Lonza’s Error Prevention System (EPS)

(Error Prevention: A Great lean Partner)

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Operational Excellence Manager
Lonza Rockland
Lonza Error Prevention System (EPS)
Lonza Overview

- Life sciences driven company
- Headquartered in Basel (Switzerland)
- Sales of CHF 3.6 billion in 2014
- Nearly 10’000 employees, 45 major production sites

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

Specialty Ingredients Segment:
- Consumer Care (incl. Hygiene, Nutrition, Personal Care)
- Agro Ingredients
- Industrial Solutions
- Wood Protection
- Water Treatment
Result of Errors in Operations

SAFETY
- Lost Time Incidents
- Recordable Accidents
- Incidents & Near Misses

QUALITY
- Complaints
- Deviations & Non Conformities
- Cost of Poor Quality

DELIVERY
- Products / Services not Delivered
- Lost Production Days
- NWC by Delayed Release
Deviations by Root Cause last Campaign

QMR-Data: Deviations by Root Cause (Planned & Unplanned)
In 2013, the BioPhorum Operations Group visited the nuclear industry and learned how they became a high Reliability Organization through Error Prevention.
Designed on INPO Best Practice

EPS is Lonza’s systematic approach to predict, manage and prevent errors thus improving consistency and reliability in the areas of safety, quality and the delivery of goods and services.

INPO: Institute of Nuclear Power Operations
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 & Qualification Modules

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
- Human Performance Excellence Drives Business Sustainability
EPS PHASE 1 | Leaders Driving Change

- All Employees Participate in Full Day Introductory Training
- All Leaders Conduct Regular EPS Observations
- Behavioral Coaching During Observations to Sustain Change
- Trending & Experience Sharing with Leadership Teams

“Nothing changes until leader behavior changes.”  Rensis Likert
EPS PHASE 1 | Over 5’000 Employees Trained

Why do errors occur?

- Brain Function
- Risk Factors
- Error Traps

How to prevent errors?

- Learning Culture
- Observations
- Behavior

Major errors do not occur without warning - precursors exist
The Human Brain – System Hierarchy

Cerebral Cortex – Learning, Knowledge processing

Limbic System – Emotions, Fight/Flight

Cerebellum – Motor & Auto functions

Reticular Activating System (RAS) – Sentry, Attention, Filter
# Behavioral Coaching During Observations

## Check Error Traps

1. Time Pressure
2. Distractions / Interruptions
3. Multiple Tasks
4. Overconfidence
5. Vague Guidance
6. First Shift / Late Shift
7. Peer Pressure
8. Changed Conditions
9. Physical Environment
10. Mental Stress (Home or Work)

## Coach Right Behavior

- Effective Communication
- Questioning Attitude
- Self Check
- Pre- & Post-Job Brief
- Knowledge
- Place Keeping & 5S
- Peer Check
- Procedure Use & Adherence
- Hand Over (Task & Shift)
- Coaching

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**Over 3’000 coaching observations per month to shift behavior**
Trap 1. Time Pressure

All working under time pressure

- Things have to be done within an allotted time
- We have to meet Deadlines

- 2 types of Time Pressure
  - Real
  - Perceived
Trap 2. Distractions & Interruptions

56
Interruptions
a day for the average employee

3
Minutes
spent working before the average employee switches tasks

2
Hours
spent recovering from distractions per day

80% of interruptions at work are considered trivial

I don't have a short attention span, I just... Oh, look a squirrel!

WARNING
THIS SIGN IS ONLY A DISTRACTION

DO NOT DISTURB
NO MOLESTE
PRIÈRE DE NE PAS DÉRANGER
BITTE NICHT STÖREN

DO NOT INTERRUPT

Share • Learn • Grow.
Trap 3. Multiple Tasks

How computers multitask

How humans multitask

The Brain Cannot Multi-task.mp4
Trap 4. Overconfidence

As we grow older and more experienced, we overrate the accuracy of our judgments.
Trap 5. Vague or Interpretive Guidance
I’m just back from vacation and I’m still in unwinding mode.

