Application of Lean Sigma in Pharmaceutical Industry – A practitioner’s reflection

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### Australian Pharmaceutical Industry

#### Challenges
- Productivity & Competitiveness
- Shrinking of Manufacturing Sector
- Geographic Isolation

#### Opportunities
- Innovation & Progressive Thinking
- Collaboration & Partnership
- Knowledge Sharing & Management
- Application of Lean & Six Sigma
1. Specify value in the eyes of the customer

2. Identify the value stream & eliminate waste & variation

3. Make value flow at the pull of the customer

4. Involve, align & empower employees

5. Continuously improve knowledge in pursuit of excellence
Application of Lean Sigma

• **Value** = f (Quality, Service, Cost)

• **Customers**
  -- Big C: patients/ doctors/ pharmacists/ health care providers/ regulators
  -- Small c: Internal customers

• **Quality**
  -- Patient safety
  -- Fit for purpose
Application of Lean Sigma

Quality by Design

-- Critical to Quality Parameters
-- Factors impacting on variability of process outputs
-- Factor range & interaction
-- Process design robustness & optimisation
-- Parameter design
-- Process performance, capability & control
-- Risk based management
-- Quality at source vs multiple checking
-- Uniformity around a target value vs compliance with specifications
Taguchi taught the business world that there is monetary loss any time a product or service deviates from the target.
Application of Lean Sigma

Process Understanding Capability & Control
-- Robust process design & development
-- Robust technology/ process transfer
-- DMAIC
-- PF/CE/CNX/SOP
-- Design of Experiments
-- Control Charting: Address causes of OOC symptoms before they become OOS
-- Understand sources of variation: Process vs measurement system
-- Measurement System Analysis: prospective vs retrospective
-- Error proofing
-- Standard work
Retrospective MSA Process

Obtain / Calculate Sigma for **Release** Product/Tests

Is Sigma < 4.0 ?

Yes

Perform Retrospective MSA as per GMS MSA Deployment

Knowledge Management : Understand causes of variation and recommend products/methods where further work (e.g. Standard Work, Prospective MSA, Process Improvement) would be of benefit

No

Usually obtainable from periodic product review

No further action required. Process sufficiently capable at this stage

Gather at least 20 batches of historical data
Application of Lean Sigma

Waste & Variation
-- SOP vs standard work
-- VA vs NVA activities
-- 7 Wastes
-- Process RFT
-- Testing RFT
-- Documentation RFT
-- Line/ equipment OEE

Process Flow Mapping

Time Value Map

Ventolin Nebules Bulk Bx Review / Release
Cycle Time = 1.75hr (105')

1' 64' 4'
15' 12' 8'

Value Added Non-Value Added
Application of Lean Sigma

Lab Bench Top Before 5S

Lab Bench Top After 5S
Flow
-- FIFO vs Laboratory scheduling
-- Visual control vs Spreadsheets
Application of Lean Sigma

Flow
- FIFO vs Laboratory scheduling
- Visual control vs Spreadsheets

Chemistry Lab Heijunka System

Chemistry Lab Sample Label
Application of Lean Sigma

Flow
-- FIFO vs Laboratory scheduling
-- Visual controls vs Spreadsheets
-- Pull vs push

Microbiology Lab “Qantas” board
Application of Lean Sigma

Spaghetti Chart

Visual Equipment Home Location

Consumables Kanban

Point of Use Consumables
Application of Lean Sigma

Sterility testing cell load chart

Pull of customer
-- Takt time
-- Staff #
-- Load levelling
Leading & Managing in a Lean Sigma Environment

- Creating the right culture
- Mentoring & coaching
- People involvement
- Visual controls
- Leadership standard work
- Adherence to accountability process
- Sensei & Gamba walk
- Problem solving & rapid process improvement
- Systems Thinking
- Change management
- Communication
- Managing expectation
- Courage & resolve
- Shadow of the Leader
### Load levelling by Takt time
- VOC analysis linked to batch release requirements
- Load levelling for products & OQ batch reviewers
- Real time tracking of actual batch review & release completed vs target
- OQ batch review & release operation at the pace of manufacture

#### Root Cause for not Meeting Target:

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Real Time OQ Customer Service Performance Monitoring System

-- Tracking of actual OQ batch review & release customer service performance against target
-- Cause & Effect Analysis
-- Action planning & tracking
-- Re-load levelling to cover staff leave & unforeseen issues