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Six Sigma: A route for Pharmaceutical Companies

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ABSTRACT: *Six Sigma, a power full idea for quality management, It is a relatively a new concept in the surplus of industries that provides a structural arrangement for monitoring quality, both qualitatively and quantitatively to attain perfection, reduce costs and defect, increases margins and improve customer satisfaction. This idea has been accepted by multinational companies throughout the world. Now, Pharmaceutical companies are also charging up for this innovative concept. This article is aimed at developing a general awareness with motivating approach justifying need to adopt Six Sigma. The purpose of this article is to explore the fundamental concepts of six sigma, its relationship with co-existing quality management strategies and to provide an in-depth, scientific understanding of the subject. Also the paper aimed at justifying the adoption of this strategy in all critical sectors of the society, chiefly in booming economies like India and China, where the least or no attention had been given to the same.*

KEY WORDS: *Definition, Problem, Analyze, Leaders, Champions*.

INTRODUCTION:

Six Sigma is a set of methodologies used by business to achieve extremely low failure rates in any process. It is derived from mathematical use of sigma as standard deviation. Sig Sigma is therefore six standard deviations. In theory, there would be approximately two failures per million attempts. But in practice due to drift of plus or minus 1.5, Six Sigma status means less than 3.4 failures per million. Imagine there is a blister packing machine; we have just three discarded strips per million strips. Imagine the savings that will be there when this method is applied throughout the company, and the good thing about this is that it is attainable. It has been proven in industry after industry over the past twenty years. One estimate of savings is that Motorola has saved $17billion using this methodology till date[1]. At present there are lots of literatures written by practitioners and consultants on Sig Sigma, but only a few academic oriented articles published in scholarly journals. Academicians have conducted latest research on this emerging phenomenon and the academic research on this subject is just beginning to come forward[2].

Sig Sigma originated as a set of practices designed to improve manufacturing processes and eliminate defects, but its application was subsequently extended to other types of business processes as well in Sig Sigma, a defect is defined as any process output that does not meet customers specifications, or that could lead to creating an output that does not meet customers specifications.

HISTORY:

Six Sigma is a business management strategy originally developed by Motorola USA in 1981. As of 2010 it enjoys wide spread application in many sectors of industry, although its application is not without controversy. Six Sigma seeks to improve the quality of process outputs by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes. It uses a set of quality management methods including statistical methods and creates a special infrastructure of people within the organization who are experts in these methods [2,3]. Each Six Sigma project carried out within an organization follows a defined sequence of steps and that not only has quantified financial targets but also has other benefits such as reduction in errors or resulting in better controls on the business processes.

The term Sig Sigma originated from terminology associated with manufacturing, mining, specifically terms associated with statistical modeling of manufacturing

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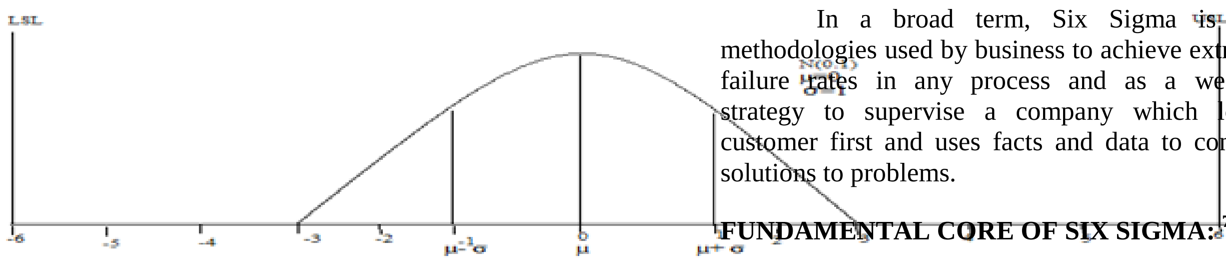
processes. The maturity of a manufacturing process can be described by a sigma rating indicating its yield, or the percentage of defect free products it creates. A six sigma process is one in which 99.99966% of the products manufactured are statistically expected to be free of defects. Motorola set a goal of "Six Sigmas" for all of its manufacturing operations, and this goal became a byword for the management and engineering practices used to achieve it. Bill smith first formulated the particulars of the methodology at Motorola in 1986 [3,4]. Six Sigma was heavily inspired by six preceding decades of quality improvement methodologies such as quality control TQM, as Zero defects based on the work of pioneers such as Shewhart Deming Juran Ishikawa Taguchi and others [4].

Other early adopters of Six Sigma who achieved well-publicized success include honey well (previously known as allied signal) and general electric, where Jack Welch introduced the method. By the late 1990's about two third of the fortune 500 organizations had begun Six Sigma initiatives with the aim of reducing costs and improving quality. In recent years, some practitioners have combined Six Sigma ideas with lean manufacturing to yield a methodology named Lean Six Sigma.

