Lonza Error Prevention System (EPS)
Changing Human Performance in Pharmaceutical Operations
Lonza Overview

- Life sciences driven company
- Headquartered in Basel (Switzerland)
- Sales of CHF 3.8 billion in 2015
- 9’800 employees, 40 major production sites

Pharma&Biotech Segment:
- Custom Manufacturing
- Custom Development
- Bioscience Solutions

Specialty Ingredients Segment:
- Consumer Care (incl. Hygiene, Nutrition, Personal Care)
- Agro Ingredients
- Coatings & Composites
- Water Treatment
Impact of Human Errors in Operations

- **SAFETY**
  - Lost Time Incidents
  - Recordable Accidents
  - Incidents & Near Misses
  - Non Conformities
  - Compliance Issues
  - Customer Complaints

- **QUALITY**
  - Late or No Delivery
  - Higher Inventory

- **DELIVERY**
  - Lost Batches
  - Remediation Activities
  - Lost Production Capacity

- **COST**
BPOG study attributed 50% of Deviation in BioPharma to Human Errors

In 2013, BPOG members visited the nuclear industry and learned how they became a high Reliability Organization by Error Prevention
EPS Five Year Cultural Change Plan

**PHASE 1**
- **2014 Jan**
  - Principles, Beliefs & Culture
    - Training For All Employees on EPS Principles & Culture
    - EPS Observations with Dialogs to Reinforce / Encourage EPS Behavior

**PHASE 2**
- **2014 June**
  - Documents & Learning
    - Effective Documents, SOPs, Work Instructions, Batch Records
    - Effective Learning and Qualification

**PHASE 3**
- **2016/17**
  - Processes & Equipment
    - Error Prevention in Process Design & Product Lifecycle
    - Error Prevention in Equipment Design & Maintenance

**PHASE 4**
- **2018ff**
  - Center Of Competence
    - Human Performance Assessments Improve System Resilience
    - System Resilience Drives Business Sustainability

Ongoing Coaching at the Workplace to Grow Proactive Culture
Number of Deviations Initiated for Lonza Network

PHASE 1: Behavior & Observations

PHASE 2: Documents & Learning

PHASE 3: Process & Equipment

“Safety (and Quality) are not the absence of something. It’s the presence of something.”

Dr. Sidney Dekker
EPS PHASE 2 | Documents & Learning Concept

»What to Learn«

LEARNING & QUALIFICATION MODULE

(Re-) Qualification

Performance Assessment

On the Job Training

Knowledge Assessment

SOP

Work Instructions

Videos

Classroom Simulation

Records & Forms

«How to Learn It»

On the Job Training

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«How to Learn It»
Document Structure & Principles

- Documents organized in execution sequence
- Work Instructions for standardized tasks
- Records capture batch pertinent data
- Task specific Learning & Qualification Modules (LQMs)
Knowledge Documents | SOP

- What the task is
- What is done in the task
- Why steps are done
- What happens as steps are completed
- What can go wrong and countermeasures

Table of Contents

1. Scope
2. Responsibility
3. Safety
4. Background/Theory/Key Elements...
6. Procedures
7. Troubleshooting
8. Associated Documents
9. Definitions
Attachments (if needed)
Working Documents | Work Instructions

- List of pre / post checks, materials and tools required
- Task broken down into small steps
- Integration of pictures to clarify instructions
- Each sub-step written in simple language using short sentences

4 PROCEDURE: EasyCal UV CHECK

1. Loosen top set screws ~ ½ turn counter-clockwise.
2. Turn Hi and Lo indicator screws clockwise towards OUT position until screw stops.
3. Hand-tighten top set screws.
Data Collection Documents | Batch Record

- Safety information at start of task with symbols on hazards and PPE
- Boxes for digits
- Clear specifications and units
- Shading of non-entry areas
- White space around task blocks
- Standardized attention activators
- Sequence of tasks reflects reality
- References to Work Instructions
Videos for Consistency in Training & Qualification
Content of Learning & Qualification Module

- Guidance on relevant task knowledge
- List of references to gain knowledge
- Identification of critical knowledge
- Questions to verify knowledge
- Assigned Mentor to help with questions
- Refresher & Requalification requirements
Performance Assessment

- Critical Questions are identified by task risk analysis (e.g. FMEA, HAZOP)
- Assessor verifies theoretical knowledge
- Independent assessor verifies task execution
- Assessment follows task specific checklist
- If all requirements met, trainee is signed off and qualified to perform the task.
Workflow for Effective Documents and Learning

- **Walk the Process**

- **Task Analysis**
  - Task Breakdown
  - Identify Critical Steps
  - Standardize Steps

- **Revise SOPs / WIs**

- SOPs organized into execution sequence

- Work Instructions (WIs) for standardized tasks

- Batch Records (BRs) capture batch pertinent data

- Task specific Learning & Qualification Modules (LQM)

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- Approval Workflow & Implementation

- **Dry Runs & Adjustments**

- Revise Learning & Qualification Modules
EPS PHASE 2 | Results

- Up to 50% reduction in number of entries per batch record
- Up to 60% reduction in number of pages for batch records
- Up to 70% reduction in number of double checks per batch record
- Up to 90% reduction in number of documentation entry errors

I-Chart of Deviation per Batch at Commercial Scale

DEVIATION by ICH Q7: Departure from an approved instruction or established standard.
Error Prevention is the First Value and Never Abandoned Because...

Patient Safety is in Your Hands.

A. Wilson, M. Moedler, G. McAuley. *PDA J Pharm Sci and Tech* 2015, *69* 658:
Changing the Performance Paradigm in Pharma/Biotech: Integrating Human Performance in Global Organizations

K. Bodmann, C. Reinhard, M. Moedler, K. Tinson, M. Johnson. *Chimia* 70 (2016) 610:
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