Human Errors
Disclaimer

This presentation is solely prepared for sharing knowledge and best practices followed by various Pharmaceutical industries. This has been collected from various guidelines, FDA 483s, Warning letters, various articles and presenters personal experience. The thoughts and knowledge presented in this presented is not thoughts of the company which I work.
Human Errors
Background

Human Error Is The Leading Cause Of GMP Deviations

25-60% of the deviations / Incidents in the companies are caused by Human errors
(xiv) An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems.

This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. **Where human error** is suspected or identified as the cause, this **should be justified** having taken care to ensure that process, **procedural or system based errors or problems** have not been overlooked, if present. Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles;

In summary,

1. Small quantity of deviations to result from human error
2. Classify it Human error as a last resort.
3. Eliminated any possible process, environment, procedural or system based issues
Human Errors
Regulatory Observations

Warning Letter / FDA 483

1. Foreign matter was identified as a known process-related defect, yet no specific root cause for the particulate was identified. And the most likely root cause of failure to identify the critical/major defects during 100% visual inspection was identified as human error.

2. High percentage rate of invalidated OOS (77%) test results without appropriate investigation was identified contributing mainly because of human error, instrument/column error, and method error.

3. Multiple LI investigations lacked scientific rationale for root cause determination. Probable root cause were attributed to contamination and analyst error

4. CAPAs have often been limited to retraining analysts. Improvement in analytical methods and equipment were not generally implemented to enhance robustness and prevent error
Human Errors
Current Ways

• Blame, Blame and Blame!

20-40% of human error

Active blaming

Passive blaming
Human Errors
Current CAPAs

- Training / Re-training
- Display notification
- Take actions on the employee
- One point lesson
- Revise SOP
**Human Errors Types**

**Human Errors**

- **Unintended Actions**
  - Action not as planned (Error) **Attention gap**
  - Lapse of memory
  - Slip of action
  - Rule based mistake
  - Understanding Gap

- **Action as planned (Mistake)**
  - Routine
  - Knowledge based mistake
  - Skill gap

- **Intended Actions (Behavioral Gap)**
  - Exceptional
  - Situational
### Human Errors

#### Human errors

<table>
<thead>
<tr>
<th>Attention Gap</th>
<th>Understanding Gap</th>
<th>Proficiency Gap</th>
<th>Behavioural Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examples</strong></td>
<td><strong>Examples</strong></td>
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<tr>
<td>Memory gap / forgetfulness</td>
<td>Learning gap</td>
<td>Inadequate knowledge</td>
<td>Work environment</td>
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<tr>
<td>Lazy</td>
<td>Decision error</td>
<td>Skill / Analytical ability</td>
<td>Attitude</td>
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<tr>
<td>Attention toward work</td>
<td>Procedural / SOP</td>
<td>Concept application error</td>
<td>Culture</td>
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<tr>
<td>Omission of action</td>
<td>Complex system</td>
<td></td>
<td>Physical / Mental limitation</td>
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<tr>
<td>Absent mindedness</td>
<td>Communication gap</td>
<td></td>
<td>Intentional errors</td>
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<td></td>
<td>Judgement error</td>
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#### Probable causes

<table>
<thead>
<tr>
<th>Attention Gap</th>
<th>Understanding Gap</th>
<th>Proficiency Gap</th>
<th>Behavioural Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear Job responsibilities</td>
<td>Training</td>
<td>Lack of knowledge</td>
<td>Incorrect R&amp;R,</td>
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<tr>
<td>Infrastructure</td>
<td>SOP / Instructions</td>
<td>Decision error</td>
<td>Collaboration</td>
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<tr>
<td>Fatigue</td>
<td>Communication mechanism</td>
<td>Suitability for the role</td>
<td>Leadership focus</td>
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<tr>
<td>Work pressure / overload</td>
<td>Over confident</td>
<td>Complex systems / procedure</td>
<td>Metrics</td>
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<tr>
<td>Work allocation</td>
<td></td>
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<td>Habitual</td>
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</tbody>
</table>
# Human Errors