Origin and meaning of the term "Six Sigma process"



Graph of the normal distribution, which underlies the statistical assumptions of the Six Sigma model. The Greek letter σ (sigma) marks the distance on the horizontal axis between the mean, μ, and the curve's inflection point. The greater the distance, the greater is the spread of values encountered. For the curve shown above, μ=0 and σ=1. The upper and lower specification limits (USL, LSL) are at a distance of 6σfrom the mean. Because of the properties of the normal distribution, values lying that far away from the mean are extremely unlikely. Even if the mean were to move right or left by 1.5σ at some point in the future (1.5 sigma shift), there is still a good safety cushion. This is why Six Sigma aims to have processes where the mean is at least 6σ away from the nearest specification limit.

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, as shown in the graph, 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. 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.

DEFINITIONS OF SIX SIGMA: [5,6]

From the name Six Sigma, the first reliable definition, sigma is a statistical expression to represent standard deviation and indicator of degree of variation, in a set of measurements of a process i.e. almost free of all defects. As the second definition, Six Sigma is considered as an organizational approach that emphasizes customer and inspires process up gradation. As the third definition, it is viewed as a strategic development methodology termed DMAIC, and abbreviation of five systematic steps i.e define, measure, analyze, improve and control.

In a broad term, Six Sigma is a set of methodologies used by business to achieve extremely low failure rates in any process and as a well-designed strategy to supervise a company which locates the customer first and uses facts and data to convey better solutions to problems.

FUNDAMENTAL CORE OF SIX SIGMA: [7]

Essentials of Six Sigma methodology-use substantial tools to identify the few tools, the one that matters most for improving quality of processes and generating bottom line results. There are 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.

- DMAIC is used for projects aimed at improving an existing business process.
- DMADV is used for projects aimed at creating new product or process designs.

DMAIC

The DMAIC project methodology has five phases:

1. **D**-Define the problem, the voice of the customer and the project goals, specifically. This is the most critical phase, often called the Achilles heel of Six Sigma. In this, the objectives to be attained are clearly set.
2. **M**-Measure key aspects of the current process and collect relevant data. In this, quality characteristic in product or process is selected; performance standards are defined; measurement systems are validated. This approach depends upon the type of industry.
3. **A**-Analyze the data to investigate and verify cause and effect relationships. Determine what the relationships are and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation.
4. **I**-Improve or optimize the current process based upon data analysis using techniques such as design of experiments, poka yoka design or mistake proofing and standard work to create a new, future state process. After painstakingly measuring and analyzing the situation, it is actually the time to test the theory and find an equation to solve the problem. In this phase key variables are identified and effects that are critical to quality outcomes are quantified. Set up pilot runs to establish process capability.
5. **C**-Control the future state process to ensure that any deviations from target are connected before they result in defects. Implement control systems such as statistical process control, production boars and visual workplace and continuously monitor the process. Since pharmaceutical companies are used to documentation, this phase is usually not a challenge; but its analysis is necessary.

DMADV

The DMADV project methodology, also known as DFSS ("Design for Six Sigma"), features five phases:

1. **D**-Define design goals that are consistent with customer demands and the enterprise strategy.
2. **M**-Measure and identify CTQs (characteristics that are Critical to Quality), product capabilities, production process capability and risks.
3. **A**-Analyze to develop and design alternatives create a high-level design and evaluate design capability to select the best design.
4. **D**-Design details, optimize the design, and plan for design verification. This phase may require simulations.
5. **V**-Verify the design, set up pilot runs implement the production process and hand it over to the process owner(s).

SIX SIGMA STAFF: [8,9]

In this, several employees are trained for implementing Six Sigma. After making a decision to implement Six Sigma, staffs have to play specific roles, names of the players are given similar to that in martial arts and are apparently coined to express aggression and commitment of Six Sigma towards fighting defects and improve quality. Six Sigma prescribes recruitment of following characters:

***Executive leader ship**:*

Executive leaders include top managers, CEO and other key top management team members, who are responsible for initiating and promoting Six Sigma throughout the group. They are responsible for setting up a vision and making clear objective as well as generate complete commitment of each individual towards Six Sigma implementation or project. The chief responsibilities of executive leaders include allocation of funds for training, ensure training sessions, appreciate staff members achievement and help them to apply metrics. They also empower the other role holders with the freedom and resources to explore new idea for breakthrough improvements.

Champions:

***T**ake responsibility for Six Sigma implementation across the organization in an integrated manner. The executive leadership draws them from upper management. Champions are high level executives, who supervise the operation and provide support for everyone involved in ongoing projects. They are so called because they support and struggle for the entire success of Six Sigma. They ensure clear understanding among team members; ensure compatibility of selected projects with the organization policy; frame and maintain projects schedule; organize needed resources, such as time, money as well as help from others; identify and eliminate problems; settle clashes, overlaps and linkages with other teams, keep the senior management authority informed about the progress of project; and specifically perform the tasks off recruiting Black Belts Champions also act as mentors to black belts.