Could you reset my biological clock? They put me on the nightshift.
Trap 7. Peer Pressure
Trap 8. Change or Abnormal Conditions
Trap 9. Physical Environment
Trap 10. Mental Stress (Home and Work)

What is your state of mind?

Stress has nothing to do with how many hours you work and everything to do with how you feel during those hours.

Significant Sources of Stress

- Personal Safety
- Housing Costs
- Job Stability
- Personal Health Concerns
- Family Health Problems
- Family Responsibilities
- Relationships
- Economy
- Work
- Money

Stress has nothing to do with how many hours you work.
10 Tools to combat the Traps

1. Effective Communication
2. Questioning attitude
3. Self Check
4. Job Briefing/Debriefing
5. Knowledge
6. Placekeeping
7. Peer Check
8. Procedures
9. Handover
10. Coaching
EPS PHASE 1 | Delivery on Error Prevention

Trending Deviations with Causal Factor “Human”

- 80% Trained & Routine Observations
- 40%
EPS PHASE 2 | Workflow in a Nutshell

- SOPs organized into execution sequence
- Work Instructions (WI) for standardized tasks
- Master Batch Records capture batch pertinent data
- Task specific Learning & Qualification Modules (LQM)
EPS PHASE 2 | Effective Documents & Learning

«What to Learn»

LEARNING & QUALIFICATION MODULE

(Re-) Qualification

«How to Learn It»

Work Instructions

Performance Assessment

On the Job Training

Knowledge Assessment

Videos

Classroom Simulation

Records & Forms

SOP

On the Job Training

Performance Assessment

Work Instructions

Records & Forms

Classroom Simulation

Videos

SOP

(Re-) Qualification

LEARNING & QUALIFICATION MODULE

«What to Learn»

«How to Learn It»
EPS PHASE 2 | Batch Records

- Safety at start of task with GHS symbols on hazards and PPE
- 30% White space around task blocks
- Shading of non-entry areas
- Boxes for digits
- Clear specifications and units
- Short but precise instructions
- References to Work Instructions
EPS PHASE 2 | Work Instructions

- Task broken down into small steps
- Each sub-step written in simple language using short sentences
- Start each step with a verb
- Use of symbols to guide user
- Integration of pictures to clarify instructions
- List of pre / post checks, materials and tools required
EPS Phase 2 | Batch Record Example: CIP

Old Format

<table>
<thead>
<tr>
<th>Description</th>
<th>Actual Value and Unit</th>
<th>Operator Init / Date</th>
<th>Verifier Init / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculate and record duration of</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pressure hold test as follows:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure hold test duration =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Date/Time (Step 8.14) –</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date/Time (Step 8.13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptable Range: ± 60 min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculate and record pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>loss as follows:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure loss =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Pressure (Step 8.13) –</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Pressure (Step 8.14)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notify supervisor if pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>loss is more than 0.5 psig for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>any of the required Cryovessels.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptable Range: ± 0.5 psig</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N/A if CIP is not to be performed on the indicated Cryovessel.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cryovessel 1</th>
<th>min</th>
<th>psig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryovessel 2</td>
<td>min</td>
<td>psig</td>
</tr>
<tr>
<td>Cryovessel 3</td>
<td>min</td>
<td>psig</td>
</tr>
<tr>
<td>Cryovessel 4</td>
<td>min</td>
<td>psig</td>
</tr>
<tr>
<td>Cryovessel 5</td>
<td>min</td>
<td>psig</td>
</tr>
</tbody>
</table>

| 8.16         |                       |                      |                      |
| Perform valve checks per SGTS-12868. N/A if CIP is not to be performed on the indicated Cryovessel. | | | |

<table>
<thead>
<tr>
<th>Cryovessel 1</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryovessel 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryovessel 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryovessel 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryovessel 5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EPS Format

7.5 CIP Pressure Hold Test

7.5.1 Cryovessel at Manifold 1 (N/A Step if Manifold is not required)
Set up and perform pre-CIP pressure hold test per SGTS-12868.

