

Six Sigma: Golden Opportunity for Pharmaceutical Industry

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ABSTRACT: Six Sigma is a term used in statistics to represent standard deviation, an indicator of the degree of variation in a set of measurements or a process. It works on the three element i.e. Process improvement, Process design/re-design and Process management. It is a highly disciplined process that focuses on developing & delivering near perfect product & services. Measure our process quality with respect to customer expectations on basis of DMAIC method. It is process for continuous improvement for any condition. Six Sigma enable for cultural change. However, due to increasing competitive market pressures, more and more Pharmaceutical Industries are beginning to adopt process improvement strategies that are established in other industries such as Six Sigma.

So in general Six Sigma is quality, along with a culture of learning, sharing, and unending excitement.

Key words: Six Sigma, Approaches of Six Sigma, DMAIC, Pharmaceutical Industry, Clinical trials.

INTRODUCTION

In statistical terms, the purpose of Six Sigma is to reduce process variation so that virtually all the products or services provided meet or exceed customer expectations. This is defined as being only 3.4 defects per million occurrences.¹

Six Sigma is a highly disciplined process that focuses on developing & delivering near perfect product & services. Six Sigma Knows what is important to Customer. It reduces Defects in process & product. The Six Sigma approach to any process is centered on Target. Six Sigma reduces variation in process. It is Measure of our process quality with respect to customer expectations-it is all about customer & data. Six Sigma is the process for continuous improvement for any condition. Six Sigma enable for cultural change. Common myths and misunderstandings about six sigma include ... that it works only in manufacturing setting, does not include customer requirements, re-packaged TQM, uses difficult to understand statistics, is an accounting game without real savings, is just a training, is a "magic pill" with little effort. It should be noted that Six Sigma actively

links people, processes and outcome in a rigorous, adaptable way to get the results companies are looking for. Tangible results should be seen no matter what the industry, product, or service where Six Sigma is applied. Although process improvement was dominating the manufacturing industry, the pharmaceutical and bio-pharmaceutical companies have not recognized broadly, the importance and potential of integrating process improvement in clinical research practice. There are no in depth studies that Six Sigma can lead to breakthroughs in reducing cycle time, and error reduction in clinical trials.²

However, due to increasing competitive market pressures, more and more pharmaceutical companies are beginning to adopt process improvement strategies that are established in other industries such as Six Sigma, lean manufacturing. Issues driving these needs include the necessity to improve cycle time, marketing and packaging efficiencies to monitor supply chain and streamline manufacturing processes to maintain profitability and remain competitive in today's global market.

MORE ABOUT SIX SIGMA

Six Sigma improvement initiatives have been successfully implemented in many companies in the US, such as General Electric, Motorola, and DuPont. It is interesting to look at Dupont's success with Six Sigma. The company's CEO originally had a vision of focusing on the integrated science, leveraging knowledge of offerings and productivity, and to meet his objectives in mind, spoke with big companies like GE and Honeywell about their success, and was eventually referred to Six Sigma Academy. Within the year, DuPont began their Six Sigma journey, with major goals in mind: achieve sustainable growth through productivity and quality improvements, significantly increase productivity, increase shareholder and societal value, and pursue "knowledge intensity" in all businesses.³

The company has implemented more than 3000 Six Sigma projects and many of these projects have resulted in reduced environmental impact or increased safety, with 10,000 Master Black Belts and Green Belts trained around the world, 500 financial analysts and managers. DuPont reported more than 1.6 billion in cost savings when Six Sigma was integrated into all their operations including distribution, sales, marketing, human resources, finance, legal and manufacturing. More than 12,000 Six Sigma projects are still underway around the world in all regions and lines of business.

Six Sigma was Developed at Motorola in the 1980's as a Method to Improve Process Quality. It Was First Used to Improve Manufacturing Process Capability and then Migrated to Business Processes Capability. Various Companies have Developed Six Sigma Culture.

HOW DOES SIX SIGMA WORK ?

There are three basic elements to Six Sigma:

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

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

Process improvement

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

Process design/re-design

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

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

Process management⁴

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

In general, process management consists of:

- Defining processes, key customer requirements, and process "owners".
- Measuring performance against customer requirements and key performance indicators.
- Analysing data to enhance measures and refine the process management mechanisms.
- Controlling process performance by monitoring process inputs, process operation, and process outputs, and responding quickly to problems and process variations.

VARIATION & PROCESS CAPABILITY

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

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

When all these four factors combined effect falls within LSL (Lower Specification Limit) & USL (Upper Specification Limit) the process is said to be capable. When the combined effect of four factor falls below LSL & above causes defect in the process & which is not desirable. When defects

are detected in process, there are two options either reject it or rework on it. Both the options are expensive in terms of money & time.

THE IMPACT OF PROCESS VARIATION

- Increase in no. of Defects
- Drop in Yield
- Increased Cost of Production
- Increased Cycle time

Goals of Six Sigma⁵

- Improving customer satisfaction
- Accelerating process cycle times and time-to-market
- Reducing defects
- Controlling variation and improving predictability
- Reducing costs – without "unintended consequences"
- Improving end-to-end process management and measurement

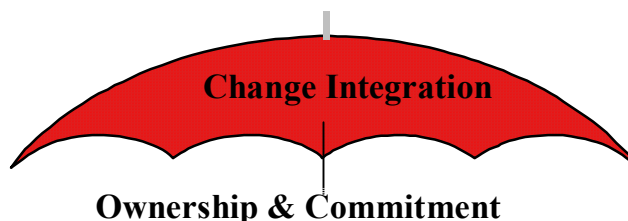
FIVE STEP METHODOLOGY OF SIX SIGMA⁶

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 ...DMAIC.