Master Black Belts:

Identified by champions, act as in-house coaches on Six Sigma. They devote 100% of their time to Six Sigma.

They assist champions and guide Black Belts and Green Belts. Apart from statistical tasks, they spend their time on ensuring consistent application of Six Sigma across various functions and departments. Master Black Belt is one who has worked on several projects and has received advanced training in several specialties of Six Sigma. They serve as trainer, counselor as well as guide for the entire organization. They provide expert opinion on projecting employees for Black Belt and Green Belt positions.

Black Belts:

are those, who have undergone a fundamental training in methods and tools of Six Sigma. They are expert of leading projects and launching improvement work. They define, measure and analyze the data, generate their opinion and views on improving work performance, productivity and profitability. Black Belts operate under Master Black Belts to apply Six Sigma methodology to specific projects. They devote 100% of their time to Six Sigma. They primarily focus on identifying projects or functions for Six Sigma.

Green Belts:

are the employees who take up Six Sigma implementation along with their other job responsibilities, operating under the guidance of Black belts. These are employees who have completed a short term course of one to two weeks to gain awareness of Six Sigma. UsuallyGreenBelts represent project teams, working part time on improvement mission.

Some organizations use additional belt colours, such as Yellow Belts, for employees that have basic training in Six Sigma tools.

ROLE OF THE 1.5 SIGMA SHIFT:[10]

Experience has shown that processes usually do not perform as well in the long term as they do in the short term. As a result, the number of sigmas that will fit between the process mean and the nearest specification limit may well drop over time, compared to an initial short-term study. To account for this real-life increase in process variation over time, an empirically-based 1.5 sigma shift is introduced into the calculation. According to this idea, a process that fits Six Sigmas between the process mean and the nearest specification limit in a short-term study will in the long-term only fit 4.5 sigmas either because the process mean will move over time, or because the long-term standard deviation of the process will be greater than that observed in the short term or both.

Hence the widely accepted definition of a Six Sigma process as one that produces 3.4 defective parts per million opportunities (DPMO). This is based on the fact that 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). So the 3.4 DPMO of a “Six Sigma” process in fact corresponds to 4.5 sigmas, namely 6 sigmas minus the 1.5 sigma shift introduced to account for long-term variation. This takes account of special causes that may cause deterioration in process performance over time and is designed to prevent underestimation of the defect levels likely to be encountered in real-life operation.

SIX SIGMA TOOLS: [11]

Black and Green Belts use a variety of tools to drive quality improvements within the DMAIC model. Many of these tools have been incorporated into Six Sigma software so that the computer carries out the underlying calculations. Most can be classified into two categories:

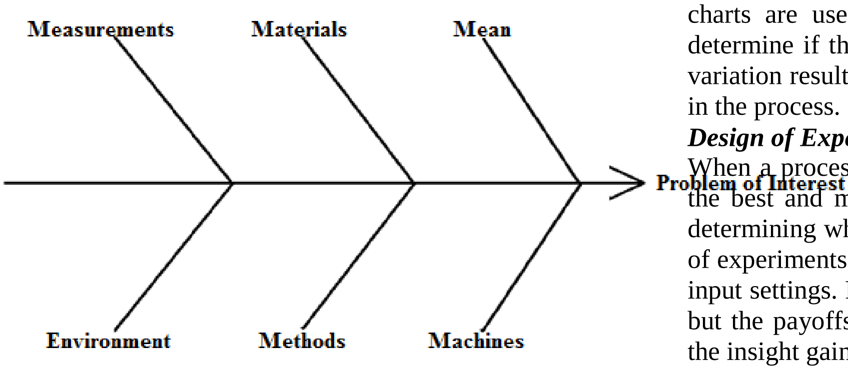
- **Process optimization tools,** which enable teams to design more efficient workflows, and
- **Statistical analysis tools,** which enable teams to analyze data more effectively.

Quality Function Deployment (QFD):[12]

The QFD is used to understand customer requirements. The “deployment” part comes from the fact that quality engineers used to deployed to customer locations to fully understand a customer’s needs. Today, a physical deployment might not take place, but the idea behind the tool is still valid. Basically, the QFD identifies customer requirements and rates them on numerical scale, with higher numbers corresponding to pressing “must-haves” and lower numbers to “nice-to-haves”. Then, various design options are listed and rated on their ability to address the customer’s needs. Each design option earns a score, and those with high scores become the preferred solutions to pursue.

