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Review

Six Sigma and Lean Concepts: A Novel Approach to Pharmaceutical Industry

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ABSTRACT

Six Sigma is a Concept of continuous enhancement aimed at reducing defects. Considerate the obstacles, key features & short comings of the six sigma technique allows organizations to enhance carry their planned directions, and escalating needs for training, mentoring, and coaching It also provides opportunities to better execute six sigma projects. This paper examines the evolution, benefits and challenges of six sigma practices and identifies the key factors influencing successful six sigma project implementations. Successful six sigma principles and practices will succeed by refining the organizational culture continuously. LEAN in order to achieve such goals as decreased wait time to discharge product to the market, reduce production waste, improve communication with end users and raise quality level both in the production and in testing laboratories. cGMP Good Manufacturing Practice, in order to work "smarter", more cost-effectively and avoid wasting time and other resources.

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Introduction

Six Sigma Concepts (Anonymous; 06/05/2020)

Six Sigma is a Concept of continuous enhancement aimed at reducing defects. It is a Quality Management System with a set of techniques and tools for Process Improvement.

Mid-1900s, Term Six sigma was coined by Bill Smith a Motorola Engineer, to describe a new QC process that emerged from the TQM strategy and was very successful in improving profits.

Today, it is used in many industrial sectors for minimizing errors, reduction of costs and increase in profit.

Sigma (σ) is a Greek alphabet used to denote standard deviation. It is a mathematical term used to measure variation or spread of any process around the average (mean). Thus, overall 6σ can be describes as:

Metric- A metric that demonstrates quality levels at 99.99967 percent performance for process.

Benchmark- A benchmark for product and process capability on a quality basis.

Tool- A practical application of statistical 'tools' to help define measure, analyze, improve the processes.

Commitment- A commitment to customers to offer the highest quality, reduced cost products.

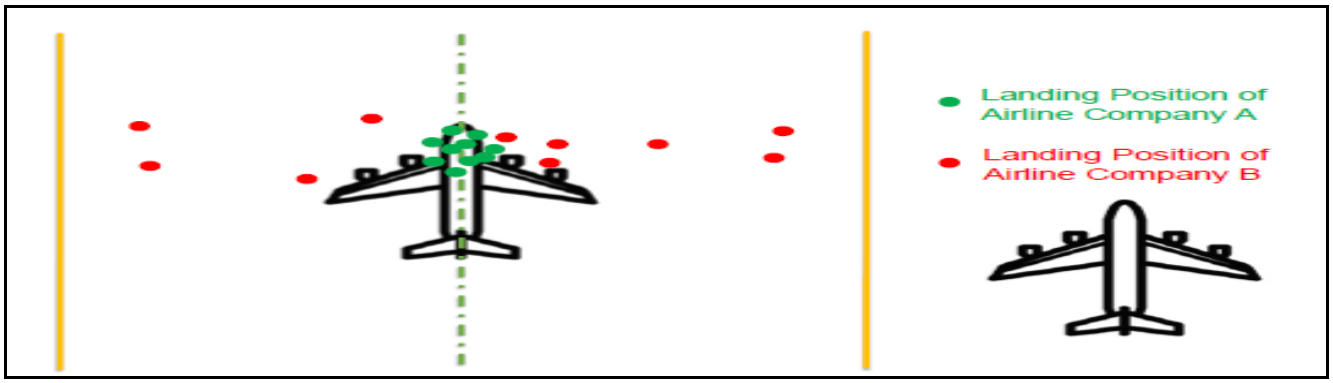

Fig. 1: Importance of Variation: Probability of derailing in Airline Company B is High

