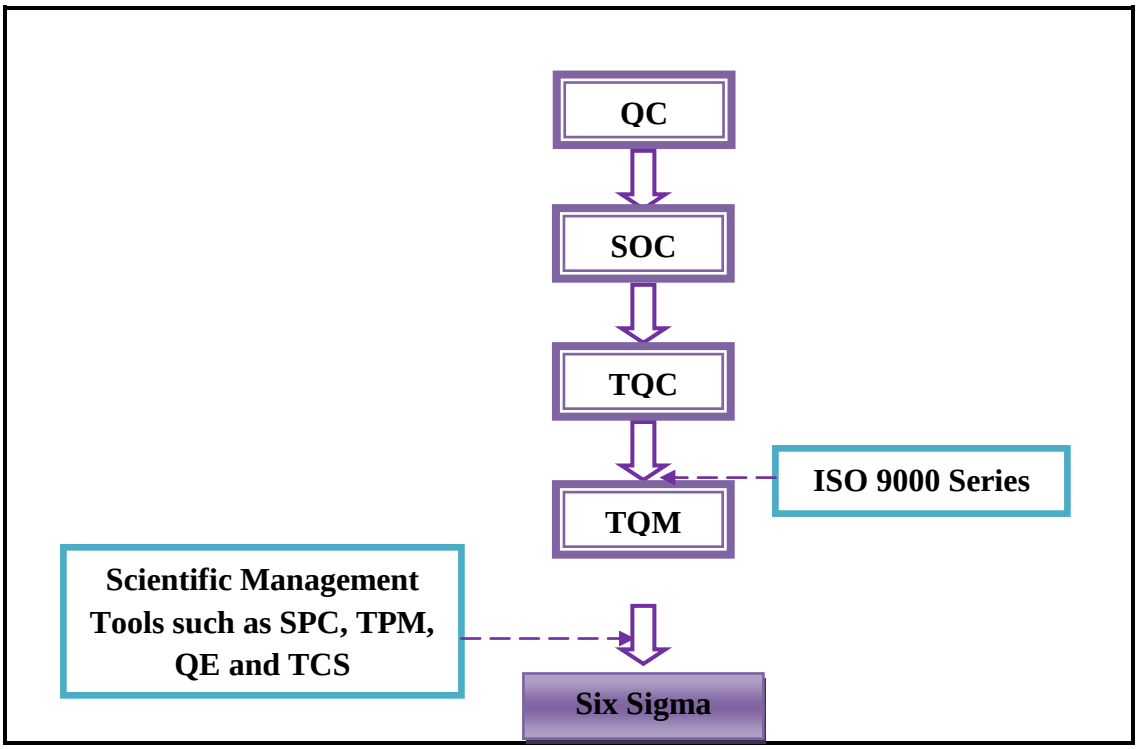

Figure 1: Development process of Six Sigma

QC: Quality Control

SQC: Statistical Quality Control

TQC: Total Quality Control

TQM: Total Quality Management

ISO: International Organization for Standardization

SPC: Statistical Process Control

TPM: Total Productive Maintenance

QE: Quality Engineering

TCS: Total Customer Satisfaction

Six Sigma is viewed as a systematic and scientific approach for management innovation by the integration of four elements; customer, process, manpower and strategy as shown in Figure 2.

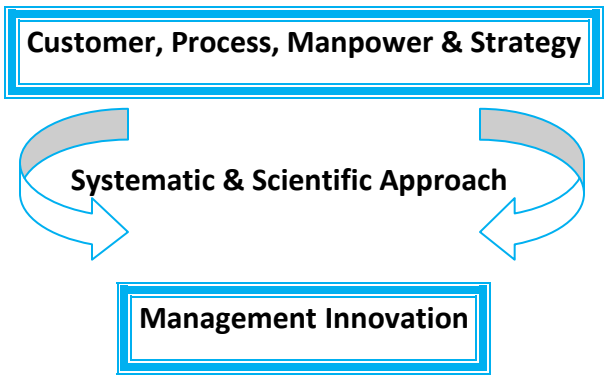

Figure 2: Essence of Six Sigma

Problem-solving Processes For Project Activities[1, 3, 9]

The original problem-solving process for Six Sigma developed from Motorola is MAIC, which means measurement, analysis, improvement and control. Later, DMAIC instead of MAIC is advocated from GE where D stands for definition. MAIC or DMAIC is mostly used as the unique problem-solving process for manufacturing areas. However, for DFSS there are multiple proposed processes. They are as follows.

1. DMADV (Define - Measure - Analyze - Design - Verify). MADV was suggested by Motorola for DFSS, and D was added to it for definition.
2. DMAIC: (Define - Measure - Analyze – Improve - Control). DMAIC is similar to DMADV.