Fishbone diagrams:

In Six Sigma, all outcomes are the result of specific inputs. This cause and effect relationship can be clarified using either a fishbone diagram or a cause and effect matrix. The fishbone diagram helps to identify which input variables should be studied further. The finished diagram looks like a fish skeleton, which is how it earned its name. To create a fishbone diagram, you start with the problem of interest- the head of the fish. Then you draw in the spine and, coming off the spine, six bones on which to list input variables that affect the problem. Each bone is reserved for a specific category of input variable, as shown below. After listing all input variables in their respective categories, a team of experts analyzes the diagram and identifies two or three input variables that are likely to be the source of the problem



Cause and Effect (C&E) Matrix:

The C&E Matrix is an extension of the fishbone diagram. It helps Six Sigma teams to identify, explore and graphically display all the possible causes related to a problem and search for the root cause. The C&E Matrix is typically used in the Measure phase of the DMAIC methodology.

Failure Modes and Effects Analysis (FMEA): [13]

FMEA combats Murphy's Law by identifying ways a new product, process or service might fail. FMEA isn't worried just about issues with the Six Sigma project itself, but with other activities and processes that are related to the project. It's similar to the QFD in how it is set up. First, a list of possible failure scenarios is listed and rated by importance. Then a list of solutions is presented and ranked by how well they address the concerns. This generates scores that enable the team to prioritize things that could go wrong and develop preventative measures targeted at the failure scenarios.

MORE SIX SIGMA TOOLS: [14,15]

T-Test:

In Six Sigma, you need to be able to establish a confidence level about your measurements. Generally, a larger sample size is desirable when running any test, but sometimes it's not possible. The T-Test helps Six Sigma teams validate test results using sample sizes that range from two to thirty data points.

Control Charts:

Statistical process control or SPC relies on statistical techniques to monitor and control the variation in processes. The control chart is the primary tool of SPC. Six Sigma teams use control charts to plot the performance of a process on one axis versus time on the other axis. The result is a visual representation of the process with three key components: a center line, an upper control limit and a lower control limit. Control charts are used to monitor variation in a process and determine if the variation falls within normal limits or is variation resulting from a problem or fundamental change in the process.

Design of Experiments:

When a process is optimized, all inputs are set to deliver the best and most stable output. The trick, of course, is determining what those input settings should be. A design of experiments, or DOE, can help to identify the optimum input settings. Performing a DOE can be time consuming, but the payoffs can be significant. The biggest reward is the insight gained into the process.

101THINGS EVERY SIX SIGMA BLACK BELT SHOULD KNOW: [8,9,10]

1. In general, a Six Sigma Black Belt should be quantitatively oriented.
2. With minimal guidance, the Six Sigma Black Belt should be able to use data to convert broad generalizations into actionable goals.
3. The Six Sigma Black Belt should be able to make the business case for attempting to accomplish these goals.
4. The Six Sigma Black Belt should be able to develop detailed plans for achieving these goals.
5. The Six Sigma Black Belt should be able to measure progress towards the goals in terms meaningful to customers and leaders.
6. The Six Sigma Black Belt should know how to establish control systems for maintaining the gains achieved through Six Sigma.
7. The Six Sigma Black Belt should understand and be able to communicate the rationale for continuous improvement, even after initial goals have been accomplished.
8. The Six Sigma Black Belt should be familiar with research that quantifies the benefits firms have obtained from Six Sigma.
9. The Six Sigma Black Belt should know or be able to find the PPM rates associated with different sigma levels (e.g., Six Sigma=3.4 PPM)
10. The Six Sigma Black Belt should know the approximate relative cost of poor quality associated with various sigma levels (e.g., three sigma firms report 25%COPQ).
11. The Six Sigma Black Belt should understand the roles of the various people involved in change

(senior leader, champion, mentor, change agent, technical leader, team leader, facilitator)