Origin of Six Sigma

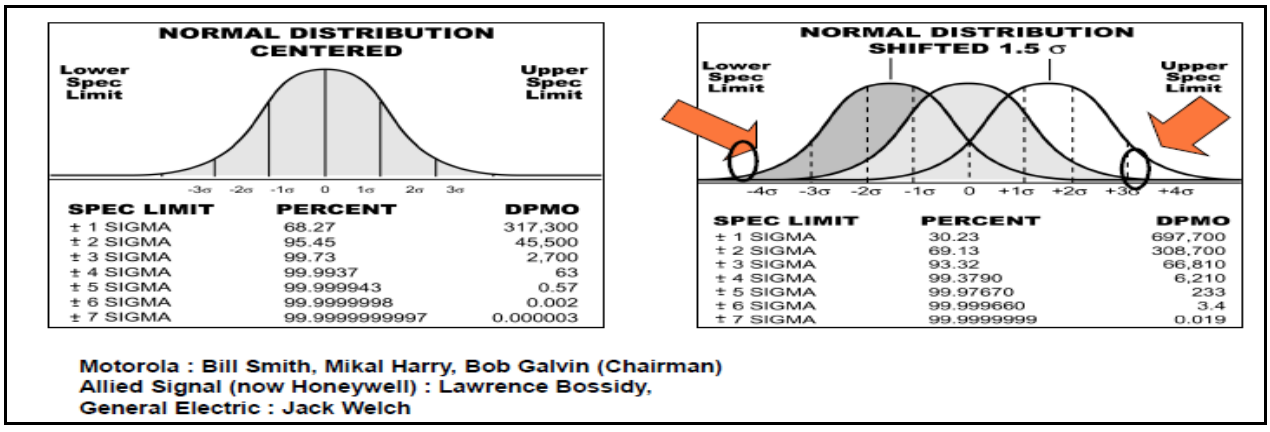

Fig.2: Origin of Six Sigma

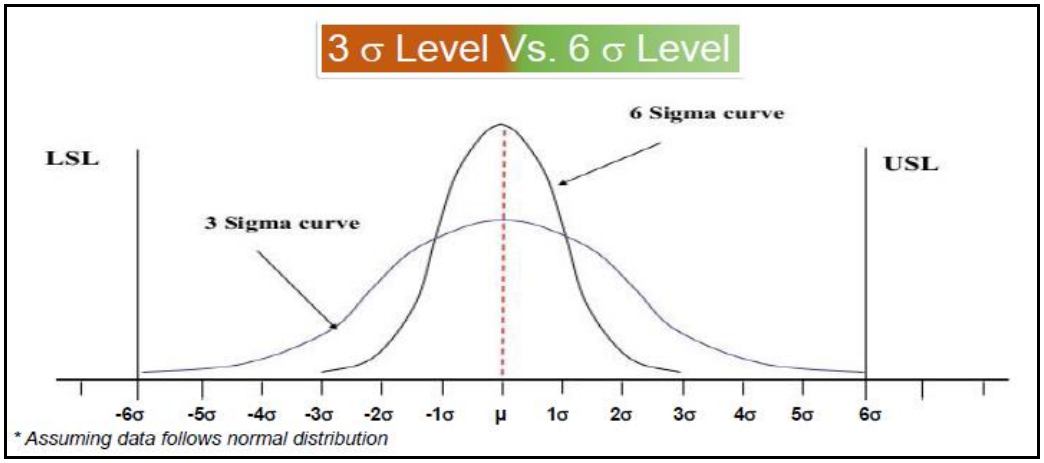

Fig.3: Sigma Level Understanding: 3σ Vs 6σ level

Table 1: Six Sigma – Its Significance

99% (2 to 4 level) Good	99.99967% (Six Sigma) Good
Lost articles 20,000 mail/hour	Lost articles 7 mail/hour
Unsafe drinking water for almost15min each day	Unsafe drinking water for only1 min each day
5000 false surgical operations per week	1.7 false surgical operations per week
200,000 incorrect prescriptions each year	68 incorrect prescriptions each year

