Principles of Lean Six Sigma and CAPA

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Agenda:

Part 1 – Lean Six Sigma

Overview

Lean and 6 Sigma integration
Workshop + Quiz

Take away:
Closing
Agenda:
Part 2 - CAPA

Objectives of course
  Med Dev + Pharmaceuticals
Operations Overview
Statistics regarding CAPA issues: FDA 483, Warning Letters + Consent Decree.
What is an effective CAPA program important for your business
CAPA regulation in detail
CAPA inputs
Effective approach
  Problem Solving
  Technical Writing
  Tracking and F/U
Ownership – your way of making business.
Principles of Lean Six Sigma

Overview of Lean Manufacturing and Six Sigma Methodologies

A Lean Enterprise
Today’s manufacturing and business environments are reaching a point that competition for survival and market share is an obligation.

Tracking the global economy will show that being good is not enough, therefore each organization really strive for excellence if want to stay in the market.
Every single organization is looking for one single outcome...
Business Facts

PROFIT
Business Facts

PROFIT is not a single concept but comes with many important implications:

• P- Process excellence
• R- Resources Management
• O- Oriented to a Goal
• F- Financially Strong
• I- Innovative – to stay ahead of competition
• T- Timely deployment of strategies
The most traditional definition of *PROFIT*
Business Facts

$$$$
LET’S MAKE MONEY
$$$$
BUT DO IT RIGHT
How we make PROFIT

In order to be a leader, most companies are realizing that traditional management, manufacturing processes, and other historic approaches, are not enough.

More effective methods are needed:

• Six Sigma
• Lean Manufacturing

With origins in the Toyota Production System, is a way of living in the business environment.
History of Manufacturing

Craft
Made to customer spec
Single piece mfg… each product unique
Variable quality
Little inventory
High cost … made for the rich

Mass Production
- Interchangeable parts – Whitney
- Division of labor – Taylor
- Assembly lines – Ford
- Labor strife

The “Lean” Enterprise
- High variety
- Small batch sizes
- PPM quality
- Engaged workforce
How we make PROFIT

Recognize a need to change and be able to do PROFIT.

*Process Analysis is the foundation toward achieving Process Excellence.*
We need to Change to make PROFIT?

A need for change is usually characterized by:

- Quality is a “Q.A.” department responsibility
- Large production lots
- Large centralized stores
- Customer dissatisfaction
- Enormous part and process variation
- Set-up measured in hours instead of minutes
- Order entry times measured other than in minutes
- Product margins eroded by increasing operating costs
- Ever-increasing competitive pressures
Need for change is a STRATEGIC ISSUE which any and every Manufacturer must address:

**Quality** - How to improve it

**Cost** - How to control it

**On-time Delivery** - How to ensure it

Failure to improve in *all* three areas means a loss of competitiveness in today’s global marketplace.

In other words, How we make PROFIT?
Why Change?

“Lean Linking” is …

Forward Thinking!
Why Change?

"Lean Linking" is... Forward Thinking!

Do not become the dinosaur of your industry
Evolutionary vs. Revolutionary Change

Having a forward looking perspective on continuous improvement is a requirement of the competitive marketplace and is the first step in becoming world-class.

DO NOT set incremental improvement goals over previous performance, rather -

Think of where we need to be:

- Continually declining costs
- Zero defects
- Minimal inventories
- Fully satisfied customers
What can we expect with Lean Thinking? (over 5 years)

- **Defects reduced** by 20% per year
- **Delivery Lead Times reduced** by more than 75%
- **On Time Delivery improved** to 99+%
- **Productivity** (sales per employee) **increases** of 15-25% per year
- **Inventory** (working capital) **reductions** of more than 75%
- **Return on Assets improvement** of 100%+
Analyzing and Improving Processes

What’s in a Name . . .

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

A Lean Definition

- 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.

Overriding Principle

- Identify and eliminate waste (MUDA).
How we make PROFIT - TPS

Toyota Production System = Operations Management System to achieve goals of highest quality, lowest cost, shortest lead time via engaging people toward goals.

