



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

**Ivy Leung
GSK Australia**

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

Lean Sigma Principles

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

Variation-Taguchi's View

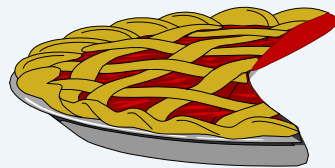


Taguchi taught the business world that there is monetary loss any time a Product or service deviates from the target.

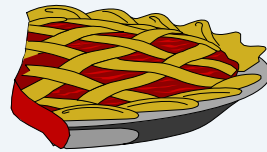
Application of Lean Sigma

Process Understanding Capability & Control

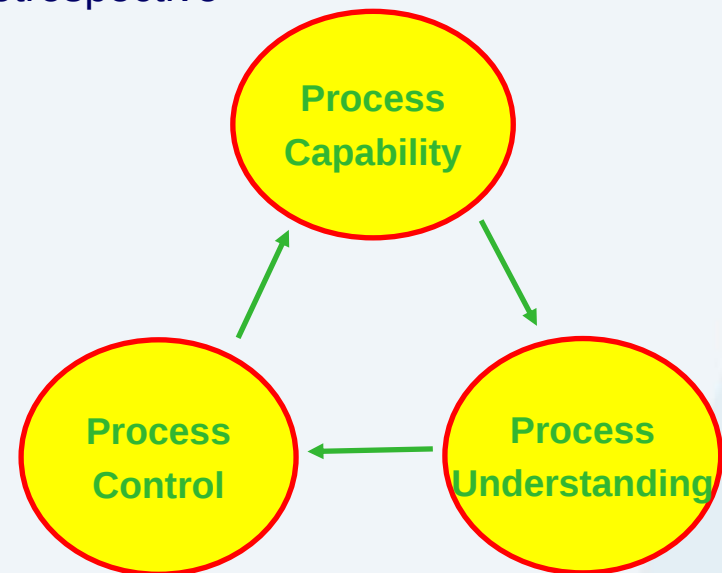
- Robust process design & development
- Robust technology/ process transfer
- DMAIC
- PF/CE/CNX/SOP
- Design of Experiments
- Control Charting: Address causes of OOC symptoms before they become OOS
- Understand sources of variation: Process vs measurement system
- Measurement System Analysis : prospective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