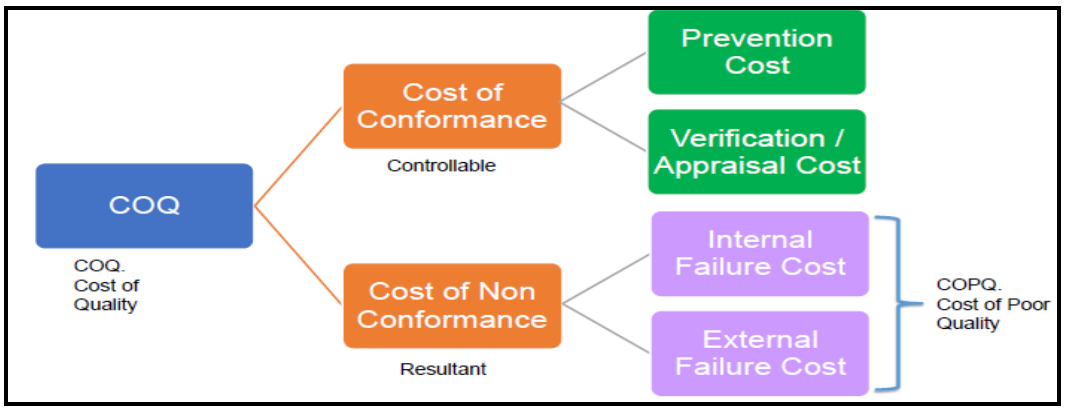

Fig.4: Need of Six Sigma

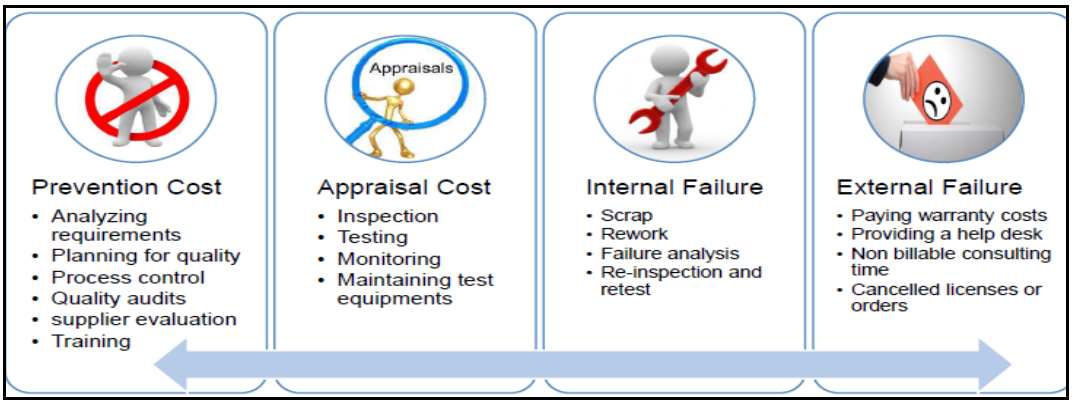

Fig.5: COQ - Examples

Purpose of Six Sigma (Greg B, *et al*., 2002)

1. Improve customer fulfillment
2. Decrease cost by using facts and arithmetical analysis
3. Minimize the non-desirable variation in the critical parameters in the processes.
4. Enlarge in the delivery of accepted units.
5. Avoids the timely and costly investigations that are caused by deviations in the process.
6. The goal of Six Sigma is to keep striving towards reduction in cost and increase in production by using the methodology to keep identifying possibilities for improvements.

Table 2: Difference between 6-σ Concept and Principles of cGMP

Area	6σ Concepts	cGMP
Objectives	Decrease Waste Create Value	Ensure Product Effectiveness, Prevent Harm
Focus	Value Stream	Manufacturing, Product Development and Quality Assurance
Improvement	Continuous and simultaneous	Regulated and prudent
Typical tools	Process Capability, Statistical Process Control, Measurement System Analysis, FMEA , Hypothesis testing, Process mapping	Documentation, Personal Qualifications and Training, Cleanliness, Validation and Qualification, Complaint review Audits

