Efficient Manufacturing

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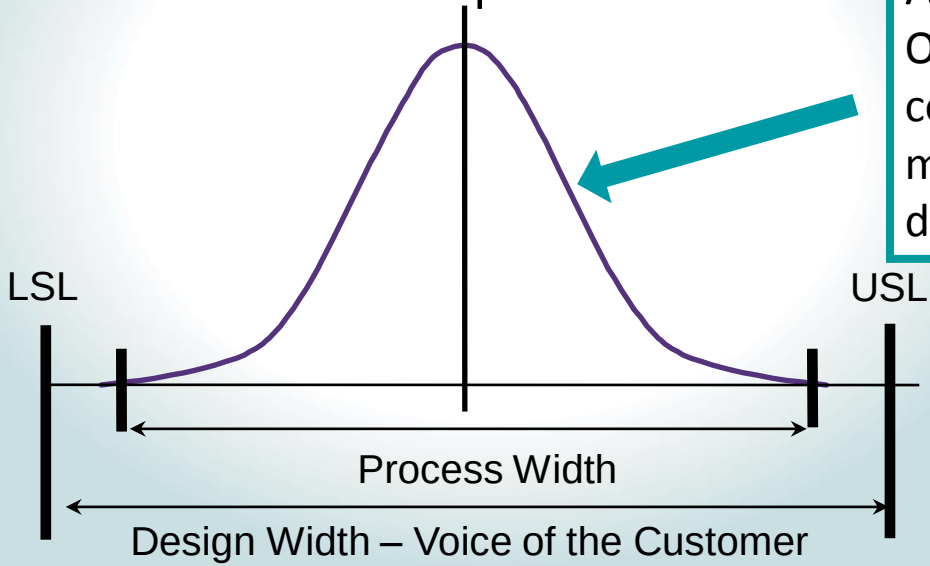
Our Goal- Maximum return for investment in our Process- An Efficient Robust process



A Robust Process: Operating in a consistent, Predictable manner with near zero defects

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See better. Live better.

Efficient Manufacturing

- Achieved through utilization of Good Manufacturing Practice in
  - Managing Equipment
  - Process/systems Engineering
- What to focus on?
  - What efforts add value?
  - Are you using time efficiently?
  - Sensibly employing technology?

Get it right first time every time- Building quality into everything you do!

People

- People- Your most important asset
  - Engage with staff on Process Engineering/improvement projects
  - Ensure up date to training
    - Train beyond specific job function as it ensures
      - Greater engagement
      - Better at troubleshooting
      - Happy empowered employees = happy customers
  - Communications- Brief 5 min meeting each morning sharing details/data on:-
    - quality, yields, targets, etc..

Systems-Lens Design Integrity

- Robust system for managing lens design changes/enhancements
- Verification Protocol for t/fer of your designs to 3rd Party Manufacturers
- It is a requirement of ISO 13485:2003 to plan and control product design and development

Systems-Lens Design Integrity

- Transferring lens design. Verification protocol:-
  - What Products?
  - With who?
  - With what?
  - How?
  - Measurement?
  - Inputs?
  - Outputs?

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CONTENTS

Process Equipment

- Ensure equipment is installed & set up correctly i.e. Validated
- Advantages:
  - Better understood process and equipment capabilities
  - Reduced scrap and defect costs
  - Reduced/optimised cycle time
  - Reduce customer returns
  - Smooth running process

Process Equipment

3 stages of equipment install & validation

1. Pre purchase phase
   - Vendor Selection
   - Build & test
   - Deliver
2. Installation
3. Operational and Performance testing

Process Equipment

1. Pre Purchase phase

- User Requirements Specification –what you want
- Functional Design Specification-Detailed technical document of how vendor meets your URS
- Test at vendor facility before shipping:-
  - Pre- Delivery Qualification (PDQ)

  Or
  - Factory Acceptance Test (FAT)