3. IDOV (Identify - Design - Optimize - Validate). This was suggested by GE (General Electric) and has been used most frequently in practice. The Division of Medical Systems in GE applied Six Sigma for 3 years to its New Product Introduction (NPI) of a newly developed computerized tomography (CT) scanner. This was the first attempt to apply the Six Sigma process to development of a new product, and GE aimed to improve the robustness of the product against variations in the manufacturing and usage environment. This Design for Six Sigma (DFSS) approach enabled GE to introduce a light speed medical CT scanner which was nine times faster and ten times more reliable than other contemporary scanners.
4. DIDES (Define - Initiate - Design - Execute - Sustain). This was suggested by Qualtec Consulting Company.

It seems that the above problem-solving processes for manufacturing and R&D areas are not quite suitable for service areas. The author believes that DMARI (Define - Measure - Analyse - Redesign - Implement) is an excellent problem-solving process for non-manufacturing service areas. Here, the phase 'redesign' means that the system for service works should be redesigned in order to improve the service function.

FIVE STEP METHODOLOGY OF SIX SIGMA[1, 3, 10]

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 phase **DMAIC.**

1. **D: Define** goals to improve the overall process between your company strategy and your customer's demands.
2. **M: Measure** your current processes. Collect relevant data on your current processes and then use this data as a baseline for future comparisons.
3. **A: 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 customer's demands.
4. **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.
5. **C: Control**. It is important ensure that you can control and correct any variances avoiding possibly costly defects and loss of quality. Many times pilot runs are set up to study process capability and production transition.

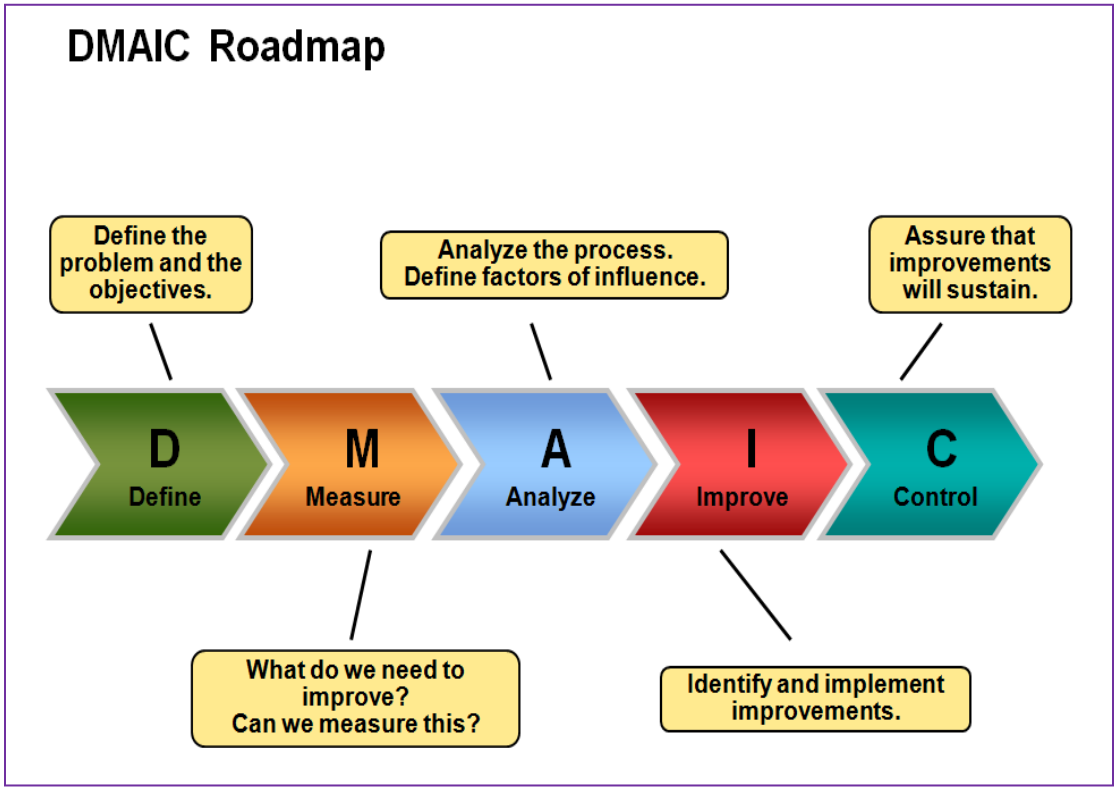

Figure 3: DMAIC Roadmap[10]

OVERVIEW OF SIX SIGMA YELLOW BELT, GREEN BELT, BLACK BELT AND MASTER BLACK BELT QUALIFICATIONS[3, 11, 12]

YELLOW BELT

Roles:

