Implementing Lean Six Sigma in FDA Regulated Technology Transfer

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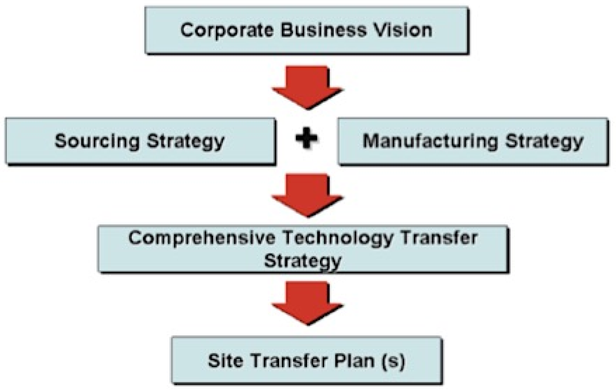
Introduction

Technology transfers from R&D to large scale manufacturing is one of the most vital processes in product development and supply. This is even more imperative in industries strictly regulated by the Food and Drug Administration (FDA), especially those of food, drug and devices.

Issues with current tech transfer processes include:

- Ill-defined timeline to meet market demands
- High process variation
- Extended cycle time
- Inefficient process flows

Technology Transfer Plan Hierarchy



(Snee, Hagen, & Alaedini, Technology Transfer By Design - The next stage in operational advantage, 2007)

The tech transfer process is highly complex and hierarchical. Simplifying the process and defining the measures to set a bar for tech transfers could reduce both cost and waste of resources and time while adhering to regulatory standards.

Objective

To develop a comprehensive methodology for improving the overall efficiently, speed and quality of the tech transfer process using Lean Six Sigma framework as the development tool.

Methods

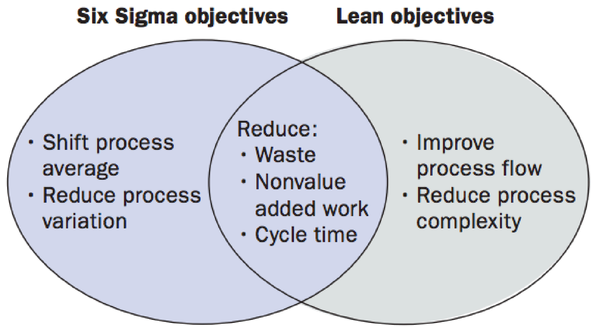
Tools such as DMAIC, statistical process control, process modeling, quality tools, statistical tools, analysis of variance and DOE, reduces the number of defects, waste, resource utilization and variability within the process

A DMAIC approach is ideal as it combines both characteristics of Lean and Six Sigma methodologies.

Measure is the most important phase to ensure that decisions are based on facts. This is achieved through:

- Identify and operationally define key metrics
- Develop a data collection plan
- Conduct a measurement system analysis to verify data accuracy
- Stratify the data
- Establish baseline charts
- Make charts and graphs to analyze processing times, errors or defects

Advantages of using DMAIC in up-scaling



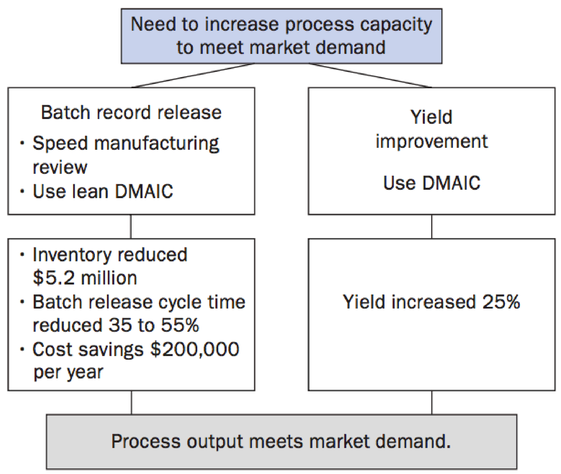
Lean Six Sigma improves quality, cost and delivery.

(Snee & Hoerl, 2007)

Phase	Tools
Define	Project Charter, VOC
Measure	FMEA
Analyze	FMEA, Risk Analysis
Improve	Robust design, Simulation, Optimization techniques
Control	Reliable testing, FMEA

Results

Advantages of using DMAIC in up-scaling



DMAIC = define, measure, analyze, improve, and control
(Snee & Hoerl, 2007)

Sustainable and long lasting, the total improvements in the process is expected to far exceed the efforts put in implementation:

- Increase in productivity and reduction in lead time
- Increase total quality through waste reduction effective planning and resource allocation.
- Resolution of high risk activities through data dependent conclusions
- Accurate reasoning of issues through root cause analysis and effective countermeasures (CAPA)

Conclusion

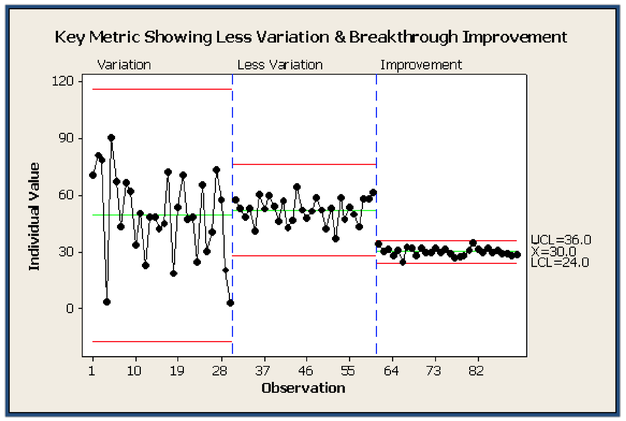
At present, technology transfer flow is non linear, involves different stages and takes more time over a decade to complete and manufacturing tech transfers on average take up to 1 year.

By implementing continuous improvement, using a generalized DMAIC framework, analyzing process variation and utilizing robust improvement methods, waste, cost and cycle time are reduced, and quality and efficiency are improved.

The Lean Six Sigma DMAIC process should continuously performed to ensure improvements and effective change responses.

Use quality by design (QbD) for a systemic approach to implement continuous improvement using the DMAIC framework.

Variation to Improvement



(Applying the DMAIC Steps to Process Improvement Projects, n.d.)

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