Process Equipment

2. Installation

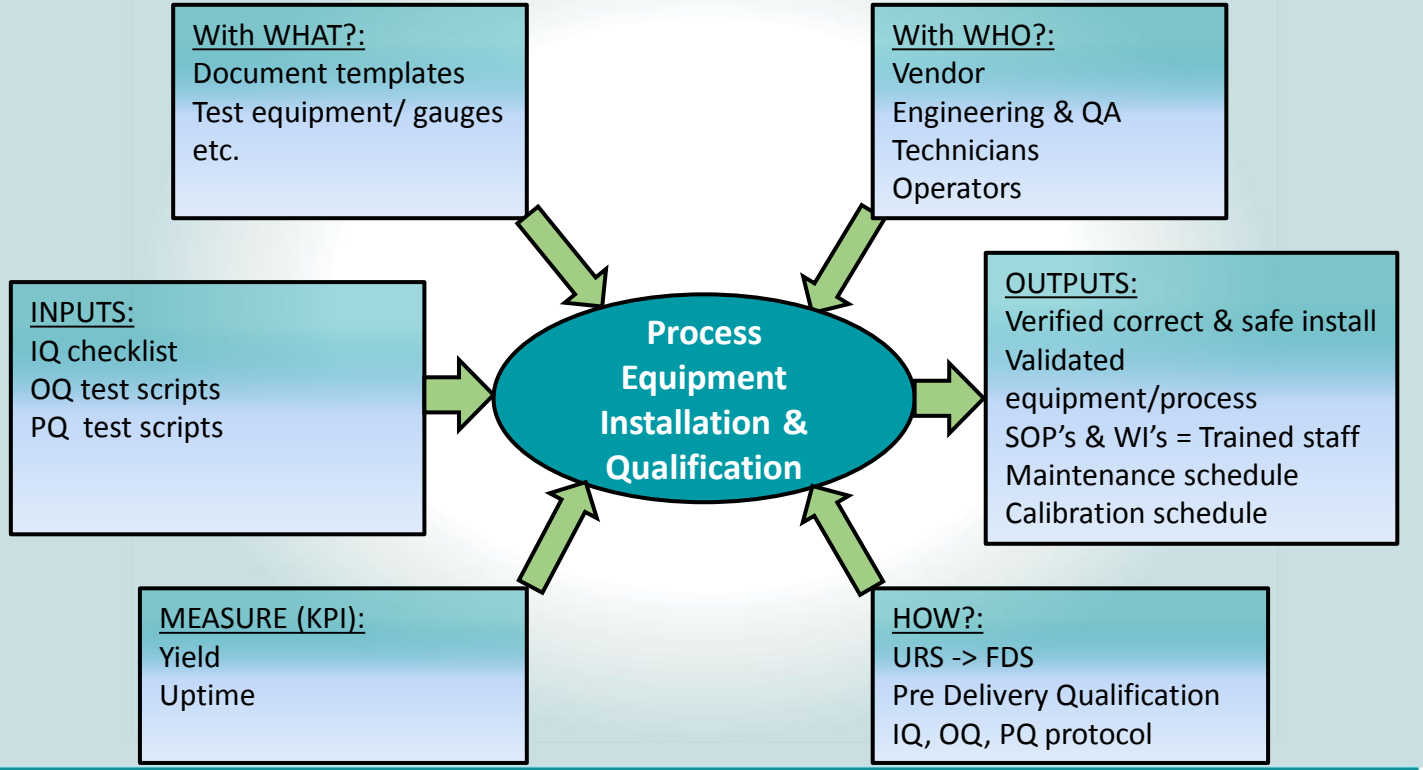
- Site Acceptance Test- conducted by vendor
- Installation Qualification (IQ)- Conducted by purchaser
  - Correct & safe hookup
  - Calibrated/set up correctly
  - Correct materials/consumables used
  - Understand critical settings
  - Operating procedures (SOP's), Work Instructions (WI's)
  - Maintenance schedule
  - Critical spares