- **D** - Define goals to improve the overall process between your company strategy and your customer's demands (can also refer to your group and the groups or individuals that you support)
- **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. Many times pilot runs are set up to study process capability and production transition.

These pilot runs can help fine tune or add additional control mechanisms.

TWO APPROACHES OF SIX SIGMA



SELECTION OF SIX SIGMA PROJECT

Six Sigma is aimed at the problem in which the solution is not known. Characteristics of a good Six Sigma projects are as follows: a) the project should be linked clearly to the business priorities as reflected in the annual operating plans b) addresses critical problems that must be solved in order for the organization to be successful the following year c) project should represent a breakthrough in terms of major improvement in both process performance and bottom-line results. It is important that the project is doable and can be completed in a short time (6-12 months) to keep the focus and interest in the project. There should be clear quantitative measures of success. Areas to be improved should also affect directly customer satisfaction

Two important criteria in selecting a project for Six Sigma are *effort required* and *probability of success*. One must have a good understanding of the duration of the project in relation to the return on investment. Must be able to evaluate efforts in terms of resources deployed and the time it takes until the resources produce the expected outcome. The probability of success for the project should be considered, what are the risks associated with being successful? One should consider time, effort and implementation factors to figure out if the project is desirable. It is best not to undertake those that are impractical and requires a lot of time.

Smaller, well focused projects are more manageable, but not too narrow that the solution is in front of you; priorities should be given to projects that address the customers expectation on quality, cost and delivery; the objectives need to be clear and usually associated with performance metrics. In non-manufacturing projects useful performance metrics are quality (accuracy, completeness and error rate) cycle time and cost.

Another important factor to consider in choosing the project is that the project should be tied to the bottom line and the scope should be attainable in 3-6 months. Most common project failures are usually the ones with unrealistic scope and takes longer period of time that those involved lose interest and focus. Furthermore, management support is very critical to the successful implementation of the project. Many failures in projects were mostly attributed to management becoming barriers⁷

A quick and easy way to remember the major aspects of a successful project is the acronym **SMART**--- Specific, Measurable, Achievable, Realistic, Time bound.

SUSTAINING OF SIX SIGMA

Six Sigma is a continuing endeavor, new projects will be initiated and completed at different time frames, and the momentum has to be maintained. There are several infrastructures needed to sustain Six Sigma. During the first year, the following are recommended to be set up:

- Set up the database for the lessons learned
- Develop ongoing project list that registers both projected and actual savings
- Establish ongoing communication plan, both internal and external
- Grow black belt and green belt staff
- Develop a common metric and reporting /review system for updates and status of all projects

For the second year, the following are recommended to be done:

- Engage the key suppliers in the Six Sigma methodology
- Build Six Sigma goals into company-wide strategic plans
- Host quarterly reviews with management
- Develop compensation/incentive plan to ensure continued support
- Get each black belt to work on 4-6 projects a year
- Create a “pull” system for the Six Sigma initiative
- Determine the following year’s goals in the number of black belts, green belts, project selection and savings projection.⁸

Whether the above lists are accomplished or not, there are sure signs of Six Sigma success: a) the internal master black belts are training black belts b) green belts represent 10% of the company population c) all training has transitioned from an outside consultant to own company resources d) communication is ongoing, internal and external e) black belts are being promoted

f) the project backlog represents no more than 3 % to 5 % of the company revenue

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.⁹

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.¹⁰

CONCLUSION

Six Sigma is becoming a cornerstone philosophy among the world’s leading corporations because it has

proven itself by generating substantial business returns. Six Sigma is also seen as a great training ground for twenty-first century leadership. It is now fairly common place for people who are well trained in Six Sigma to achieve top leadership positions. According staunchest champion, Jack Welch: “We

believed then and we are convinced today that there is an ‘infinite capacity to improve everything’ but there was no methodology or discipline attached to that belief. There is now. It’s Six Sigma quality, along with a culture of learning, sharing, and unending excitement.”¹¹

REFERENCES

1. Hughes, Thomas. 2004. The Secrets of Six Sigma.
2. www.cptpharma.com
3. Kleinert, Andreas. 2005. Implementing Design for Six Sigma (DFSS) in Europe.
4. www.dti.gov.uk/bestpractice
5. www.sixsigmaway.com
6. www.tech-faq.com/six-sigma.shtml
7. Snee, Ronald. Dealing with the Achilles heel of Six Sigma Initiatives : project selection Is key to success
8. www.saching.com/Article/Six-Sigma-Concepts
9. Samuel, Philip and Lisa Modesitt. . Leveraging next generation Six Sigma : addressing challenges in pharmaceutical industry
10. Liu, Elliott. Breakthrough : Do clinical research the Six Sigma way
11. Juran Institute's Six Sigma Breakthrough and beyond - By Joseph A De Feo, William Barnard, Joseph Defeo.
