Reducing Human Error: Processes and Strategies that Get to the “Root” of the Problem

Objectives...

• Understand human error: factors and causes
• Understand the importance: regulatory and business
• Define the process to manage human error deviations
• Identify what can I do to support human reliability
Background

• Human Error
  – Technology improves humans...
  – Major contributor (80%) of failures (Pharmaceutical mfg.)
    • Quality
    • Impacts efficiency
    • Regulatory standing
    • Customer Service
    • Costs

• Training proven effective
  – New employees
  – New set of KSAs
  – New processes
  – Changes are made to existing processes
  – Design, delivery, method and content is based on the intention (by design)

  Training mostly used to correct or prevent these failures

Human Error

• Any action, or lack of a required action, that exceeds the system tolerance.

• Any action, or lack thereof that results in an outcome that is different than expected.
Human Error Vision

• Old Vision
  – Human Error is the cause of accidents/incidents
  – You must find people’s inaccurate assessments, wrong decisions, bad judgment

• New Vision
  – Human Error is a symptom of trouble deeper inside a system
  – Instead, find how peoples assessments and actions made sense at the time, given the circumstances that surrounded them.

What is happening? The 5 Errors...

- Investigate technical problem not HE
- Real Root Cause is not identified
- IA/CA/PA Ineffective
- Human Error as a “Root Cause”
- Wrong problem is addressed
Types of error

<table>
<thead>
<tr>
<th>Omission</th>
<th>Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skips step to shorten the time</td>
<td>Adds an ingredient because he/she thinks is better</td>
</tr>
<tr>
<td>Forgets to add the ingredient</td>
<td>Adds the wrong ingredient</td>
</tr>
</tbody>
</table>

Unintentional

Performance is affected by...

- Internal Factors (biophysical)
- External Factors (things)
- Human Factors (capability)
- Systems

Ginette M. Collazo, Phd.
ginette@ginettemcollazo.com
What is it about people?

- We have limitations
- Memory
- Attention
- Visual detection
- Overconfidence
- Brain

Common Causes

- Memory
  - Multitasking
  - Hurry
  - Stress (eustress-distress)
  - Slips
- Attention
  - Need to know what is it that needs my attention
- Visual detection
  - Very bad after 2 ½ hours...
  - Eyes lie to you...
- Overconfidence
  - Calibration and supervision
The human equipment...

<table>
<thead>
<tr>
<th>Equipment</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>User requirements</td>
<td>Job description, task analysis, minimum</td>
</tr>
<tr>
<td></td>
<td>requirements for execution.</td>
</tr>
<tr>
<td>Selection based on objective requirements.</td>
<td>Selection based on mixed elements.</td>
</tr>
<tr>
<td>Formal qualification programs: Master plan,</td>
<td>Training program, qualifications, testing,</td>
</tr>
<tr>
<td>protocols, reports…</td>
<td></td>
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<tr>
<td>Installation qualifications.</td>
<td>Routine training and refreshers.</td>
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<tr>
<td>Operation Qualification</td>
<td></td>
</tr>
<tr>
<td>Performance Qualification.</td>
<td></td>
</tr>
<tr>
<td>Preventive/predictive maintenance</td>
<td>Vacations, resting periods</td>
</tr>
</tbody>
</table>

Humans will make mistakes...

- Let’s clarify expectations.
  - Humans WILL make mistakes.
  - It is part of our nature.
- You can:
  - Have zero major deviations due to human error.
  - Keep errors (because they will happen) where you can control the magnitude of the consequences.
- Want ZERO errors-you have to eliminate the human interaction.
What else can be done...

- Some things CAN be done
- 80% Human Factors (systems) 20% Internal/Individual
- You cannot change human condition but you can change the conditions in which humans work...

Let’s understand the 80%...
Human Error Cause Categories

- Administrative/Management Systems
- Procedures
- Human Factors Engineering
- Training
- Supervision
- Communication
- Individual Performance

Human error rates

- Instances (events)
- Opportunities (lots/tests)
20% INDIVIDUAL

The Blame Cycle

- More flawed defenses and error precursors
- Latent organizational weaknesses persist
- Management less aware of jobsite conditions
- Less Communication
- Reduced trust
- Individual counseled and/or disciplined

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Motivation/Attention

- Emotion
- Stress
- Eustress
- Distress

Self regulation

- Understand the why’s
- Generational factors
- Blame cycle

- Individual
  - **Slip/Lapse**: Unintentional action: memory and attention failures.
  - **Mistake**: Intentional, failure in judgment/inferential process, no harm intended.
  - **Violation**: Repeated event, consequences known.
Case Study

And it worked...

