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Lonza

Structured Continuous Improvement to Achieve Operational Excellence

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Manufacturing Continuous Improvement Lead

Outline of Presentation

Lonza

- Lonza Biologics – Slough site
- Manufacturing Continuous Improvement role
- Lonza's continuous improvement philosophy & case studies
- Where are Lonza on the operational excellence journey?
- Closing remarks

Lonza Biologics – Slough Site

- Lonza Biologics UK site based in Slough, England
- R&D facility with 3 main areas of expertise
  - Cell culture process development
  - Purification development
  - Assay development
- Small scale GMP manufacturing
  - 200L & 2000L airlift fermenter capacity
  - 50L – 200L disposable capacity
- Products
  - Custom manufacturing for recombinant therapeutic proteins and monoclonal antibodies

More details @ www.lonza.com

Continuous Improvement Role

- Manufacturing Continuous Improvement role initiated in May 2003
- Dedicated full time positions in Manufacturing to focus on continuous improvement activities
- Focused on achieving specific business goals
- Training and coaching in continuous improvement techniques needs to be provided

Continuous Improvement Role (cont.)

- Report directly to the Head of Operations
- Long term secondment role - ensures transfer of skills and knowledge back to Manufacturing teams
- Continuous Improvement team must promote the philosophy and encourage the use of techniques within the organisation to ensure continuous improvement is carried out by everyone

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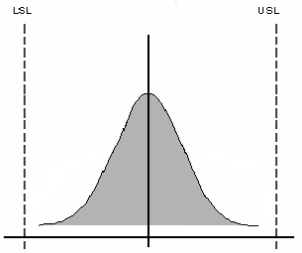
Continuous Improvement Philosophy

Lonza

On target with minimum variation

- Understanding variation
- Prevention not just cure
- Structured problem solving
- Root cause elimination
- Transfer key learnings



Continuous Improvement Philosophy

Lonza

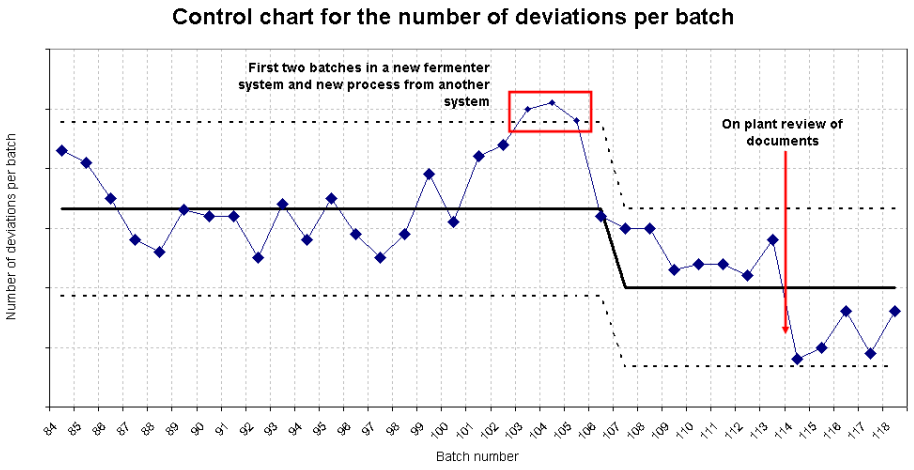
Understanding variation - Control charting

- Theory
  - Separate “Common” and “Special” cause variation
  - Establish statistical control limits
- Uses at Lonza
  - Deviations per batch
  - Discrepancies per batch
  - Process alarms per batch

Continuous Improvement Philosophy

Lonza

Understanding variation - Control charting



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Continuous Improvement Philosophy

Lonza

Prevention not just cure - Failure Mode Effect Analysis

- Theory
  - List all possible ways in which a process could fail
  - Prioritisation of all possible failure modes
- Uses at Lonza
  - FMEA technique used on harvest system to identify and prioritise
    - Continuous Improvement focus
    - Engineering investment in plant
    - Training & method improvement opportunities

Continuous Improvement Philosophy

Lonza

Prevention not just cure - Failure Mode Effect Analysis

- Multidiscipline team
  - Manufacturing
  - Process scale up and support
  - QA Compliance
  - Engineering
- Before FMEA
  - Update centrifuge
  - Other engineering modifications
- After FMEA
  - Document updates
  - Knowledgeable and motivated users!