12. The Six Sigma Black Belt should be able to design, test, and analyze customer surveys.
13. The Six Sigma Black Belt should know how to quantitatively analyze data from employee and customer surveys. This includes evaluating survey reliability and validity as well as the differences between surveys.
14. Given two or more sets of survey data, the Six Sigma Black Belt should be able to determine if there are statistically significant differences between them.
15. The Six Sigma Black Belt should be able to quantify the value of customer retention.
16. Given a partly completed QFD matrix, the Six Sigma Black Belt should be able to complete it.
17. The Six Sigma Black Belt should be able to compute the value of money held or invested over time, including present value and future value of a fixed sum.
18. The Six Sigma Black Belt should be able to compute present value and future value for various compounding periods.
19. The Six Sigma Black Belt should be able to compute the break-even point for a project.
20. The Six Sigma Black Belt should be able to compute the net present value of cash flow streams, and to use the results to choose among competing projects.
21. The Six Sigma Black Belt should be able to compute the internal rate of return for cash flow streams and to use the results to choose among competing projects.
22. The Six Sigma Black Belt should know the COPQ rationale for Six Sigma, i.e., he should be able to explain what to do if COPQ analysis indicates that the optimum for a given process is less than Six Sigma.
23. The Six Sigma Black Belt should know the basic COPQ categories and be able to allocate a list of costs to the correct category.
24. Given a table of COPQ data over time, the Six Sigma Black Belt should be able to perform a statistical analysis of the trend.
25. Given a table of COPQ data over time, the Six Sigma Black Belt should be able to perform a statistical analysis of the distribution of costs among the various categories.
26. Given a list of tasks for a project, their times to complete, and their precedence relationships, the Six Sigma Black Belt should be able to compute the time to completion for the project, the earliest completion times, the latest completion times and the slack times. He should also be able to identify which tasks are on the critical path.
27. Given cost and time data for project tasks, the Six Sigma Black Belt should be able to compute the cost of normal and crash schedules and the minimum total cost schedule.
28. The Six Sigma Black Belt should be familiar with the basic principles of benchmarking.
29. The Six Sigma Black Belt should be familiar with the limitations of benchmarking.
30. Given an organization chart and a listing of team members, process owners and sponsors, the Six Sigma Black Belt should be able to identify projects with a low probability of success.
31. The Six Sigma Black Belt should be able to identify measurement scales of various metrics (nominal, ordinal, etc.).
32. Given a metric on a particular scale, the Six Sigma Black Belt should be able to determine if a particular statistical method should be used for analysis.
33. Given a properly collected set of data, the Six Sigma Black Belt should be able to perform a complete measurement system analysis, including the calculation of bias, repeatability, reproducibility, stability, discrimination (resolution) and linearity.
34. Given the measurement metric systems, the Six Sigma Black Belt should know whether or not a given measurement system should be used on a given part or process.
35. The Six Sigma Black Belt should know the difference between computing sigma from a data set whose production sequence is known and from a data set whose production sequence is not known.
36. Given the results of an AIAG Gage R&R study, the Six Sigma Black Belt should be able to answer a variety of questions about the measurement system.
37. Given a narrative description of “as-is” and “should –be” processes, the Six Sigma Black Belt should be able to prepare process maps.
38. Given a table of raw data, the Six Sigma Black Belt should be able to prepare a frequency tally sheet of the data, and to use the tally sheet data to construct a histogram.
39. The Six Sigma Black Belt should be able to compute the mean and standard deviation from a grouped frequency distribution.

40. Given a list of problems, the Six Sigma Black Belt should be able to construct a Pareto Diagram of the problem frequencies.
41. Given a list which describes problems by departments, the Six Sigma Black Belt should be able to construct a cross tabulation and use the information to perform a chi-square analysis.
42. Given a table of x and y data pairs, the Six Sigma Black Belt should be able to determine if the relationship is linear or non-linear.
43. The Six Sigma Black Belt should know how to use non-linearity's to make products or processes more robust.
44. The Six Sigma Black Belt should be able to construct and interpret a run chart when given a table of data in time-ordered sequence. This includes calculating run length, number of runs and quantitative trend evaluation.
45. When told the data are from an exponential or Erlang distribution the Six Sigma Black Belt should know that the run chart is preferred over the standard X control chart.
46. Given a set of raw data the Six Sigma Black Belt should be able to identify and compute two statistical measures each for central tendency, dispersion and shape.
47. Given a set of raw data, the Six Sigma Black Belt should be able to construct a histogram.
48. Given a stem and leaf plot, the Six Sigma Black Belt should be able to reproduce a sample of numbers to the accuracy allowed by the plot.
49. Given a box plot with numbers on the key box points, the Six Sigma Black Belt should be able to identify the 25^{th} and 75^{th} percentile and the median.
50. The Six Sigma Black Belt should know when to apply enumerative statistical methods, and when not to.
51. The Six Sigma Black Belt should know when to apply analytic statistical methods and when not to.
52. The Six Sigma Black Belt should demonstrate a grasp of basic probability concepts, such as the probability of mutually exclusive events, of dependent and independent events, of events that can occur simultaneously, etc.
53. The Six Sigma Black Belt should know factorials, permutations and combinations and how to use these in commonly used probability distributions.
54. The Six Sigma Black Belt should be able to compute expected values for continuous and discrete random variables.
55. The Six Sigma Black Belt should be able to compute univariate statistics for samples.
56. The Six Sigma Black Belt should be able to compute confidence intervals for various statistics,
57. The Six Sigma Black Belt should be able to read values from a cumulative frequency gave.
58. The Six Sigma Black Belt should be familiar with the commonly used probability distributions, including: hyper geometric, binomial, poison, normal, exponential, chi-square, student's t and F.
59. Given a set of data the Six Sigma Black Belt should be able to correctly identify which distribution should be used to perform a given analysis and to use the distribution to perform the analysis.
60. The Six Sigma Black Belt should know that different techniques are required for analysis depending on whether a given measure (e.g., the mean) is assumed known or estimated from a sample. The Six Sigma Black Belt should choose and properly use the correct technique when provided with data ant sufficient information about the data.
61. Given a set of sub grouped data, the Six Sigma Black Belt should be able to select and prepare the correct control charts and to determine if a given process is an a state of statistical control.
62. The above should be demonstrated for data representing all of the most common control charts.
63. The Six Sigma Black Belt should understand the assumptions that underlie ANOVA and be able to select and apply a transformation to the data.
64. The Six Sigma Black Belt should be able to identify which cause on a list of possible causes will most likely explain a non-random pattern in the regression residuals.
65. If shown control chart patterns, the Six Sigma Black Belt should be able to match the control chart with the correct situation //9e.g., an outlier pattern vs. a gradual trend matched to a tool breaking vs. a machine gradually warming up).
66. The Six Sigma Black Belt should understand the mechanics of PRE-Control.
67. The Six Sigma Black Belt should be able to correctly apply EWMA charts to a process with serial correlation in the data.
68. Given a stable set of sub grouped data, the Six Sigma Black Belt should be able to perform a complete Process Capability Analysis. This includes computing and interpreting capability