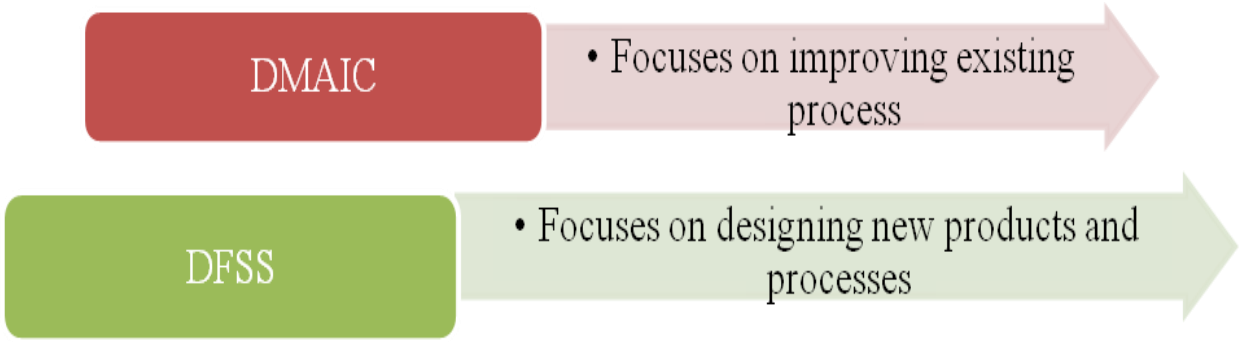

Fig. 6: Six Sigma Methodology

Table 3: Difference between DMAIC and DFSS/DMADV

Parameters	DMAIC	DFSS/DMADV
Define	Selection of performance characteristics critical in meeting customer necessities	Initiate, Scope and plan the project
Measure	Creation and Validation of a Measurement system	Understand customer needs and specify Critical to Quality Attributes (CTQs)
Analyze	Identification of sources of variation from the performance objectives	Develop design concepts and high-level design
Improve	Discovery of Process relationships and establishment of new procedures	Develop detailed design and control/ test plan
Control	Monitoring of implemented improvements to maintain gains and help ensure corrective actions are taken when necessary	Test design and implement full scale process.

Hierarchy in 6σ

To be able to use the tools professionally it is important that the users have great understanding about these tools and the methods to be used. Six Sigma therefore uses a structured learning program with Six Sigma leaders and specialists on several levels.

Table 4: Hierarchy

Champions	– To remove roadblocks – Many times, Process owner acts as a champion
Project Leader	– Green Belt/ Black Belt – Act as leader and manage improvement project
Process Owner	– A person who is decisive to the process in scope
Team Members	– Person involved in process of supply input and output chain
Extended Team Members	– Team members whose input to be taken as and when required

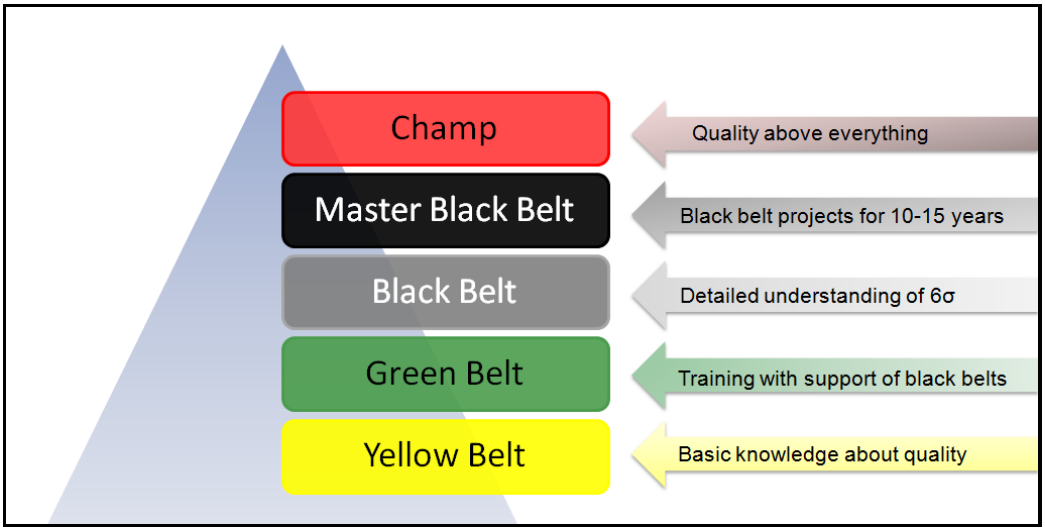

Fig.7: Hierarchy

Six Sigma Tools

Cp, Cpk and Pp, Ppk (Cholayudth, P. 2013)