<table>
<thead>
<tr>
<th>Acceptable Range</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.0 to 22.0 psig</td>
<td>A Start</td>
</tr>
<tr>
<td></td>
<td>B End</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable Range</th>
<th>Hold Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.5 psig</td>
<td></td>
</tr>
</tbody>
</table>

DECREASE – TICK ONE OPTION:
- Pressure loss and hold time test passed
- Pressure loss and/or hold time test failed

Update FOR016905/FN4022
Notify supervisor. Repeat Pre-CIP pressure hold test per Attachment A

<table>
<thead>
<tr>
<th>Operator Init / Date</th>
<th>Verifier Init / Date</th>
</tr>
</thead>
</table>

7.5.2 Cryovessel at Manifold 2 (N/A step if not required)
Set up and perform pre-CIP pressure hold test per SGTS-12868.

<table>
<thead>
<tr>
<th>Acceptable Range</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.0 to 22.0 psig</td>
<td>A Start</td>
</tr>
<tr>
<td></td>
<td>B End</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable Range</th>
<th>Hold Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.5 psig</td>
<td></td>
</tr>
</tbody>
</table>

DECREASE – TICK ONE OPTION:
- Pressure loss and hold time test passed
- Pressure loss and/or hold time test failed

Update FOR016905/FN4022
Notify supervisor. Repeat Pre-CIP pressure hold test per Attachment A

<table>
<thead>
<tr>
<th>Operator Init / Date</th>
<th>Verifier Init / Date</th>
</tr>
</thead>
</table>
## EPS Phase 2 | Batch Record Example: Sampling

### Old Format

<table>
<thead>
<tr>
<th>Description</th>
<th>Actual Value and Unit</th>
<th>Operator Init / Date</th>
<th>Verifier Init / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.23 Collect WFI Rinse TOC samples per SGTS-1375. Attach LIMS label to TOC vial. Attach LIMS ID Number and record Collection Date/Time for samples below. N/A if CIP is not to be performed on the indicated Cryovessel.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Template ID</strong></td>
<td><strong>Sample Name</strong></td>
<td><strong>LIMS ID Number</strong></td>
<td><strong>Collection Date/Time</strong></td>
</tr>
<tr>
<td>SG12435_16</td>
<td>Cryovessels Pre-use CIP WFI Rinse (Vessels 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG12435_16</td>
<td>Cryovessels Pre-use CIP WFI Rinse (Vessels 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG12435_17</td>
<td>Cryovessels Pre-use CIP WFI Rinse (Vessels 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG12435_18</td>
<td>Cryovessels Pre-use CIP WFI Rinse (Vessels 4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SG12435_19</td>
<td>Cryovessels Pre-use CIP WFI Rinse (Vessels 5)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Submit TOC sample to QC Lab per SGTS-1389. Initial/Date Attachment A when result is attached.

### EPS Format

<table>
<thead>
<tr>
<th>7.9.3 Manifold 1 (N/A Step if not required.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect WFI rinse samples from manifold per SGTS-1375 and submit to QC per SGTS-1389.</td>
</tr>
<tr>
<td>Template ID</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>SG12435_16</td>
</tr>
<tr>
<td>Ad hoc sample</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.9.4 Manifold 2 (N/A Step if not required.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect WFI rinse samples from manifold per SGTS-1375 and submit to QC per SGTS-1389.</td>
</tr>
<tr>
<td>Template ID</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>SG12435_17</td>
</tr>
<tr>
<td>Ad hoc sample</td>
</tr>
</tbody>
</table>
EPS PHASE 2 | Pilot on Engineering Batches

Numbers of Deviations per batch

Typical 1st batch

1st batch with experienced operators only

1st batch with experienced operators + EPS Phase 1+2

71% reduction in deviations

38% Human related

0% Human related
EPS PHASE 2 | Impact on Commercial Batches

Number of Deviations Per Batch

80% reduction in Deviations
EPS PHASE 3 | Outlook

PROCESS ROBUSTNESS

EQUIPMENT RELIABILITY

AUTOMATION
Error prevention is the first value and never abandoned because...

Patient safety is in your hands.

EPS Error Prevention System
Thank You!

Please complete the session survey at:
www.ame.org/survey

Session: WP/20 -
Error Prevention: A Great Lean Partner
Jon Kirsch

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