**Technical**
- Stability
- JIT
- Jidoka
- Kaizen
- Heijunka

**Management**
- True North
- Tools to focus management attention
- Go and See
- Problem-solving
- Presentation skills
- Project management
- Supportive culture

**Philosophical**

**Philosophy/Basic Thinking**
- Customer First
- People are most important asset
- Kaizen
- Go and See → Focus on Floor
  - Give feedback to team members and earn respect
- Efficiency Thinking
  - True (vs. apparent) condition
  - Total (vs. individual) team involvement

**Diagram**

- Long-term asset → Learned Skills
- Machinery depreciates → Loses Value
- People appreciate → Continue to grow
Building Blocks of The Lean Enterprise

“Continuous Improvement”

- Training
- Rewards / Recognition
- Teamwork
Building Blocks of The Lean Enterprise

“Continuous Improvement”

- Training
- Rewards / Recognition
- Teamwork

Value Stream Mapping
Building Blocks of The Lean Enterprise

“Continuous Improvement”

- Pull / Kanban
- Cellular / Flow
- TPM
- POU
- Mistake Proofing
- Quick Changeover
- Standard Work
- Batch Reduction
- Layout
- Projects
- 5S System
- Visual Management
- Value Stream Mapping
- Training
- Rewards / Recognition
- Teamwork
Develop the ability:

To recognize and identify waste
To have to courage to call it waste
To have the desire to eliminate it
Eliminate the waste

Truly understand that waste
Raises costs
Produces no corresponding benefit
Threatens all of our jobs
To do PROFIT we can use the Lean Six Sigma Strategy ...

... for turning manufacturing and business processes into competitive weapons.

Producing what is needed, when it is needed, with a minimum amount of materials, equipment, labor and space.

“Prime Directive” - to continually seek out and eliminate waste and wasteful practices.
The Lean Six Sigma Strategy …

… with these 4 Main Goals:

#1) IMPROVE QUALITY
#2) ELIMINATE WASTE
#3) REDUCE LEAD TIME
#4) REDUCE TOTAL COSTS

With an overriding principle: Safety 1st!

to continually seek out and eliminate unsafe operating conditions and practices in every aspect of our Business.
The Lean Enterprise is a Strategy …

… with these 4 Main Goals:

#1) IMPROVE QUALITY
#2) ELIMINATE WASTE
#3) REDUCE LEAD TIME
#4) REDUCE TOTAL COSTS

With an overriding principle:
• to continually seek out and eliminate unsafe operating conditions and practices in every aspect of our Business and every process within our Operations and to constantly, and consistently, enhance Health/Welfare, Safety and Environmental concerns and issues.
With a well-planned implementation, overall expected RESULTS may include a …
(within 12 months)

35% to 50% reduction in lost time/safety-related incidents and accidents
15% to 30% decrease in scrap and rework
25% to 40% reduction in total cycle time
Lean Six Sigma – Benefits.

The Benefits Are There For The Taking

The Benefits **Always** Include Increased Market Share, Lowered Cost Higher Profits And Happier Customers (And Shareholders)

“Lean” Is The Only Answer Known That Provides These Benefits

“Lean” *Never Fails If You (R-E-A-L-L-Y) Do It*

Saying “Lean” Is Not Doing Lean

Every Successful Business That Competes In An Over-capacity Or Price-sensitive Market Is Doing “Lean” Whether They Know It Or Not
Lean Six Sigma

Philosophy and Key Concepts

• The 5 core principles of Lean
• Define value-added and non-valued added activity
• Define the 7 most common types of waste
• and their causes.
• Review a systematic approach to discover waste within a process.
Learn the 5 Core Principles of Lean:

1) Specify value in the eyes of the customer

2) Identify value stream and eliminate waste

3) Make value flow at pull of the customer

4) Involve & empower employees

5) Continuously improve in pursuit of perfection
**Lean Six Sigma**

**Customer perceives value**

**Value Added Activity**
An activity that changes the size, shape, fit, form, or function of material or information (for the first time) to satisfy the customer.

**Non-Value Added Activity**
Those activities that consume time or resources, but do not add value in the eyes of the customer.
Lean Six Sigma - Definitions

Value Added

• Any activity or operation performed that helps transform a product or service from its raw state into its finished form.
• Completed right the first time.
• Any activity customer is prepared to pay for. Activity required to ensure that a product or service is delivered in conformance to specification.

Non-Value Added

• Any activity that doesn’t help to transform a product or service into its final form. Activity not performed right. Activity customer not willing to pay for.
• This includes:
  ➢ Unnecessary process steps
  ➢ Movement of inventory, paperwork, etc.
  ➢ Re-work, corrections, etc.
  ➢ Storage between operations, batching inventory
  ➢ Wait times, delay times, idle times
Lean Six Sigma - 7 most common wastes

**MUDA = non-value added activity (waste)...**

Identify and reduce:

- Defects (repair, rework, scrap)
- Overproduction (inventory)
- Transportation (conveyance)
- Waiting (queue time)
- Inspection (reliance on mass inspection/ verification)
- Motion (parts, paper, people)
- Process, itself (over-processing, long cycles)

“Commonly referred to as the 7W’s...”
*7 common wastes of production (Shingo)
The Causes of Waste in most Processes

Types of Waste (7W’s)

- **Motion**
- **Waiting time**
- **Overproduction**
- **Processing time**
- **Defects**
- **Inspection**
- **Transportation**

Problems/ Causes

- Incorrect layouts
- Lack of proximity of machines
- Off-line resources
- Waiting workers, machines, materials
- Long set-ups and lead times
- Large batches, raw material stocks
- High WIP, finished goods stocks
- Making for the sake of it
- Ignoring customer demands
- Long cycle times - process, itself
- Reduced efficiency - over processing
- High overall lead times
- Long delays for rectification
- Costly rework
- Dissatisfied customers
- Approvals of approvals
- High number of verification steps
- Reliance - Mass inspection techniques
- Unnecessary movement
- Extra handling

Focus on reduction

- Waste
- Value Added
- Non- Value Added, but necessary

People

Process

Product

Types of Waste

- **Value Added**
- **Non-Value Added, but necessary**

The Causes of Waste in most Processes

The Causes of Waste in most Processes
Lean Six Sigma

Product Lead-Time

Raw Materials → TIME → Finished Goods

- Value Added Time
- Non-Value Added Time
Lean Six Sigma

Product Lead-Time

95% Non-Value Added

Historically, improvement efforts have been focused here.
Lean Six Sigma

Product Lead-Time

95% Non-Value Added

Whereas, “Process Analysis” activities should
Focus here - the Elimination of Waste (MUDA)
Identifying Waste

Waste can take many forms; some causes of the most common forms of waste include:

- lack of adherence
- unnecessary approvals or signatures
- reviews of reviews
- multiple hand-offs
- transportation
- long setup time
- correction, and
- over-production
Identifying Waste

Other causes of waste may include:

- poor maintenance
- lack of training
- poor supervisory skills
- ineffective production planning/scheduling
- lack of workplace organization
- Supplier quality/reliability

In most cases, inventory is wasteful; more importantly, **inventory** hides all sorts of problems in the company
Learn to Recognize the Types of Waste

From Taiichi Ohno, Architect of the Toyota Production System

Overproduction / Making To Much
Ties up capital, diverts production from customer requirements, loss of inventories

Transporting / Moving Things
Unnecessarily increases production time, extra WIP

Unnecessary Stock / Inventory
Ties up capital, risk of changes

Waiting
Decreases productivity, wastes personnel resources

Unnecessary Motion
Increases production time, unnecessary operator motion

Processing
Poorly designed / incapable processes

Defects
Scrap, rework, returns

Lead time reduction is achieved by identifying and eliminating waste
Lean Six Sigma

Inventory Hides Problems

Raw Material

Your Company

Finished Goods

- Line Imbalance
- Poor Communication
- Long Set-up Time
- Quality Problems
- Vendor Delivery Problems
- Poor Scheduling
- Down-Time
- Poor 5-S
- Absenteeism
- Poor Process Capability

Your Company

Inventory Hides Problems
Lean Six Sigma

*Process Analysis to the Rescue*

… we have only begun to deal with issues involved in trying to tie everything together for a whole-system approach. Some of the problems that continue to confound us are the following:

- The way manufacturing works with Sales makes scheduling and running the plants difficult.
  - We compound the above problem by the way we order from suppliers.
  - Labor and management still don’t trust each other.
  - The way we measure performance doesn’t provide information useful to running a plant and often encourages wrong decisions.
Lean Six Sigma – How to Discover Waste

Look at the “3 Real Things” in every operation …

Material Flow
(or Business Steps i.e. transactional processes)

Information Flow (data)

Work-in-process (could be both…)
Lean Six Sigma – How to Discover Waste

Ask **what**?
What is the operation doing?

Ask **why**?
Why is the operation necessary?
Ask *why* at least 5 times to lead you to the root cause

Everything that is not work is waste
Once you know the function, you can identify as waste anything that does not execute that function

Draft an improvement plan…
Ask **how**?
Lean Six Sigma – How to Discover Waste

Be on the look-out for these 3 Major contributors …

• Overburden/ Overdoing

• Unevenness

• Process methods
Lean Six Sigma – How to Discover Waste

Be on the look-out for these 3 Major contributors …

• **Overburden/ Overdoing** *(muri)*
  - waste caused by how work and tasks are designed

• **Unevenness** *(mura)*
  - waste caused by poor quality (process unpredictability)

• **Process methods** *(muda)*
  - waste caused by “DOT WIMP”
Lean Six Sigma - What actions must we take?

We must …

• decrease cycle times
• reduce travel distances
• standardize our processes
• reduce scrap, rework and waste
• improve all of our business processes
• reduce the variation in our schedules
• provide a constant, steady supply of parts to production, assembly, and test
Lean Six Sigma - What actions must we take?

We must …

• design products to match a stable, standard production process
• gain Market share
  - and -
• increase our competitiveness!

• Now – how do we get there ??
Lean Six Sigma

Utilize the process “DMAIC” ...
(Define, Measure, Analyze, Improve and Control)

• Understand the Problem
• Form the Team
• Understand the Process
• Gather Process Data
• Analyze the Process
• Identify possible Corrective Actions
• Screen/ Experiment to select best action
• Implement Action
• Verify Action
• Sustain Improvement
Lean Six Sigma

The Lean Six Sigma is a Strategy ...

... for turning manufacturing and business processes into competitive weapons.

**Producing what is needed, when it is needed, with a minimum amount of materials, equipment, labor and space.**

“**Prime Directive**” - to continually seek out and eliminate waste and wasteful practices.
SIX SIGMA
Six Sigma

Six Sigma is the term applied to the application of the DMAIC methodology.

It is a structured, disciplined, rigorous approach to process improvement.

The five steps link to each other into a logical sequence, creating an infinite loop for process improvement.

The goal of the method is to achieve 3.4 defects per million parts (or opportunities of doing it wrong), most commonly known as 6 Sigma.
Six Sigma

Implementation of Six Sigma requires commitment of the organization and team leaders.

Is quite common to see, Yellow Belts, Green Belts, Black Belts and too often the … Soft Belts.…

Being the last ones the ones obstructing the implementation.
If the organization you work for has a Six Sigma Program in place, not necessarily guarantee the success of the organization. It depends on good teams, good steering committee and champions as well as management support.

In any Six Sigma program, keeping the right people engaged towards success is the key.
Six Sigma – DEFINE Stage:

The objective in this area is to create a clear statement, a Team Charter, that depicts the success story to be created. Shows a high level description of the processes being improved and the expected achievements.

Show how your customers will be impacted

The most critical stage to catch the support from your organization.
Six Sigma – MEASURE Stage:

The whole objective here is to gather data and information that will help you in pinpointing the real causes of the problem being resolved.

Here you will know your current situation and the expectation on how much can be improved.

Information here, helps to refine your define stage if needed.

Set up the basis for the next stage:
Six Sigma – ANALYZE Stage:

The objective here is to get the data and use statistical tools to identify the root cause(s), create a hypothesis (or several ones) and prove them out. The ones that prove to be the real causes, are the ones needed to be addressed on the next stage.
Six Sigma – IMPROVE Stage:

The target id to implement actions to correct the problems identified on the previous stage.

These actions need to be tested and measured to verify that are effective.

The effective methods set the basis for the next stage.
Six Sigma – CONTROL Stage:

The target in here is to turn the solutions found into a rentable change in the processes. These changes are to monitor the performance, maintain the benefits from the solution implemented and set the ground for new improvement opportunities as the new data being collected feeds the DMAIC cycle for another project.

In the regulated industry, theses changes might require, new procedures (SOP) and Validations to ensure compliance to ISO and FDA regulations as applicable.
Six Sigma – Summary

Each single stage relies on the previous one for a comprehensive effect.
Cutting corners is prohibited in Six Sigma.
All data generated and used must be kept in an organized fashion, might be helpful when the DMAIC cycle gets you to a problem where that particular information was already gathered.
## Six Sigma – Tool Box

<table>
<thead>
<tr>
<th>TOOL NAME</th>
<th>CYCLE STAGE</th>
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<td>D M A I C</td>
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<td>Affinity Diagram</td>
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<td>Frequency Plots</td>
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<td>Brainstorming</td>
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<td>FMEA (Failure Mode &amp; Effect Analysis)</td>
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<td>Business Case</td>
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<td>Cause-and- Effect Diagrams</td>
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<td>Consensus</td>
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<td>Control Charts</td>
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<td>Continuous data</td>
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<td>X-Bar, R</td>
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<td>Data Collection Forms</td>
<td>X X X X X</td>
<td>Process Sigma</td>
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<td>Check Sheet</td>
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<td>Quality Control Process Chart</td>
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<td>P-Frequency Plot Check Sheet</td>
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<td>Concentration Diagram</td>
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<td>Sampling</td>
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<td>Data Collection Plan</td>
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<td>Design of Experiment</td>
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<td>SIPOC (Suppliers, Inputs, Process, Outputs, Customers)</td>
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<td>Full Factorial</td>
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<td>Screening Designs</td>
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<td>Stratification</td>
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<td>Stratified Frequency Plots</td>
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<td>More than Two Levels</td>
<td>X X X X X</td>
<td>Time Series Plots (Run Charts)</td>
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<td>Flow Diagrams</td>
<td>X X X X X</td>
<td>VOC (Voice of the customer)</td>
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### Cycle Stage

- **D**: Define
- **M**: Measure
- **A**: Analyze
- **I**: Improve
- **C**: Control
Six Sigma - Summary

After each stage is completed, demand a meeting with the people that must know, the progress is your best selling tool to keep getting the support.

Don’t be shy – your champion is there to assist you, the Black Belt is there to help you; no one is an expert on all the statistical tools, so ask for help before assuming incorrectly.
Lean Six Sigma

Six Sigma alone is not Lean Manufacturing, is just one tool, that combined with statistics can give you solutions.

Using the DMAIC cycle and using other Lean Manufacturing tools instead of Statistics can also produce results.
## Lean Six Sigma - Approaches and Techniques

<table>
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<th>CATEGORY OF WASTE</th>
<th>TYPE OF WASTE</th>
<th>WASTE REDUCTION APPROACH</th>
<th>METHOD</th>
<th>FOCUS POINTS</th>
<th>PRINCIPAL WORKSHEETS</th>
<th>DESIRED RESULT</th>
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<td>PEOPLE</td>
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<td>Workplace Management</td>
<td>Standard Work</td>
<td>Layout, Labeling, Tools/Parts Arrangement, Work Instructions, Efficiency, Takt Time, Skills Training, Shift Meetings, Cell/Area Teams, Visual Displays</td>
<td>Standard Work Sheet (SWS), Time Observation Form (TOF), Standard Work Combination Sheet (SWCS), Work Load Balancing Sheet (WLBS), Kaizen Target Sheet (KTS), Kaizen Action Sheet (KAS)</td>
<td>Highly Efficient, Safe Work Areas With High Output</td>
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<td></td>
<td>Motion</td>
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<td>Workplace Organization</td>
<td>Kaizen</td>
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<td>Waiting</td>
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<td>20 Keys</td>
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<td>QUANTITY</td>
<td>Inventory</td>
<td></td>
<td>Leveling, Kanban, Quick Setup, Preventive Maintenance</td>
<td>Work Balance, WIP, Location/Amount, Kanban Location, Kanban Types, Lot Sizes, Changeover Analysis, PM Analysis</td>
<td>SWS, SWCS, WLBS, Kanbans, Table of Production Capacity By Process (TPCP), PM Scheduling Sheet (PMSS)</td>
<td>What You Need, When You Need It</td>
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<tr>
<td></td>
<td>Moving Things</td>
<td>Just-in-time</td>
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<td>Making Too Much</td>
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<tr>
<td>QUALITY</td>
<td>Fixing Defects</td>
<td>Error Proofing, Autonomation</td>
<td>Detection, Warning, Prediction, Prevention</td>
<td>Appropriate Automated Assistance, Fixture Modifications, Successive Checks, Limit Switches, Check Sheets, Photocells, Templates, Etc., Cross Training</td>
<td>SWCS, Error Proofing Action Sheet (EPAS), Error Proofing “To Do” List (EPL), Skill Versatility Visual Display</td>
<td>Good Quality</td>
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*Kaizen - one effective method among many that engages PEOPLE and “recruits” the other tools*
Kaizen = Continuous Improvement

“Kai” = Small, Continuous Change
“Zen” = Ongoing Change For The Better

Structured, Focused, Coached, Mandated & Required Activity To Compel Every Employee To Participate In Improving The Quality And Efficiency Of Their Day-to-day Micro-processes

Not A “Suggestion Box” Program

Building Blocks of Lean Production
Just-in-time
Standard operations
Mistake-proof processing
Pull production & single piece flow
Cellular manufacturing
Visual workplace

Kaizen is the “transport vehicle” to import these building blocks of lean production

These concepts are equally applicable to the factory floor and within the office
<table>
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<th>Lean Six Sigma – Guides for Kaizen</th>
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<tr>
<td>• Reject the current situation</td>
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<td>• Keep an open mind to change</td>
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<td>• Maintain a positive attitude</td>
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<td>• Make problems visible; make the workplace visual</td>
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<td>• Never leave in silent disagreement</td>
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<td>• Practice mutual respect every day</td>
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<td>• One person, one voice - no position or rank</td>
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<td>• There’s no such thing as a dumb question</td>
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<td>• Take action over excuses and make actual improvements now</td>
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<td>• Get on base rather than go for the long ball (small progress vs. all)</td>
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<td>• Use your head rather than your money</td>
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<td>• Destroy myths of fixed production</td>
</tr>
<tr>
<td>• It’s a never ending task</td>
</tr>
<tr>
<td>• HAVE FUN and JUST DO IT!</td>
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VALUE
STREAM
MAPPING
Lean Six Sigma – Short History

Origins in Toyota, circa 1955 – The way of doing business…

Also called “Material and Information Flow Mapping”

Used by Toyota Motors to show both current and ideal states as part of the lean implementation process

Discussed in “Lean Thinking”
Further developed and documented by the Lean Enterprise Institute of Brookline, Mass.
“Learning to See”
Lean Six Sigma – What is Value Stream?

All the actions, both value added and non-value added, currently required to bring a product from raw materials to the customer.
Lean Six Sigma – Value Stream Perspective

A value stream is all the actions (both value added and non-value added) currently required to bring a product (or transaction) through the main flows essential for every product/service: from raw material/(customer need), through all the required steps, then – back to the arms of the customer.

Taking a value stream perspective means working on the big picture, not just individual processes, and improving the whole, not just optimizing the parts.
Lean Six Sigma – Value Stream Map

Operational example

Map major process steps
I.D. Value (green/ yellow) / Non-value (red)
Capture all times, quantities
Prioritize areas to improve

Operational example
X SHIPPED PER DAY
850K
1.870 WIP BEING WORKED
4.276 WIP BEING STORED
Lean Six Sigma – Value Stream Map

Big Picture example

Supplier

Orders

Prod’n Cont.

Orders

Customer

MACHINING

C/T=1568 m

C/O=50 min.

2 SHIFTS

OPER. 48

2 DAYS

Daily

1 DAY

12 WEEK FORECAST

ASSEMBLY

C/T=936 m

C/O=0 min.

1 SHIFT

OPER. 24

2 DAYS

OXOX

PITCH = 60 MINUTES

TEST

C/T=60 m

C/O=30 min.

1 SHIFTS

OPER. 5

2 DAYS

TEST

C/T=60 m

C/O=30 min.

1 SHIFTS

OPER. 5

2 DAYS

FINISH

C/T=210 m

C/O=0 min.

1 SHIFTS

OPER. 6

2 DAYS

DISPATCH

C/T=30 m

C/O=0 min.

1 SHIFTS

OPER. 2

2 DAYS

12 WEEK FORECAST

MANUFACTURING LEADTIME = 3 1/2 DAYS

CUSTOMER LEADTIME = 2 WEEKS

IRREGULAR

LT<3 1/2 DAYS

900 MINS

900 MINS

240 MINS

150 MINS

120 MINS

<2 ENGINES

<2 ENGINES

<1/2 DAY
Lean Six Sigma – Why do Value Stream Mapping?

- To understand the current situation - The “big picture” point of view (To use as a tool to improve the whole vs. optimizing the parts…)

- Exposes sources of waste - not just the waste

- Shows linkage between information flow and material flow

- Forms the blueprint to identify areas of improvement
Lean Six Sigma – Why do Value Stream Map do for us?

- It helps visualize more than just the single-process level, i.e. assembly, welding, etc., in production. You can see the whole flow.

- It helps to see more than waste. Mapping helps to see the sources of waste in your value stream.

- It provides a common language for talking about manufacturing (and transactional) processes.

- It makes decisions about the flow apparent, so you can discuss them. Otherwise, many details and decisions in your area just happen by default.

- By adding data, it ties together lean concepts and six sigma techniques, which helps you avoid “pet projects”.
Lean Six Sigma – Value Stream Map is an Essential Tool

It forms the basis of an implementation plan. By helping you design how the whole door-to-door flow should operate - a missing piece in so many lean efforts - value stream maps become a blueprint for improvement. Imagine trying to build a house without a blueprint!

• It shows the linkage between the information flow and the material flow. No other tool does this.
Lean Six Sigma – Value Stream Map is an Essential Tool

It enhances the quantitative tools and layout diagrams that produce a tally of non-value added steps, lead time, distance traveled, the amount of inventory, and so on.

• Value stream mapping is a qualitative tool by which you describe in detail how your facility should operate in order to create flow. Numbers are good for creating a sense of urgency or as before/after measures. Value stream mapping is good for describing what you are actually going to do to affect those numbers.
Lean Six Sigma – Process Map Analysis

Steel Fabrication Process (Current State)
Can you identify areas for improvement?
Lean Six Sigma – Process Map Analysis

Steel Fabrication Process (Future State)

- Steel Recd
  - Structural Steel Sawed
  - Plate Steel burned
  - Components machined
  - Weld Shop
  - Blasting Booth Sand Blast
  - Paint Shop
  - Inspection
  - All parts to Assembly Staging
  - Mech/Elect Assembly
  - Inspection & Run Test
  - Shipping & Crating
  - Ship to Customer

- Elect/Mech Parts Recd
  - All parts to Assembly Staging
  - Mech/Elect Assembly
  - Inspection & Run Test
  - Shipping & Crating
  - Ship to Customer
The Benefits of Implementing “5S”

5S provides a basis for being a world-class competitor and the foundation for a disciplined approach to the workplace.

5S Improvements:

- Safer working conditions
- A cleaner and more organized work area
- Reduction in non-value added time
- Effective work practices
- Efficient work processes

Facilitating a change: Safer, Better, Faster!
And The 5-S’s are...

Seiri – (Separate) or Sort
Seiton – (Straighten) Store, or Put-in Place
Seiso – (Clean) or Shine
Seiketsu – (Standardize)
Shitsuke – (Discipline) or Sustain

+ Safety!
Sometimes called 5S + 1 or “6S”

Safety 1st! (in everything we do!)

Seiri – (Separate) or Sort
Seiton – (Straighten) Store, or Put-in Place
Seiso – (Clean) or Shine
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Shitsuke – (Discipline) or Sustain
Lean Six Sigma - Other Lean Tools

• Root Cause Analysis and Corrective Action (RCCA) – 5 Why Technique
• Spaghetti Charts
• Pareto Analysis
• Visual Displays
• Visual Controls
• Total Predictive Maintenance
• SMED – Single Minute Exchange of Dies.
Lean Six Sigma
LEAN SIX SIGMA

REFERENCES:
• The Lean Enterprise – http://www.freeleansite.com/
• Six Sigma Green Belt and Champion Training – BD Training
• The Kaufman Consulting Group, LLC (KCG) – BD Training