The Challenge

• Reduce HUMAN ERRORS and improve HUMAN RELIABILITY, while...

  – New technologies and equipment (new skill set needed)
  – No additional resources (headcount)
  – 25-30% reduction in budget
Process

• Diagnosis (re-analyze failure investigations)
  – random sample: 12-month period
  – correct problem defined?
  – correct root causes / causal factors identified?
  – appropriate immediate, corrective and preventive actions?

Process

• Categorize and code
  – Four levels (deductive: general to specific)
    1. Causal factor type
    2. Root cause category
    3. Near root cause
    4. Root cause(s)

• Quantify
• Plan based on priorities (GUT)
More than 80% Human Error

More that 50% related to procedures

Less than 30% distributed in all other categories

8%-10% training (KSA's)

Less than 10% related to individuals

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Accomplishments

<table>
<thead>
<tr>
<th>Baseline</th>
<th>4.7%</th>
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</thead>
<tbody>
<tr>
<td>Result</td>
<td>1.9%</td>
</tr>
<tr>
<td>60% Reduction</td>
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</tbody>
</table>
How is Human Error controlled?

- 80% by using human factors in **SYSTEMS** (any aspect of the workplace or job implementation that makes it more likely for the worker to make an error)
  - Management Systems
- 20% by managing acquired behaviors- **PEOPLE**

We focus on systems... and then people. We believe people make mistakes because they can. Our systems allow it.
What is happening?

The 5 Errors

Investigate technical problem not HE

Real Root Cause is not identified

IA/CA/PA Ineffective

Human Error as a “Root Cause”

Wrong problem is addressed

We don’t ask why. Root cause analysis for human error events is mostly inexisten.

What can be done?

THE METHOD
Will answer...

- What happened
- How I happened
- When it happened
- Where in the process did it happen
- Who was involved and then

**Why**

And then correct, prevent, predict and control.

Human error:.... but where?

Ginette M. Collazo, Phd.
ginette@ginettemcollazo.com
What?

- Human Error
- System Problem
- Human Performance Problem
- Administrative Management Systems
- Operation Controls (factors)
- Individuals

This explains why...
We can predict based on previously identified areas of opportunities.

Upside down root cause analysis.

Break the process

1. Type (Equipment/People/Systems)
2. Categories
   1. Administrative Management System
   2. Procedure
   3. Human factors engineering
   4. Training
   5. Supervision
   6. Communication
   7. Individual
3. Near Root Causes
4. Root causes
Move away from human error creation.

Break the Blame Cycle

Human Error

- More flawed defenses and error precursors
- Latent organizational weaknesses persist
- Management less aware of jobsite conditions
- Reduced trust
- Less Communication
- Individual counseled and/or disciplined

Diagnosis
- 12 Month
- Categorize & Code
- HE Rate

Training
- Investigators
- Management
- Supervision and Operational

Pulse Check

Monitor/Trend

Implement System Changes 80

Culture Change Process 20
Human Error (HE) Diagnostic Flow Chart

Start Diagnostic Study

Identify Investigations related to Human Error

Determine sample to be evaluated

Evaluate Events

Human Error is the Correct Root Cause?

Yes?

Use the Chart to Locate the code (Root Cause Chart)

Document the Code (HC Assessment Tool)

Tabulate Analysis Data (Root Cause Determination Tool)

No?

Re-evaluate the investigation

Tabulate Analysis Data (Final Diagnostic Report)

Present Report to Client

Human error rates

• Instances (events)
• Opportunities (lots/tests)
Data

- By site
- By department
- By type - Human Error, System Error and Equipment Failure.
- By category
- Near root cause
- Root cause

How it will look? Examples

![HE Rate Plant Graph](image-url)
Distribution by categories

Recurrence

- Administrative Management Systems: 36%
- Procedures: 23%
- Human Factors Engineering: 16%
- Training: 9%
- Immediate Supervision: 9%
- Communication: 5%

Near root cause

Procedures

- Not used: 25%
- Confusing: 33%
- Wrong/incomplete: 42%

Ginette M. Collazo, Inc.
ginette@ginettemcollazo.com
Root Cause

Wrong/Incomplete

- Typographical: 9%
- Sequence: 14%
- Facts wrong: 10%
- Wrong revision: 22%
- Inconsistency between requirements: 33%
- Incomplete: 12%