Process Equipment

3. Operational & Performance Testing

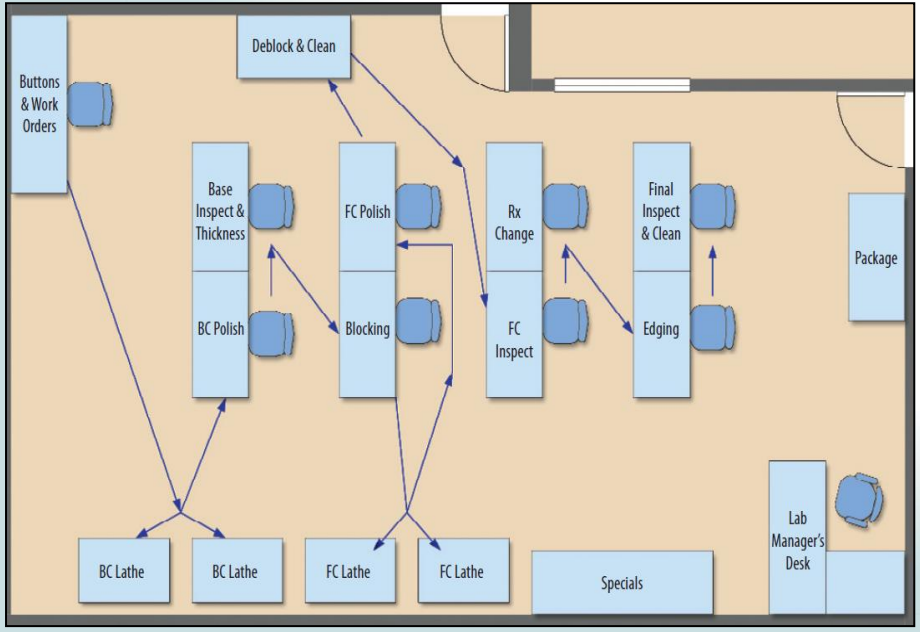
- Operational, Performance Qualification (OQ/PQ)
  - Parameters set to recommended
  - Worst case testing- limits of equipment for different products?
  - If needed conduct testing with different lens designs to determine settings
  - Test to ensure yield and quality to required standard is repeatable
  - Revise SOP's WI's as needed during OQ/PQ stage

Process Equipment Turtle diagram



Process layouts

- Functional/Process Layout: Similar Ops grouped together



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- Greater equipment Utilisation
- Easy to supervise & expand

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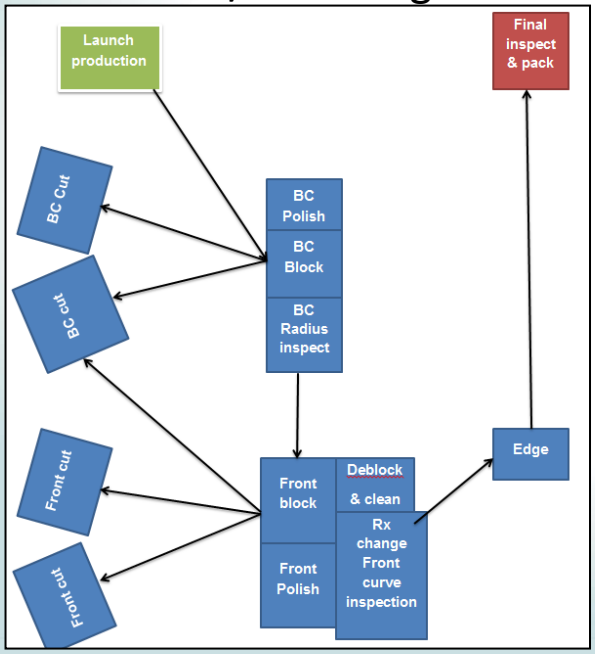
- High WIP & handling
- More space needed

Process Layouts

- Cellular Layout: Dissimilar m/c's arranged to economise flow



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- Improved workflow
- High utilization of resources

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- Costly to re-arrange/expand
- Possible equipment duplication

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Roadmap to Improvement

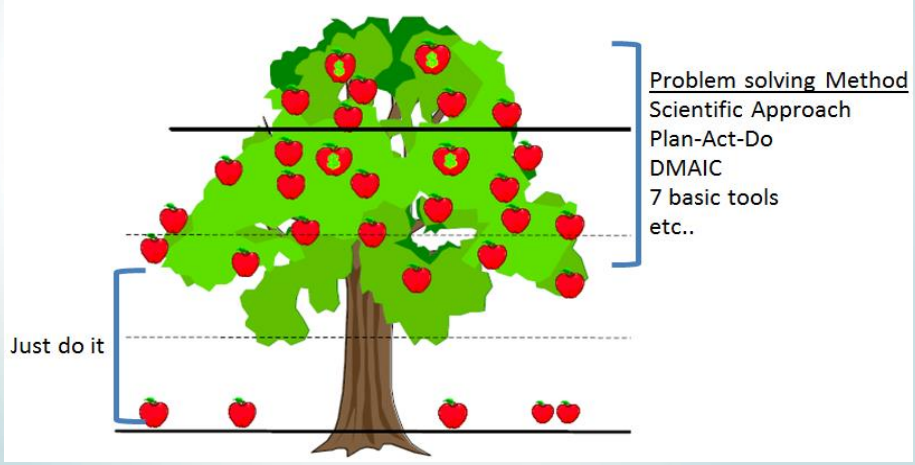
- Two approaches to help you problem solve

Just do it!