Statistical Process Control Tool

↓

Monitors Process

↓

Tells Whether Capable or Not Meeting Desired Level of Performance

↓

Action to Be Taken

↓

To Investigate Concerns

↓

Helps In Process Improvement and To Achieve Desired Capability Levels

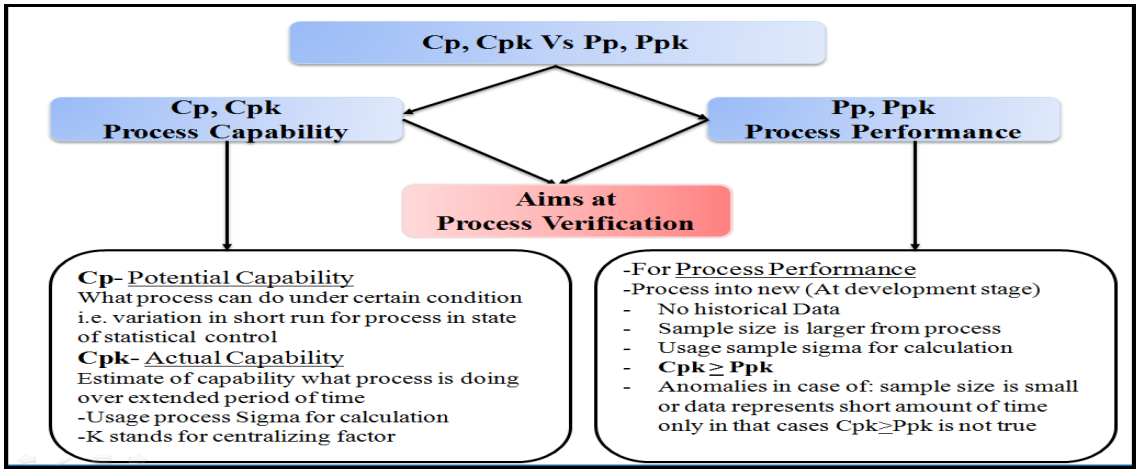

Fig. 8: Flow for 6σ Tools

Table 5: Sigma Level

Sigma Level	Defect Rate (Dpmo)	%Defective	Yield %Goods	Short Term Cpk	Long Term Cpk
1σ	691462	69	30.9	0.33	-0.17
2σ	308770	31	69.10%	0.67	0.17
3σ	66811	6.7	93.33%	1.00	0.5
4σ	6210	0.62	99.40%	1.33	0.83
5σ	233	0.023	99.98%	1.67	1.17
6σ	3.44	0.00034	99.99967%	2.00	1.5

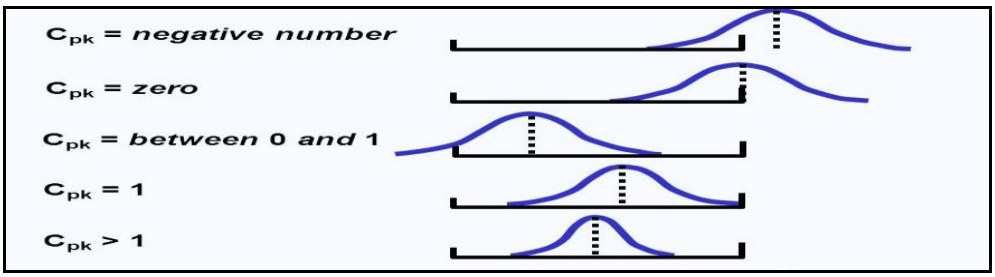

Fig. 9: IX Ranges for Cp

Ranges for Cp (Three possible)

Cp = 1, process variability just meets specifications.