Tools

Human Error Prevention Program

HUMAN RELIABILITY CONSULTANCY
Our Tools

- Human Error Related/ Customized Courses
- Human Error (HE) Diagnostic Flow Chart
- Human Error – Assessment Tool
- Root Cause Determination Tool
- HE- Floor Assessment Checklist Assessment
- SOPs/ MBR/ Documents to Prevent Human Errors
- Process vs. Procedure Analysis Tool
- On the Job Training Test – Template

RCDT
Human Error – Assessment Tool

Human Error Assessment Form
Diagnosis for XYZ Company

<table>
<thead>
<tr>
<th>ID number</th>
<th>Event Date</th>
<th>Event Description</th>
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</table>

Problem Stated
Root Cause Stated (As is) - Error/Other (Describe) Root Cause Code (As is)

Investigation
Notes:

A B C D E F
Equipment, Software Problem Admin, Mgmt Problem Human Performance Problem Natural Phenomena Sabotage Horseplay Other Difficulty

Related to the individual (9)
Root Cause Determined Root Cause Code (Determined)

Immediate action
Corrective Action Preventive Action Recurring Root Cause:

Evaluation
Completed by: Date Evaluation Completed:

Root Cause Determination Tool

**Problem Type**: Human Performance Problem
**Cause Category**: Procedures
**Near Root Cause**: Wrong / Incomplete
**Root Cause**: Incomplete / Situation Not Covered

**DEFINITION OF C4O5**
Details in the procedure are incomplete. Information presented is not enough. All critical situations that may occur during the task execution are not covered in the procedure.

**RECOMMENDATIONS**
Perform a Process vs. Procedure assessment and make corrections as needed. Perform a technical assessment (e.g., HAZOP, What-If Analysis).
HE – Floor Assessment Checklist

SOP Template to Prevent Human Error

One Step Column and One Detail Column for easy follow
Conditional Statements
Warning Statements: For major critical and safety related (if required)
Caution Statements: For critical (not major) (if required)
One instruction per row
(Note: Not all rows needs Warning and/or Cautions)
Process vs. Procedure Analysis Tool

<table>
<thead>
<tr>
<th>Process vs Procedure Analysis</th>
</tr>
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<tbody>
<tr>
<td><em>Answer (Y) for YES or (N) for NO (MUST BE CAPITAL LETTER). Action Recommended for SOP</em></td>
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</table>

<table>
<thead>
<tr>
<th>SOP Number</th>
<th>Is the Procedure Followed by a Controlled Document?</th>
<th>Can the SOP be followed and understood as written?</th>
<th>Are the critical parameters defined correctly (e.g., units of measurement)?</th>
<th>Are the environmental controls defined (e.g., temperature, humidity)?</th>
<th>Does the SOP mitigate contamination (keep contamination from happening)?</th>
<th>Does the SOP mitigate product defect (keep product defects from happening)?</th>
<th>SOP acceptable, No Action required</th>
<th>Submit Procedure to Document Control</th>
<th>Make SOP easier to understand and follow</th>
<th>Update SOP to address validated process with emphasis on:</th>
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On the Job Training – Test Template

SOP Related Doc. #

Instructions/
SOP Critical Step

SME Initials/ Date

Trainee Initials/ Date

7.1 Critical Steps

Copies of this page can be done if required.

Page ___ of ___

<table>
<thead>
<tr>
<th>SOP Reference (036-SOP-D-0112s)</th>
</tr>
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<tbody>
<tr>
<td>Step</td>
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</table>

1. Operator pressed ABC button and letter A was shown on the screen.  
   □ Yes  □ No
2. Operator select and pressed ABC button and letter B was shown on the screen.  
   □ Yes  □ No
3. Operator select and pressed ABC button and letter C was shown on the screen.  
   □ Yes  □ No
4. Pressed (key “)” to change from upper case to lower case, then entered any text and pressed ABC to accept the insertion.  
   □ Yes  □ No
5. Entered lot number numbers and appeared on the screen  
   □ Yes  □ No
6. To store ID information, Operator pressed SP/ID (P/FUNCTION)  
   □ Yes  □ No
7. Pressed PRINT key and assured the information entered was correct included into entered on step 6  
   □ Yes  □ No

Comments: