P017:Lean – Sigma Six: Measure and Improve

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Lean - Six Sigma in a Nut Shell

Lean

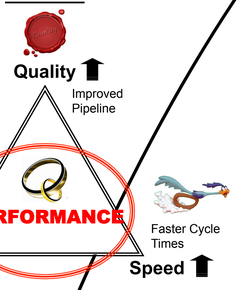
Maximise customer value while minimising waste. Simply, lean means more value for customers with fewer resources.

Sigma

Six Sigma is a quality improvement methodology with a particular goal of reducing defects to near zero.

Combined Lean - Sigma provides tools to minimise waste and cost while improving speed and quality

Continuous Improvement Model



In the competitive world of drug development costs are constantly rising. The average cost to bring a drug to market is in excess of *£800m. Drug patents are limited to 10-20 years. Companies need to be constantly improving to stay ahead.

"Focusing on quality actually reduced cost more than focusing on cost"

Jeffery K Liker – 'The Toyota Way'

*(Journal of Health Economics 2003)

Visible Planning

Visible Planning is about turning the lights on. Breaking silo working, and fostering good communication is the key to improving quality whilst reducing waste.



"Tell me and I will forget, show me and I may remember, involve me and I'll understand."

- Confucius

History

"Quality can truly change GE from one of the great companies to absolutely the greatest company in world business."

- Jack Welch – General Electric

Six Sigma

Originally founded by Motorola in the early 80's headed by George Fisher at Motorola's Communicators Sector. Developed in a crisis attempt to improve quality.

General Electric (GE) saved $12 billion over five years and added $1 to its earnings per share.

Lean

Developed from the concepts comprising the Toyota Production System (TPS) and named in the early 90's. Lean practices have existed for hundreds of years.

The techniques have widely been used outside of the manufacturing processes from Hospitals to Financial institutions.

From the Drug development industry Eli Lilly, Merck, J&J, Pfizer and Covance are just a few companies to have made direct cost savings.

Waste

"Time waste differs from material waste in that there can be no salvage."

- Henry Ford

Waste exists in every organisation in some way, shape or form. Eliminating / reducing waste will make you and your organisation leaner. Quality should improve as a by product. Less steps means less chance of deviation.

Types of waste **TIMWOOD**

Transport waste

Inventory

Motion

Waiting

Over producing waste

Over processing waste

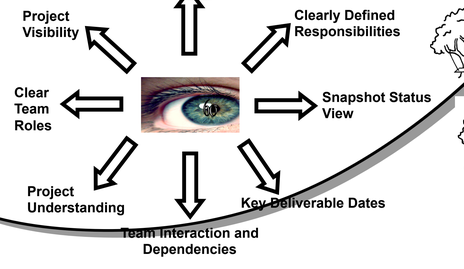
Defects



What is Visual Planning all About?

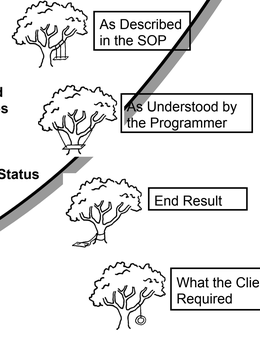
Visual planning aims to charter the flow of a project and enable the team to visualise all the processes and interactions.

Creates Pull within a team to achieve objectives



Where Did it all go Wrong?

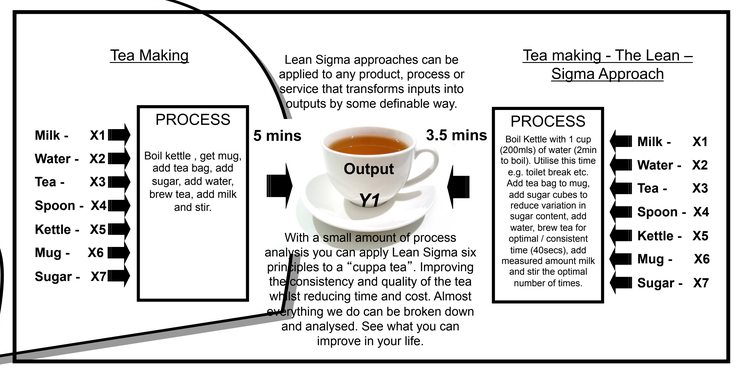
Production lines in manufacture are much easier to picture whilst Invisible work processes are more difficult to fully identify and improve.