Cp ≤ 1, process not capable of producing within specifications.

Cp ≥ 1, process exceeds minimal specifications

One shortcoming, Cp assumes that the process is centered on the specification range

Cp = Cpk when process is centered.

Six Sigma Advantages and Application (Anonymous; 02/05/2020)

1. Product/Process Design and Understanding Stage:

- According to experimental design change input material attributes and process parameter
- Allows identifying special causes and developing control strategy to eliminate or reduce variability

2. Process Scale up and Qualification Stage

- Create scientific proof that the process is reproducible at commercial scale and the process will consistently deliver a product that meets the quality standard established in development stage.

3. Routine Commercial Manufacturing Stage

- Continual assurance that the process remains in a state of control during commercial manufacture.
- Statistical process control tools to monitor the process.
- Cpk/ Ppk monitoring and trending data of process batches.

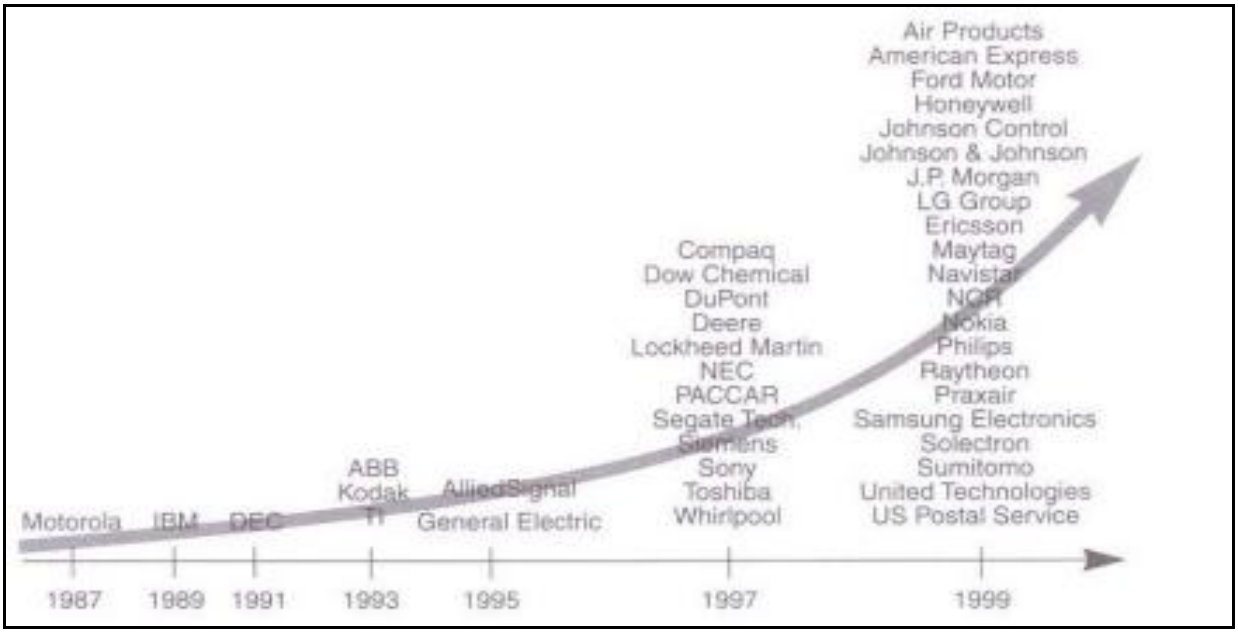

Fig. 10: Companies with Six Sigma

Companies with Six Sigma

World's most victorious companies has used Six Sigma, leading for savings of billions of dollars, striking the speed and capacity in their processes and achieving new, stronger customer relationships (Fig. 10).

Fig. 11: Concepts Lean Six Sigma

Lean Six Sigma Concepts

Toyota Production System, J.I.T., Lean Manufacturing, Demand Flow Technology, Kaizen, is really Process Analysis!