indices, estimating the % failures, control limit calculations, etc.

69. The Six Sigma Black Belt should demonstrate an awareness of the assumptions that underlie use of capability indices.
70. Given the results of a replicated 22 full-factorial experiment, the Six Sigma Black Belt should be able to complete the entire ANOVA table.
71. The Six Sigma Black Belt should understand the basic principles of planning a statistically designed experiment. This can be demonstrated by critiquing various experimental plans with or without shortcomings.
72. Given a "clean" experimental plan, the Six Sigma Black Belt should be able to find the correct number of replicates to obtain a desired power.
73. The Six Sigma Black Belt should know the difference between the various types of experimental models (fixed-effects, random-effects, mixed).
74. The Six Sigma Black Belt should understand the concepts of randomization and blocking.
75. Given a set of data, the Six Sigma Black Belt should be able to perform a Latin Square analysis and interpret the results.
76. Ditto for one way ANOVA, two way ANOVA (with and without replicates), full and fractional factorials, and response surface designs.
77. Given an appropriate experimental result, the Six Sigma Black Belt should be able to compute the direction of steepest ascent.
78. Given a set of variables each at two levels, the Six Sigma Black Belt can determine the correct experimental layout for a screening experiment using a saturated design.
79. Given data for such an experiment, the Six Sigma Black Belt can identify which main effects are significant and state the effect of these factors.
80. Given two or more sets of responses to categorical items (e.g., customer survey responses categorized as poor, fair, good, excellent), the Six Sigma Black Belt will be able to perform a Chi-square test to determine if the samples are significantly different
81. The Six Sigma Black Belt will understand the idea of confounding and be able to identify which two factor interactions are confounded with the significant main effects.
82. The Six Sigma Black Belt will be able to state the direction of steepest ascent from experimental data.
83. The Six Sigma Black Belt will understand fold over designs and be able to identify the fold over design that will clear a given alias.
84. The Six Sigma Black Belt will know how to augment a factorial design to create a composite or central composite design.
85. The Six Sigma Black Belt will be able to evaluate the diagnostics for an experiment.
86. The Six Sigma Black Belt will be able to identify the need for a transformation in y and to apply the correct transformation.
87. Given a response surface equation in quadratic form, the Six Sigma Black Belt will be able to compute the stationary point.
88. Given data (not graphics), the Six Sigma Black Belt will be able to determine if the stationary point is a maximum, minimum or saddle point.
89. The Six Sigma Black Belt will be able to use a quadratic loss function to compute the cost of a given process.
90. The Six Sigma Black Belt will be able to conduct simple and multiple linear regressions.
91. The Six Sigma Black Belt will be able to identify patterns in residuals from an improper regression model and to apply the correct remedy.
92. The Six Sigma Black Belt will understand the difference between regression and correlation studies.
93. The Six Sigma Black Belt will be able to perform Chi-square analysis of contingency tables.
94. The Six Sigma Black Belt will be able to compute basic reliability statistics (mtbf, availability, etc.).
95. Given the failure rates for given subsystems, the Six Sigma Black Belt will be able to use reliability apportionment to set mtbf goals.
96. The Six Sigma Black Belt will be able to compute the reliability of series, parallel and series-parallel system configurations.
97. The Six Sigma Black Belt will demonstrate the ability to create and read an FMEA analysis.
98. The Six Sigma Black Belt will demonstrate the ability to create and read a fault tree.
99. Given distributions of strength and stress, the Six Sigma Black Belt will be able to compute the probability of failure.
100. The Six Sigma Black Belt will be able to apply statistical tolerancing to set tolerances for simple assemblies. He will know how to compare statistical tolerances to so called "worst case" tolerancing.