Assume

Solution

Implementation



Scientific Approach

Observe

Hypothesis

Test

Understanding Your Process

- Metrics

  Measure **E**verything **T**hat **R**esults in **C**ustomer **S**atisfaction

  - Statistical tools
    - Capability analysis
    - MSA: Gauge Repeatability & Reproducibility etc.…
  - Understanding Efficiencies
    - Process map & Activity study help gather data on waste:-
      - Transport
      - Inventory
      - Motion
      - Waiting
      - Over producing
      - Over Processing
      - Defects

Activity Study

A study of activities (equipment & people) in a production process over a fixed time period

- Gather data to help answer:-
  - Process Efficiency & Overall Equipment Effectiveness (OEE)
    - Are equipment & personnel being utilized sensibly?
    - Hidden process steps?
    - Do you have capacity to increase or introduce new products or
      - Do you need more equipment?
      - Do you need more personnel?

Activity Study

- Develop codes for machine & personnel tasks:

Codes					
Machine codes		**Operator codes**			
		Productive		18	coolant fill
A	run	1	load/Unload m/c	19	Prepare wheels for m/c'ing
B	stop- waiting on operator	2	-	20	investigate dim. errors
C	stop - waiting on maint.	3	change over	**Non productive**	
D	stop- waiting on tech.	4	tool change	21	present but unoccupied
E	stop- change over	5	measure wheel	22	absent
F	stop- tooling change	6	paperwork	23	personal breaks
G	stop- crash	7	clean m/c	24	meal breaks
H	stop- coolant fill	8	clean area, packaging, swarf etc		
J	stop- adjustment	9	transport product	Date	
K	stop- part load error	10	absent- sourcing product	Shift	
L	stop- wash tank water fill	11	absent- sourcng tooling	Observer	
M	Stop- investigate dim. errors	12	absent- sourcing gauging	Operator 1	
N	Stop- no product	13	absent- sourcing paperwork	Operator 2	
O	Stop- load/unloaded	14	m/c adjustment	Operator 3	
P	Stop-tech	15	print part		
Q	Stop-maint	16	adjust reamer		
R	Stop-clean	17	dry part (after wash)		