An integrated approach to utilizing Capital, Materials, and Human Resources to produce just what is needed, when it is needed. In the amount needed with;

Minimum materials,

Equipment,

Labor and Space (Fig. 11).

Lean Management (Sharma O P., et al. 2011)

Lean Streamlines a process, resulting in increased revenue, reduced costs and improved customer satisfaction.

A lean process is;

– Faster
– More efficient and economical
– Delivers satisfactory quality

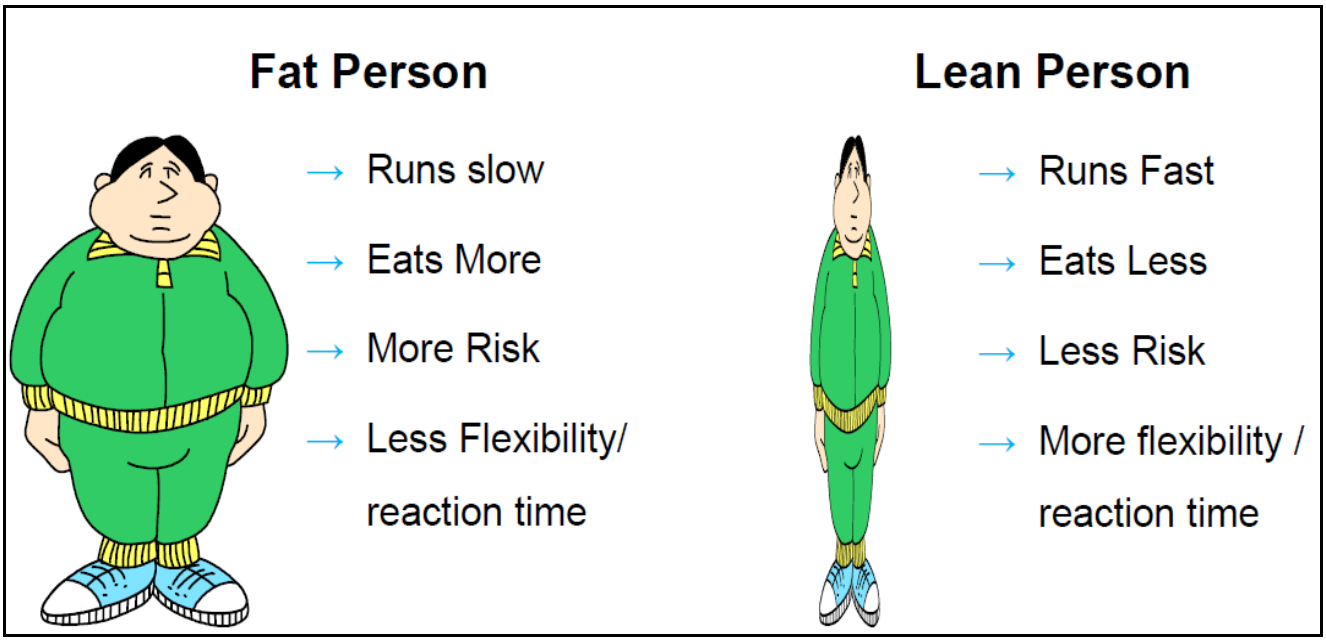

Fig. 12: Difference between for Two Organizations

Table 6: Difference between Fat and Lean Organization

Fat Organization	Lean Organization
Eats More	Eats Less
Resources - Money, Machinery, Time, Space	Resources - Money, Machinery, Time, Space
Waste	Waste
Produces	Produces
Less – Products, Work	More – Products, Work
High Risk	Less Risk

Table 7: Eight Wastes That Kills an Organization

	TIMWOODS
T	Transportation
I	Inventory
M	Motion
W	Waiting
O	Overproduction
O	Over processing
D	Defects
S	Skill

Table 8: Difference between Lean and Six Sigma

Lean	Six Sigma
Involves all Employees	May not involve all employees
Like Industrial Engineering	Data based, Project Approach
Any small improvement is acceptable	Only Breakthrough Improvement
Needs simple training to all employees	Needs sophisticated training to handpicked employees
No software is required	Statistical software like Minitab is required
Method for reaching to root causes is not rigor	Very structured approach to reach root causes (DMAIC)
Improvement target may vary	Improvement target is 6 sigma
Review of improvement doesn't have structured phases	Very sophisticated tools are and systematic process is adopted.