101. The Six Sigma Black Belt will be aware of the limits of the Six Sigma approach.

Sigma Levels: [16]

A control chart depicting a process that experienced a 1.5 sigma drift in the process mean toward the upper specification limit starting at midnight. Control charts are used to maintain Six Sigma quality by signaling when quality professionals should investigate a process to find and eliminate special-cause variation.

Criticism Lack of Originality:

Noted quality expert Joseph M. Juran has described Six Sigma as "A basic version of quality improvement", stating that there is nothing new there. It includes what we used to call facilitators. They have adopted more flamboyant terms, like Belts with different colours. I think that concept has merit to set apart, to create specialists who can be very helpful. Again, that's not a new idea. The American Society for quality long ago established certificates, such as for reliability engineers.

Role of Consultants:

The use of "Black Belts" as itinerant change agents has (controversially) fostered an industry of training and certification. Critics argue there is over selling of Six Sigma by too great number of consulting firms, many of which claim expertise in Six Sigma when they only have a rudimentary understanding of the tools and techniques involved.

Potential negative effects: [17]

A fortune article stated that "of 58 large companies that have announced Six Sigma programs, 91% have trailed the S & P 500 since". The statement is attributed "an analysis by Charles Holland of consulting firm Qualpro (which espouses a competing quality improvement process). The summary of the article is that Six Sigma is effective at which it is intended to do, but that it is "narrowly designed to fix an existing process" and does not help in "coming up with new products or disruptive technologies". Advocates of Six Sigma have argued that many of these claims are in error or ill-informed.

A Business Week article says that James McNerneys introduction of Six Sigma at 3M may have had the effect of stifling creativity. It cites two Wharton School professors who say that Six Sigma leads to incremental innovation at the expense of Blue-sky work. This phenomenon is further explored in the book, Going Lean which describes a related approach known as lean dynamics and provides data to show that Ford's "Six Sigma" program did little to change its fortunes.

Based on arbitrary standards:

While 3.4 defects per million opportunities might work well for certain products or processes, it might not operate optimally or cost effectively for others. A pacemaker process might need higher standards, for example, whereas a direct mail advertising campaign might need lower standards. The basis and justification for choosing 6 (as opposed to 5 or 7, for example) as the number of standard deviations is not clearly explained. In addition, the Six Sigma model assumes that the process data always conform to the normal distribution. The calculation of defect rates for situations where the normal distribution model does not apply is not properly addressed in the current Six Sigma literature.

Criticism of the 1.5 sigma shift: [18]

The statistician Donald J. Wheeler has dismissed the 1.5 sigma shift as "goofy" because of its arbitrary nature. Its universal applicability is seed as doubtful.

The 1.5 sigma shift has also become contentious because it results in stated "sigma levels" that reflect short-term rather than long-term performance: a process that has long-term defect levels corresponding to 4.5 sigma performance is, by Six Sigma convention, described as a "Six Sigma" process. The accepted Six Sigma scoring system thus cannot be equated to actual normal distribution probabilities for the stated number of standard deviations, and this has been a key bone of contention about how Six Sigma measures are defined. The fact that it is rarely explained that a "Six Sigma" process will have long term defect rates corresponding to 4.5 sigma performance rather than actual Six Sigma performance has led several commentators to express the opinion that Six Sigma is a confidence trick."The quality performance" is the foundation stone of all types of industries. The growth of an industry depends on its performance quality. So checking out of the performance quality of an industry is something which is inevitable. "SIX SIGMA"-The statistical representation, is a process of quality measurement, which helps the organization in the improvement of their quality.

Six Sigma is a systematical process of "quality improvement through the disciplined data analyzing approach and by improving the organizational process by eliminating the defects or the obstacles which prevents the organizations to reach the perfection".

Six Sigma points out the total number of the defects that has come across in an organizational performance. Any type of defects, apart from the customer specification, is considered as the defect, according to Six Sigma. With the help of the statistical representation of the Six Sigma, it is easy to find out how a process is performing on quantitatively aspects. A defect according to Six Sigma is nonconformity of the product or the service of an organization.

Since the fundamental aim of the Six Sigma is the application of the improvement on the specified process, through a measurement-based strategy, Six Sigma is considered as a registered service mark or the trade mark. Six Sigma has its own rules and methodologies to be applied. In order to achieve this service mark, the process should not produce defects more than 3.4. These numbers of defects are considered as "the rate of the defects in a process should not exceed beyond the rate 3.4 per million opportunities". Through the Six Sigma calculation the number of defects can be calculated. For this there is a sigma calculator, which helps in the calculation.