Activity Study

- Determine time frame to study:
  - Full shift most accurate

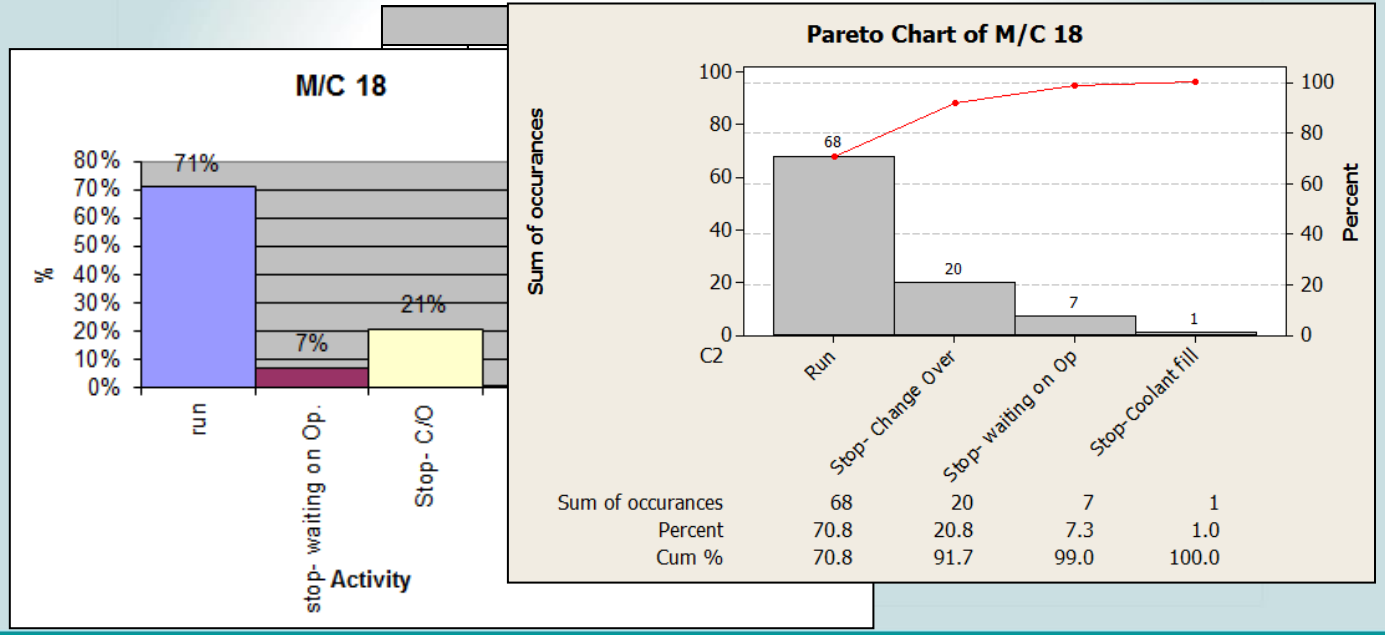
List all equipment & People

Break hour into 5 min segments

		M/C 18	M/C 19	M/C 20	Check M/C	Wash tank	Op 1
hour 1	0.00	Run	Run	C/O	Run	Run	C/O
6-6.55	0.05						
	0.10						
	0.15						
	0.20						
	0.25						
	0.30						
	0.35						
	0.40						
	0.45						
	0.50						
	0.55						
hour 2	0.00						
7-7.55	0.05						

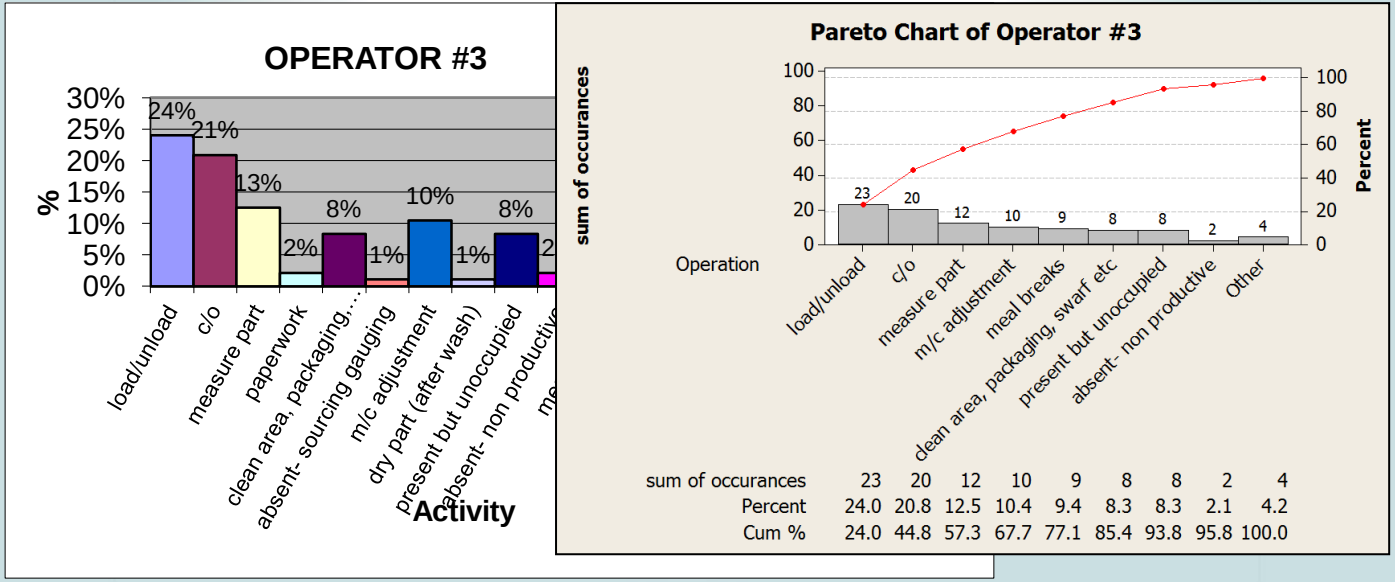
Activity Study

- Example of monitoring:



Activity Study

- Example of monitoring:



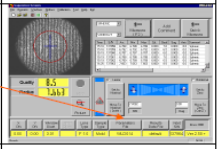
Understanding Your Process

- Following study categorize process into
  - Value-added to customer
  - Non-value-added to customer (traditional waste)
  - Non-value –added-but necessary (e.g. regulatory)
- Express as Process Efficiency
  - Map process (inputs, steps, outputs) into value add and non value added steps to determine process efficiency

$$Process\ Efficiency = \left(\frac{Value\ added\ time}{Value\ added\ time + non\ value\ added\ time}\right)$$