What can we expect with Lean Thinking?

Over 5 Years

1. Reduced Defects by 20% per year
2. Reduced Delivery lead times by more than 75%
3. Improved On Time Delivery to 90+%
4. Increases Productivity by 15-25% per year
5. Inventory reductions of more than 75%
6. Return on Assets Improvements.

Why Six Sigma + Lean

The reason explain in Fig. 13.

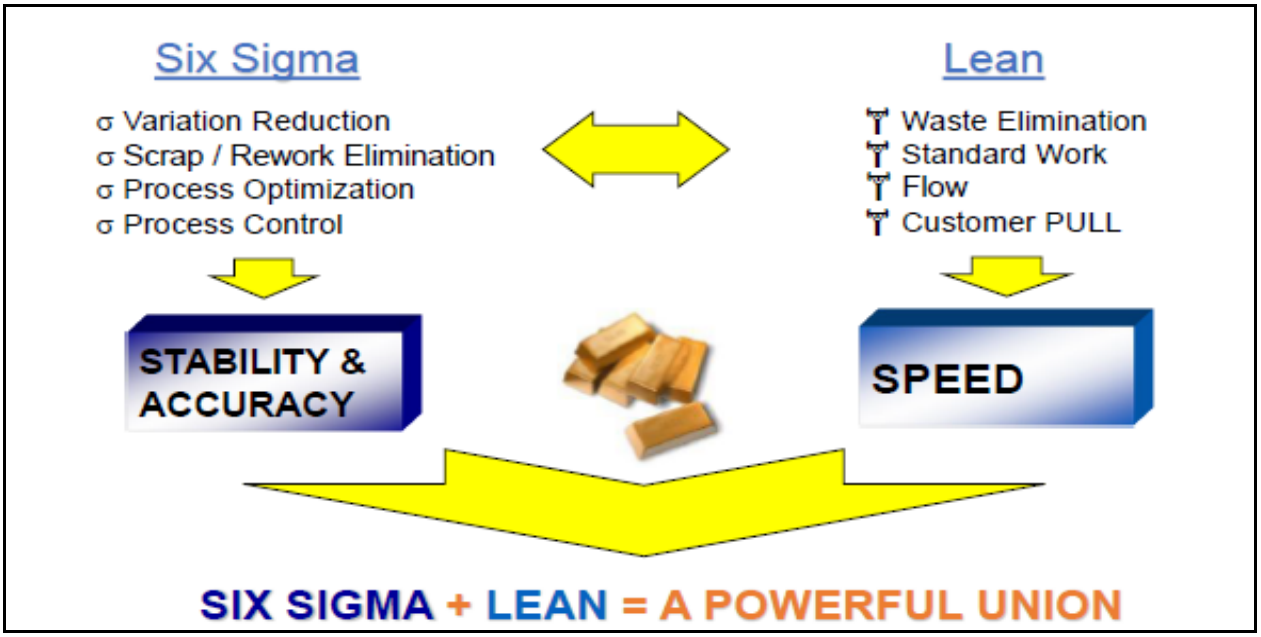

Fig. 13: Difference between for Two Organizations

Conclusion

Six Sigma performances have the potential to improve customer benefits with regards to improved quality and in some cases also by shortening time to market for new products.

Pharmaceutical companies need to embrace Six Sigma in the entire organization and not just manufacturing to realize the full potential of the method. The Pharmaceutical industry can use the experiences of other industries as a benchmark to formulate applications of Six Sigma. Leadership and commitment is critical to the success of Six Sigma in the pharmaceutical industry.

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