In order to attain the fundamental objectives of Six Sigma, there are Six Sigma methodologies to be implemented. This is done through the application of Six Sigma improvement projects, which is accomplished through the two Six Sigma sub-methodologies. Under the improvement projects came the identification, selection and ranking things according to the importance. The major two sub-divisions of the improvement projects are the Six Sigma DMAIC and the Six Sigma DMADV. These sub-divisions are considered as the processes and the execution of these processes are done through three certifications. The three types of certifications used for the execution of the Six Sigma DMAIC and Six Sigma DMADV are:

"Six Sigma Green Belts and Six Sigma Black Belts, which is overseen by Six Sigma Master Black Belts"

The Six Sigma ensures the quality control, total quality management and zero defects. Through the implementation of the Six Sigma it is made sure that the goals are set on the improvement of all processes to reach the level of better quality. "The Six Sigma" shows the organization's ability of highly capable processing in producing the outputs within the limited specifications. Therefore it can be said that the processes that operates with the Six Sigma quality, is able to produce a quality products at a low rate of defects.

When a process attains the certification of Six Sigma quality, it is clear that the organization has attained the standard deviations from the means of the production till the specific limitation, and so can make sure that there is no room for the items to fail to meet the specifications. Altogether we can consider the Six Sigma as the professionalizing of the quality management functions.

THE FUTURE OF SIX SIGMA

Although Six Sigma has been around since the 1980's, it continues to evolve and change. Some of those changes involve the addition of new tools that have been developed and refined in practical, real-world situations. Other changes are related to how Six Sigma teams are organized. For example, in recent years, the Six Sigma White Belt has emerged. White Belts require much less training than Green or Black Belts and therefore offer a more rapid return on investment. Now, medium and small-sized companies have access to all of the benefits that come with Six Sigma implementation.

But even large companies such as Motorola continue to push their Six Sigma programs to new levels. In 2003, the company began to see fewer benefits and savings coming from its Six Sigma methodology as costs related to poor quality began to rise once again. As a result, Motorola overhauled Six Sigma with powerful new tools, insights and advances. The changes worked: In 2004, Motorola achieved 42% revenue growth and an increase of 257% in earnings per share over the previous year's first quarter performance. This has rejuvenated interest in Six Sigma and has ensured its position as a serious business tool, not just a fad that will slowly fade into business history.

CONCLUSION:

In the coming times it is for sure that resources will reduce, competition will increase and regulation bodies will grow more stringent. Therefore, a program that ensures us of highest quality, which is inherent in pharmaceutical companies, will definitely help in having an edge over the competitors. But Six Sigma is not a one man battle; the spirit of sigma as to be infused with the culture of the company. The essence and purpose of Six Sigma must be clear to every employee of company. Therefore, so as to play safe in coming times, Six Sigma will be the major armor of a company to survive and succeed. Right from CEO to lowest level employee Six Sigma should perfuse to reap immense benefits, to attain perfection, to gain edge over competitors and for long-team viability of the company.

REFERENCES

1. Richardson, Karen. The Six Sigma Factor for Home Depot. 2007 July;101: 2256-59.
2. Adams R, Warner P, Hubbard B, Goulding, T Journal of Nurs Administration. 2004; 34:140-148.
3. Harry, Mikel J, Schroeder, Richard Six Sigma. Random House 2004 Jun;26(3):137-42.
4. Harry, Mikel J, The Nature of Six Sigma Quality. Rolling meadows, Illinois: Motorola University Press .1988
5. Tennant, Geoff. Six Sigma SPC and TQM in Manufacturing and Service Gower Publishing. 2001.
6. Stahl R, Schulz B, Pexton C, Six Sigma Forum Magazine, 2003.
7. Green F B, International Journal on Six Sigma Comp. Adv. 2006.
8. Koning H D, Mast J, First International Conference on Six Sigma. Glasgow, Scotland, 2004.
9. Daft R L. South-Western, Mason, OH 2001;7:143-47.
10. Su C, and Chou C, Expert Systems with Applications . 2008;78(2):87-90.
11. Thomerson L D, Annual Quality Congress Proceedings. 2001.
12. Aggour K, Pavese M, Proc. Soft. Eng. Know. Eng. Conf. (SEKE'03). 2003.
13. Breyfogle F W, Technometrics . 2003.
14. Celerant's News, Filtration Industry Analysts . 2005 Jan; 37(1):6-16.
15. Gygi, Craig, De Carlo, Neil, Williams, Bruce. Six Sigma for dummies. 2005.
16. Eckes G, New York. John Wiley & Sons. 2001.
17. Gnibus R J, Krull R, Quality 2003.
18. Goel S, Chen V, International Journal of Production Economics.2008 Apr; 37(2):16-19.