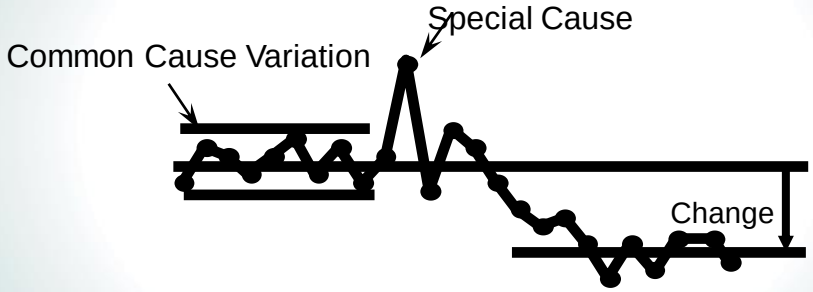
Keeping control-sustain

- Process Control vital to sustaining and supporting an efficient process
- Work Instructions/SOP's. Mistake proof procedures using graphs, photo's, flow charts etc…

Step	Task	Symbol
	Set-up of Rotlex	
1.	**Ensure Rotlex Brass 2000 is calibrated before taking measurements.** • Ensure the correct male or female Rotlex is being used. • Remove any dust or lint on Rotlex lens using can of "Dust Off" or equivalent.	Q
2.	**Enter** data onto mould data sheets provided by protocol originator.	
	How to measure Male / Female Mould Radius	
1.	**Blacken** moulds using permanent marker on opposite side to critical surface, i.e. concave surface for male moulds and convex surface for female moulds.	
2.	**Place** mould on correct nest (I.E Female ,SL59/MOD90Z or Hypergel) with gate facing forward, press down slightly to make sure mould is sitting properly on nest.	
3.	**Click** on "Parameter File" dialog box.	
4.	**Select** parameter file required.	
5.	**Click** on "Load" dialog box.	
6.	**A Dialog box** will appear asking the operator if they want save changes to the previous parameter file, click "No"	
7.	**Click** on "Measure" dialog box.	
8.	**Radius** average, Cylinder and Image Quality values will be displayed when measurement is completed. (For image quality 10.0 is the best value possible and decreases accordingly)	
9.	**Record** value of measurement required on relevant mould data sheet.	

Keeping control-sustain

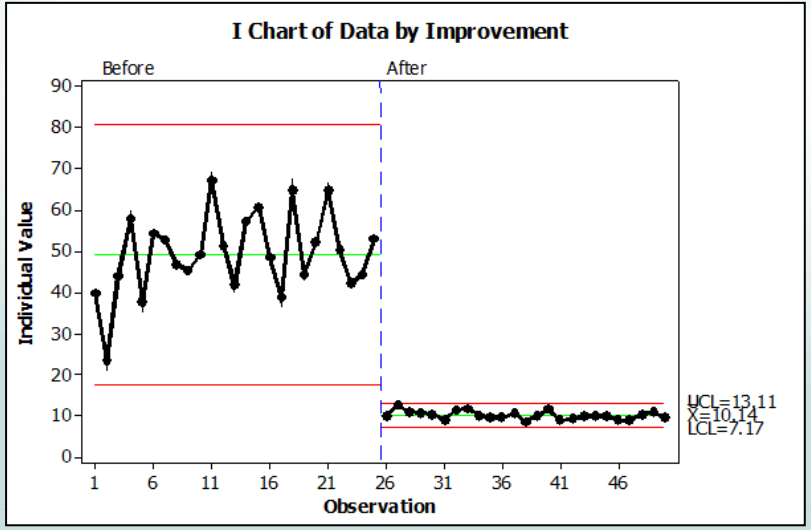
- On going monitoring- Run Chart



- Distinguishes between common and special cause variation
- Helps with decision making regarding making process adjustments

Keeping control-sustain

- On going monitoring
  - Monitor performance over time to detect trends and monitor changes made



Efficient Manufacturing

In summary, an efficient process leads to

- Reduced non value added activities
- Increased capacity & quality
  - Optimised process layout
  - Mistake Proof streamlined procedures
  - Engaged productive employees
  - Optimised use of equipment

Continuous monitoring and improvement are key to long term success

Thank you for your time!!