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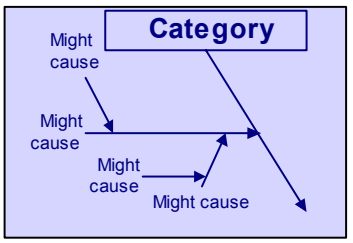
Continuous Improvement Philosophy

Lonza

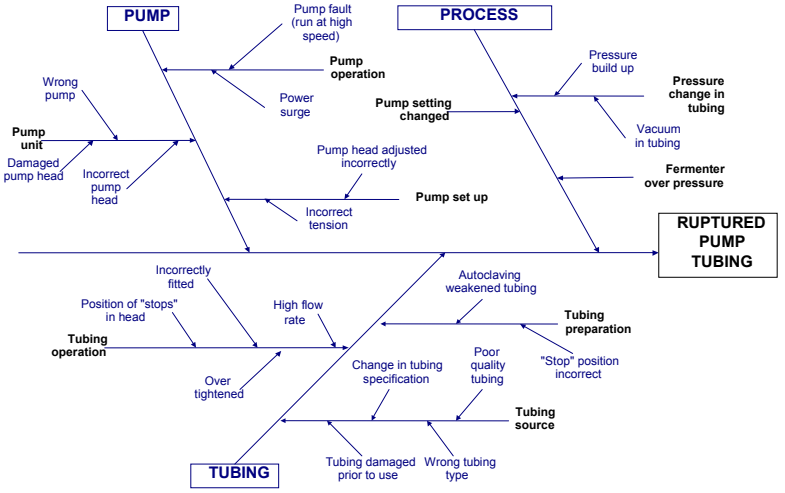
Structured problem solving - Cause & Effect

- Theory
  - Graphical display **all possible** causes of failure
- Uses at Lonza
  - A split tubing event
  - A contamination event



Lonza

Structured problem solving - Cause & Effect



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Structured problem solving - Cause & Effect

Structured problem solving - Cause & Effect

- Advantages to using technique
  - Documented investigation that can be used to help with the closure of deviations
  - Cause and Effect diagram that can be used as a template if event happens in future
  - Standard problem solving & investigation method that can be applied to other situations
  - Faster determination of root causes

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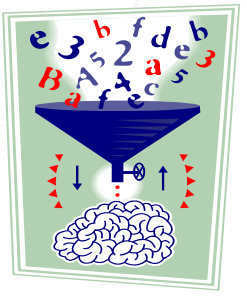
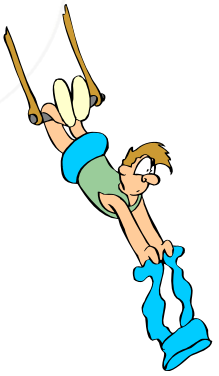


Continuous Improvement Philosophy

Lonza

Root cause elimination - Mistake proofing & failsafing

- Theory
  - Mistake Proofing - avoid opportunities to make errors
  - Failsafing - Ensure it cannot go wrong
- Uses at Lonza
  - Pump roller-gap measuring devices
  - Vessel blanking plugs



Continuous Improvement Philosophy

Lonza

Root cause elimination - Mistake proofing & failsafing

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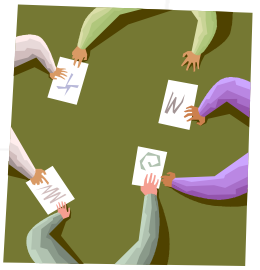

Continuous Improvement Philosophy

Lonza

Transfer key learnings

- Theory
  - Ensure that the knowledge and solutions are transferred to other areas or systems
- Uses at Lonza
  - Knowledge from FMEA being applied to other similar systems
  - C&E analyses have been shared with other Lonza sites
  - Roller-gap measuring device solution passed to purification

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Lonza's Drive for Operational Excellence

- Two new Manufacturing Continuous Improvement Leads
- Starting an Engineering & Maintenance Continuous Improvement team
- Six Sigma training – initial rollout
  - Four Lonza sites
  - 13 Black Belts
  - 28 Green Belts

Closing remarks

Lonza

- Pick the best people
- Projects must be aligned with business goals
- Prioritise projects to ensure focus, completion and implementation
- Provide targeted training
- Adapt tools to suit your needs
- Encourage data-driven decision making