**Most common human errors in Pharma**

<table>
<thead>
<tr>
<th>Laboratory / OOS</th>
<th>Manufacturing</th>
<th>Quality Assurance</th>
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</thead>
<tbody>
<tr>
<td>2. Dilution</td>
<td>2. Labeling</td>
<td>2. Retain sample review</td>
</tr>
<tr>
<td>3. Weighing</td>
<td>3. Line clearance</td>
<td></td>
</tr>
<tr>
<td>4. Documentation</td>
<td>4. Schedule misses</td>
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</tbody>
</table>

**Engineering**

1. PM / Calibration schedule misses
2. Documentation
Human Errors
Do all human errors require investigation?

- Does all human errors be investigated and CAPA implemented?
  E.g. Skips, Lapses

- Risk tools
  - Severity: Safety, Quality
  - Detectability: Already checks available to detect it
  - Frequency: No. of occurrences
Complex human error

Simple human error (Non product impacting, rare, easily detectable)

Human Errors Investigation

- DMAIC
- 5 Why’s
- FGD / Gemba walks
- Brainstorming
Human Errors
Categorization: Human Factor

Physical
Physical Capability
- Vision / Hearing / Sensory
- Disabilities
- Restricted body movements
- Difficult body positions

Physical Condition
- Injury
- Illness
- Insufficient Rest
- Oxygen deficiency

Mental
Mental State
- Memory
- Reaction time
- Medication

Mental Stress
- Frustration
- Conflicting communications
- Too many problems

Behavior
- Shortcuts
- Improper reward
- Avoids discomfort
- Relax attitude

Skills
- Wrong skills
- Insufficient trainings / OJT
- Improper assessment
Human Errors
Categorization: Systems Factor

Knowledge Transfer
- OJT
- Clear and concise operating instructions
- Improper risk assessments and controls

Engineering Design
- Design of area / equipment / system
- Standards
- Ergonomics
- Change management of engg changes

Work Planning
- Work allocation
- Output orientation (e.g. In-sufficient PM)

Policies
- Induction
- R&R
- Risk assessments: Acceptable risk ratings

Management / Supervision
- Assignment of roles
- Delegation
- Standard work
- Performance dialogues

Communications
- No clear communication
- Focus on speed
Important points for human error investigations

• Pre-defined Interview checklist.
• Photographic evidence
• Approved hypothesis plan (Wherever required)
• Spot verification (Gemba walks)
• Data analysis based on system, person, area, process, system etc
Human Errors
Corrective and Preventive Actions

- Elimination
- Substitution
- Engineering Control
- Duplication
- Administrative controls
- On-spot Fixing

Most Effective

Less effective
Human Errors
Case Study

Repeat mistakes and errors in documentation even after multiple trainings (discipline)

Repeat mistakes are made as the shopfloor time/resource constraints continue to exist

Complexity (process inefficiencies) creates artificial time pressure

The processes/systems continues to allow mistakes (not fool proof)

"Mistakes are inevitable" mindset in some operators

Need to deliver daily/short term delivery targets

Significant waiting / non-value added time on the shopfloor

The systems (e.g. training) are not designed to be fool proof

Belief that everybody does it and individual caught are unlucky

Limited cross-functional forums at the shopfloor level

Difficult to follow SOPs

The system/process design does not adequately take into account how it is implemented on the shopfloor

Most issues are never raised

Limited value added (problem resolution, issue identification) senior management time on the shop-floor

Lack of effective systems/processes to raise, prioritize, implement, monitor and communicate progress of quality improvement ideas

Greater day to day share of voice for delivery (as compared to quality)

Belief that delivering the output is most important
1. Human errors do happen

2. Categorize it as Human error after all possible causes have been negated.

3. Small quantity of deviations to result from human error

4. Investigation should be thorough to ensure that cause is identified.

5. Eliminated any possible process, environment, procedural or system based issues

6. Classify human errors in Attention gap, understanding gap, skill gap and behavioral gap

7. Take appropriate actions based on the causes

8. Look for error proofing instead of blame, duplication etc.
Questions
Thank You