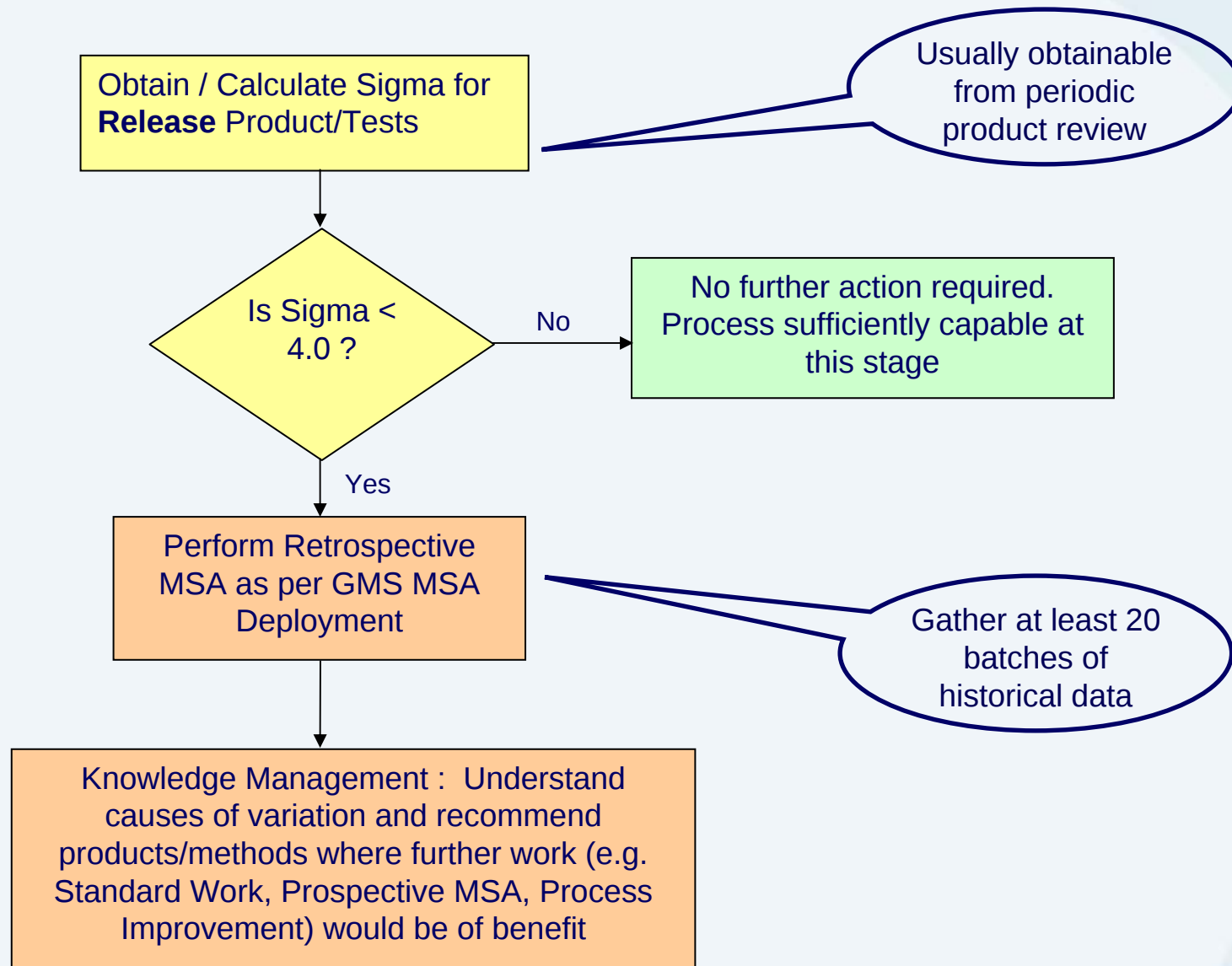
**Product
Variability**



**Measurement
Variability**



Retrospective MSA Process

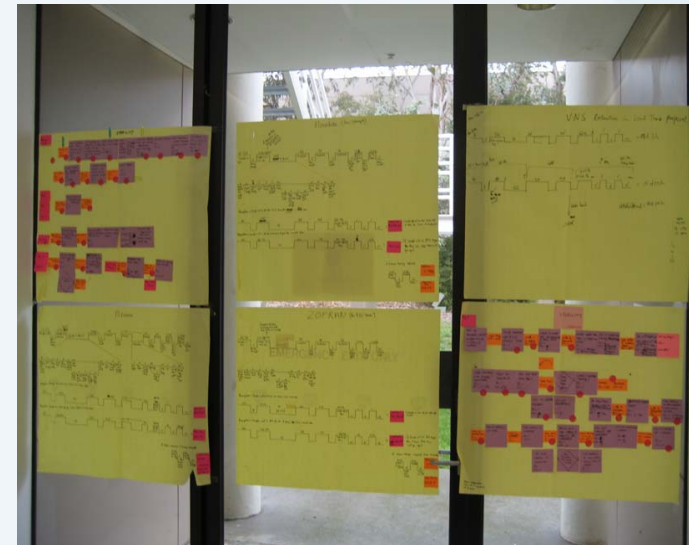


Application of Lean Sigma

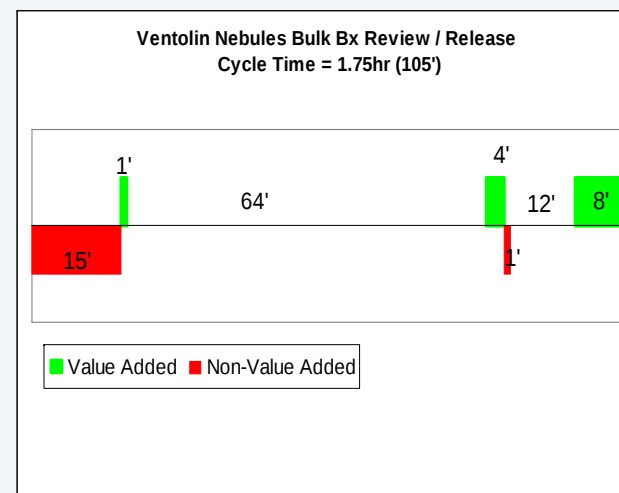
Waste & Variation

- 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



Application of Lean Sigma

Lab Bench Top Before 5S



Lab Bench Top After 5S



Application of Lean Sigma

Microbiology Lab Heijunka System

Flow

- FIFO vs Laboratory scheduling
- Visual control vs Spreadsheets



Application of Lean Sigma

Flow

- FIFO vs Laboratory scheduling
- Visual control vs Spreadsheets

Chemistry Lab Sample Label

SAMPLE LABELS – COLOUR CODES				
BATCH STATUS	<50% LEAD TIME (GREEN) ●	50-75% LEAD TIME (YELLOW) ●	75-100% LEAD TIME (ORANGE) ●	>100% LEAD TIME (OVERDUE) (RED) ●
TEST STATUS	TEST NOT COMMENCED (Blank) ●	UNDER TEST (BLACK) ●	TESTING COMPLETED (SILVER) ●	CHECKED (GOLD) ●
TECHNIQUE CELLS	Dissolution Disintegration UV	HPLC	INHALED	TOC TLC NIR Titrations