Processes can be understood in different ways and results are not always as expected.

Visual planning aims to bring stake holders together to achieve a "Right first time approach."

Input Output Model: Y =f(X) Concept

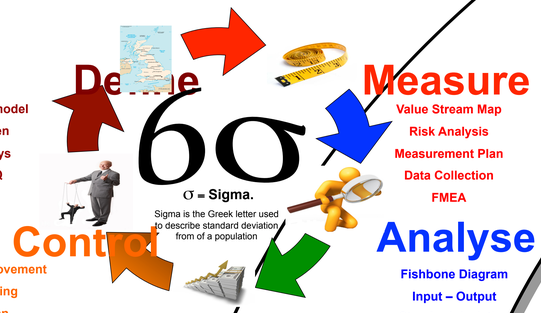


Lean Sigma approaches can be applied to any product, process or service that transforms inputs into outputs by some definable way.

With a small amount of process analysis you can apply Lean Sigma six principles to a "cuppa tea". Improving the consistency and quality of the tea whilst reducing time and cost. Almost everything we do can be broken down and analysed. See what you can improve in your life.

DMAIC Model

The DMAIC methodology is commonly used in Six Sigma projects. There are many models that can be utilised (see below). Models included in the poster can lend benefits to the study level programming process.



Define
- SIPOC model
- Kaizen
- 5 Whys
- CTQ

Measure
- Value Stream Map
- Risk Analysis
- Measurement Plan
- Data Collection
- FMEA

Analyse
- Fishbone Diagram
- Input – Output
- Standard deviation
- Median

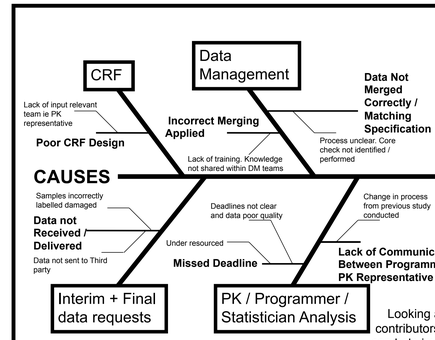
Improve
- Creativity
- Future State VSM
- Brain-Storm
- Pilot

Control
- Continuous Improvement
- Visual Planning
- Control Plan
- Poka Yoke
- SOP's

The Visual Planning (VP) Board - Instructions

1. Ensure all the stakeholders are present at the session or at least a representative is there on their behalf.
2. Team Introductions and Ice-breakers.
3. As a team, complete Study Team / Objectives Board. Agree primary objectives of the study. Key milestones maybe added whilst detail should be kept minimal.
4. As a team think of 3 – 5 key project deliverables / milestones based on the project objectives and add to the VP board under project milestones.
5. Each team member must write on Post-it notes key deliverables associated with their role. Use the input Output model above to assist. The Post-it notes should be dated with deadline. Assign potential risk level.
6. Place the Post-it notes on the VP board and review the process and steps involved. Look at how the project flows from process to process. Can value be added? Discuss.
7. Look for duplication in efforts, wasted time, interactions, dependencies where x1 and x2 need to be completed to start y1. Assess timeframes in which tasks need to be completed.
8. Hang the VP board where all team members can see. For virtual teams electronic VP boards exist. Photographs of the VP board can be taken and emailed.

Cause and Effect Analysis: Fishbone or Ishikawa Diagram



Fishbone Diagram Showing Cause and Effect Analysis of Delays in PK Output Delivery.

Aim of the model is to find root causes of problems and visualise the process from all perspectives allowing solutions to be derived.