1. Support Green Belt and Black Belt project within their own work area
2. Generate ideas for potential Green Belt/Black Belt projects
3. Improve own processes

Requirements:

1. One day training course is created from the Green Belt materials

GREEN BELT

Roles:

1. Project leaders
2. Capable of forming and managing teams and projects from concept to completion

Requirements:

1. 5 days formal classroom training that covers: Project management, Quality management tools, Quality control tools, Problem solving, Descriptive data analysis

BLACK BELT

Roles:

1. Individuals are technically oriented individuals
2. Held in high regard by their peers
3. Actively involved in the process of change and development

Requirements:

1. Candidates may come from a wide range of disciplines
2. Do not need to be formally trained statisticians or analysts
3. Expected to master a wide variety of technical tools quickly
4. University level mathematics useful
5. Training in statistical methods a plus or even a prerequisite
6. Approximately 160 hours of classroom instruction
7. 1 on 1 project coaching from Master Black Belts or consultants
8. Must be computer literate

a. Proficient with one or more operating systems
b. Spreadsheets
c. Database managers
d. Presentation programs
e. Word processors
f. Proficient in the use of one or more advanced statistical analysis software packages

MASTER BLACK BELT

Roles:

1. Highest level of technical and organizational proficiency
2. Provide technical leadership of the Six Sigma program

Responsibility:

1. Able to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods
2. Statistical training should be conducted only by qualified Master Black Belts or equivalently skilled consultants.
3. Must know everything the Black Belts knows
4. Must possess excellent communication and teaching skills Plus additional skills like,

a. Deep understanding of the mathematical theory

b. A gift for project management

c. Coaching skills to help Black Belts

d. Program organization at the enterprise level

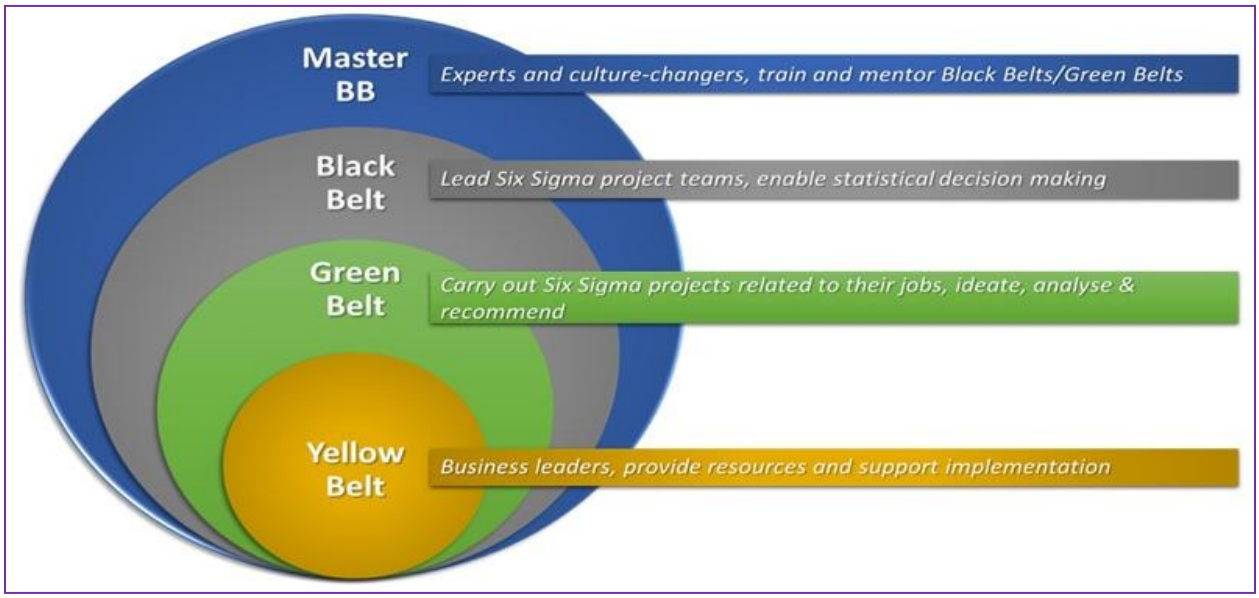

Figure 4: Six Sigma Certifications[11]

CONCLUSION:

Design for Six Sigma has been implemented in many companies to enhance their business performance and customer satisfaction. Overall the customer benefits from the implementation of Six Sigma in the pharmaceutical industry because of higher quality, better control of quality and faster R&D processes. Six Sigma strategy which offers increased operational efficiency quality improvement while retaining and facilitating compliance, benefits the customer in the pharmaceutical industry by reducing the cost, shortening the time to

market and increasing the perceived quality of the final product. Six Sigma is the best strategy for quality management so far.

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