Chemistry Lab Heijunka System



Application of Lean Sigma

Microbiology Lab “Qantas” board

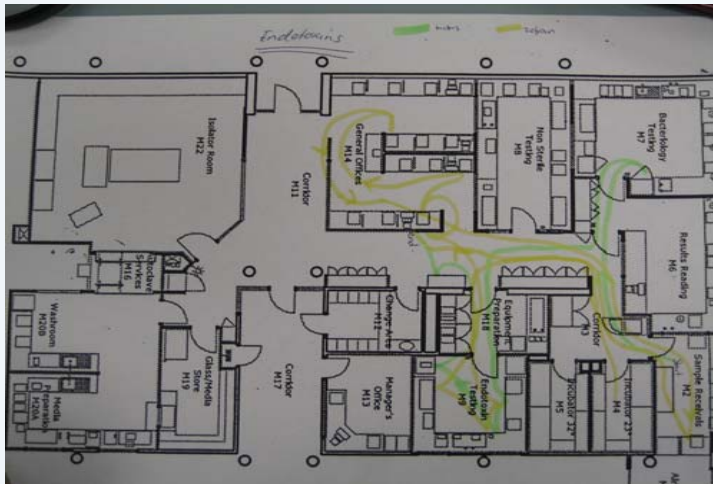
Flow

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



Application of Lean Sigma

Spaghetti Chart



Visual Equipment Home Location



Consumables Kanban



Point of Use Consumables





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

Leading & managing in a Lean Sigma Environment

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

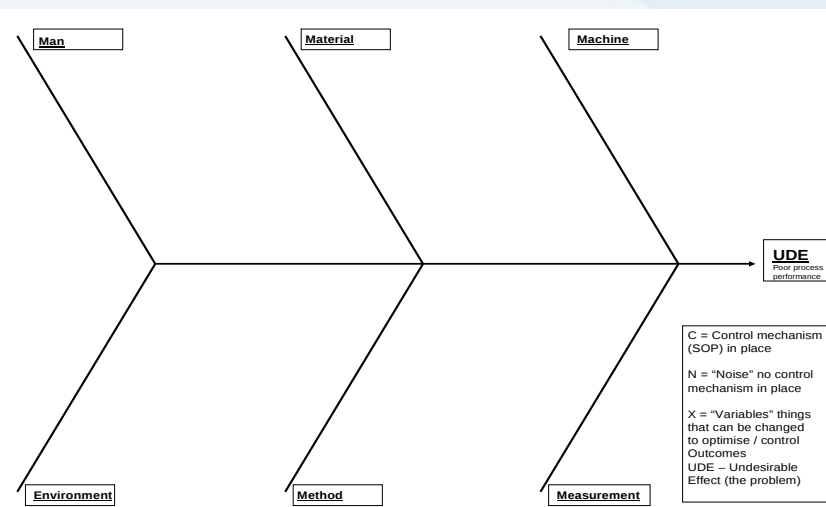
Product Category	Monday		Tuesday		Wednesday		Thursday		Friday		Total (Target)	Total (Actual)
	Target # Bx	Actual # Bx	Target # Bx	Actual # Bx	Target # Bx	Actual # Bx	Target # Bx	Actual # Bx	Target # Bx	Actual # Bx		
VNS Bulk											0	0
Flixotide Bulk											0	0
Flixonase Bulk											0	0
Zofran Bulk											0	0
VNS Filling											0	0
Flixotide Filling											0	0
Flixonase Filling											0	0
Zofran Filling											0	0
VNS Packing											0	0
Flixotide Packing											0	0
Flixonase Packing											0	0
Zofran Packing											0	0
Total	0	0	0	0	0	0	0	0	0	0	0	0

Root Cause for not Meeting Target :

Leading & Managing in a Lean sigma Environment

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



Agenda Item	Action	👤	🕒	Comments
<u>Performance Status</u>				
<u>Source of Variation</u>				
<u>Root Cause of Variation / Poor Performance</u>				
<u>Trends</u>				