1. Make sure all the stakeholders are present who are involved in the process to allow all views to be voiced (use a white board).
2. Briefly name the problem or effect to be analysed and write it at the "Head" of the diagram.
3. Determine the key contributors to the process. Add to the diagram.
4. Add the processes each contributor makes to the diagram; These can be broken down into sub-levels.
5. Use the Risk Analysis Matrix / Brainstorm as a team outlining the key issues and how they maybe resolved.

Looking at the diagram you can see there are a number of issues and a lot of team contributors working in different departments. Implementing Visual Planning techniques can help improve communication and show clearly where all the interactions / handovers occur. A step by step process map with roles, responsibilities and contacts will help to solve bottlenecks (See Visual Planning section below):

Meetings – The Lean Way

When planned and executed, meetings can be an efficient way to share information and solve problems. When meetings are scheduled without reason, too often, or not enough, they become a waste of time, energy and can cause frustration.

Here are a few meeting Dos and Don'ts

Meeting Dos

- Short and regular
- Meeting ground rules – Team consensus
- Agenda - regular meetings
- Standardised format anyone can lead
- Invite only key stakeholders (Mandatory attendance)
- Problem focused
- Park non agenda items to end and then plan appropriate course of action
- Sigma 7 second rule for responses. (7 second pause for answers)
- Schedule meetings appropriately
- Summarise outcomes and responsibilities and timelines
- A few minutes to appraise the meeting

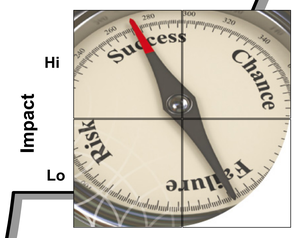


Meeting Don'ts

- Go off topic
- Over run
- Let any one person dominate the meeting
- Lecture – Meetings are for discussion, feedback, questions etc
- Avoid discussions of deliverables that are on track



Risk Analysis Matrix



Assessing risk is a very important part of project / process management. Dependencies often exist within processes and issues can often lead to a bottleneck in flow.

Conduct a simple risk analysis to assess the probability of any issues affecting the project flow. It is important to hear everyone's views and discuss why a process has been assigned to a particular impact versus probability section.

A consensus should be reached.

VP Board

Study Team / Objectives

Project Name XXX-XXX

Phase I DLT study –

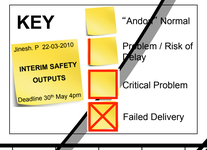
Primary Objective

Primary Endpoints – Maximum tolerated dose

Team members: Jin, Will, Anne, Simon, Nera , Vaibhav

Contact information: XXX xXXX xXXX xxXXX xX xXXX

All key study information is present. Primary objectives and endpoints are also included to ensure the project fulfils it's objectives, and does not turn into exploratory analysis e.g. outputs for the sake of outputs.



Post-it notes showing Name, Date, Deliverable and Deadline are placed on the VP board. Interactions, overlaps, handovers and dependencies become visible and can be assessed. Joining lines can be drawn on to the VP board to highlight touch points between processes. The team can assess the project flow and eliminate waste.

Objectives / Deliverables

Week commencing	Jan 1st	Feb 8th	Mar 15th	Jul 1st	Aug 18th	Oct 15th	Nov 2nd	
Project Milestones	SAP / Protocol review	CRF sign off 8th Feb	Templates sign off 22nd March	Interim Review 5th July	2010 IND reporting 23rd Aug	Draft Review Oct 16th	xxxxxx xxxx	xxxxxx
Jin - Deliverables Programmer								
Will - Deliverables Statistician								
Anne - Deliverables Data Manager								
Simon - Deliverables Physician								
Nera - Deliverables Medical writer								
Vaibhav - PK PD								

Issues

All critical issues are placed on the issues board and circled with red marker. Name, date the issue is acknowledged and date resolved are all added. The board allows clear summary of study issues and easy source of agenda items to discuss and resolve issues.

New Info / Decisions

Xxx x x xx xxx xxxxx xxxx xxxx xxx xxx

New information / Decision information is recorded, dated and initialled by the team to show who agreed the decision.

"It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change."

- Charles Darwin

Quanticate