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IPA
Innovation, Quality and Global Reach

Human Errors

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Agenda

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- Understanding Human Errors
- Regulatory expectations
- Current way of handling human errors
- Types of human errors
- Investigation of human errors
- CAPAs
- Case study

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Disclaimer

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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 Error Is The Leading Cause Of GMP Deviations

25-60% of the deviations / Incidents in the companies are caused by Human errors

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Human Errors
Regulatory expectations

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PIC/S PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 009-14 (Part I)
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EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and Products
Medicinal Products - Quality, safety and efficacy

Volume 4
EU Guidelines for
Good Manufacturing Practice for
Medicinal Products for Human and Veterinary Use

Chapter 1
Pharmaceutical Quality System

(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

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Human Errors
Regulatory Observations

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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

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Human Errors
Current Ways

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- Blame, Blame and Blame!

Active blaming

Passive blaming

20-40% of human error

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Human Errors
Current CAPAs

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

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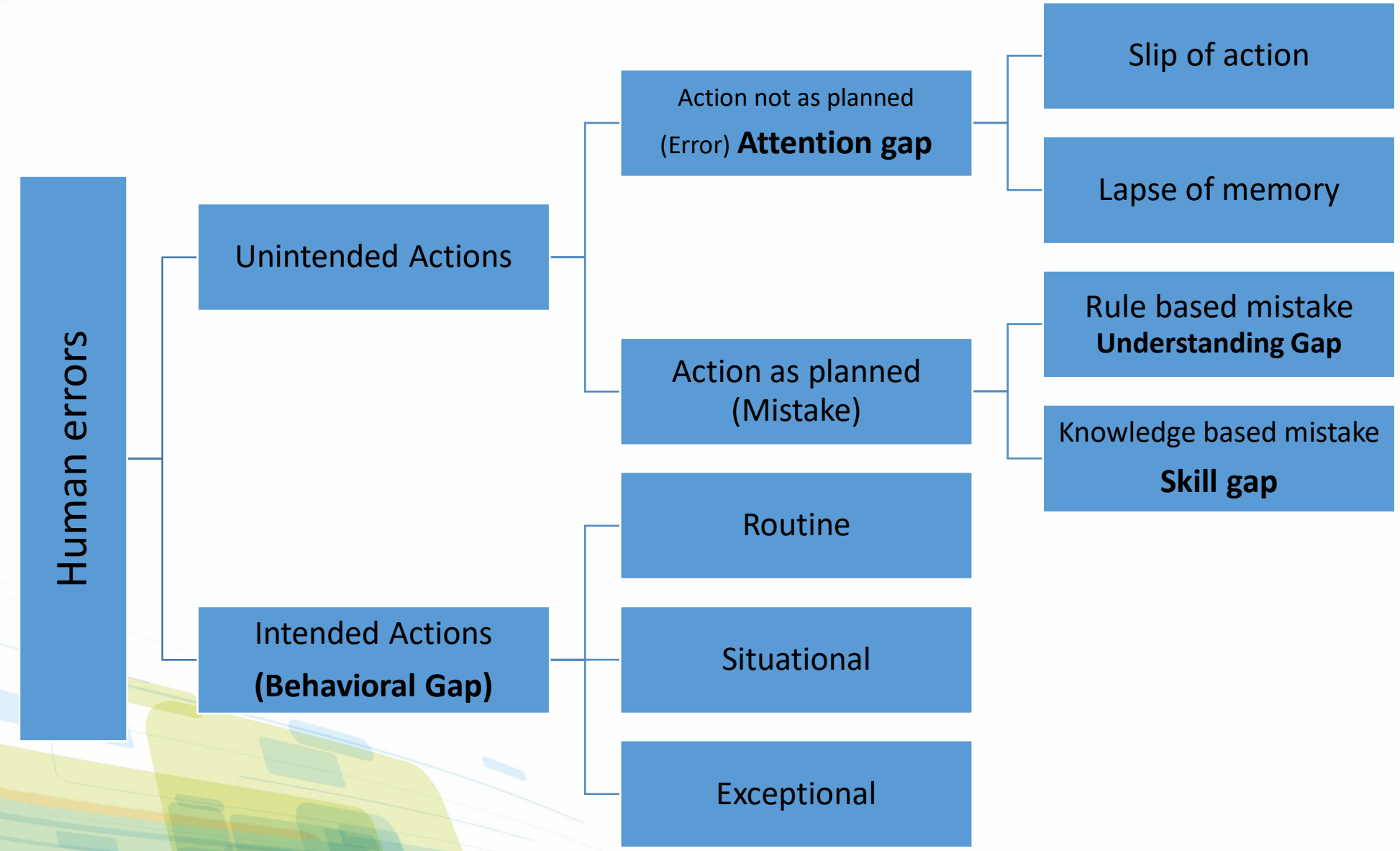
Human Errors
Types



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Human Errors
Human errors

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Attention Gap

Examples

- Memory gap / forgetfulness
- Lazy
- Attention toward work
- Omission of action
- Absent mindedness

Probable causes

- Clear Job responsibilities
- Infrastructure
- Fatigue
- Work pressure / overload
- Work allocation

Understanding Gap

Examples

- Learning gap
- Decision error
- Procedural / SOP
- Complex system
- Communication gap
- Judgement error

Probable causes

- Training
- SOP / Instructions
- Communication mechanism
- Over confident

Proficiency Gap

Examples

- In adequate knowledge
- Skill / Analytical ability
- Concept application error

Probable causes

- Lack of knowledge
- Decision error
- Suitability for the role
- Complex systems / procedure

Behavioural Gap

Examples

- Work environment
- Attitude
- Culture
- Physical / Mental limitation
- Intentional errors

Probable causes

- Incorrect R&R,
- Collaboration
- Leadership focus
- Metrics
- Habitual

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Human Errors

Most common human errors in Pharma

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Laboratory / OOS

1. Solution preparation
2. Dilution
3. Weighing
4. Documentation

Manufacturing

1. Documentation
2. Labeling
3. Line clearance
4. Schedule misses

Quality Assurance

1. Document review misses
2. Retain sample review

Engineering

1. PM / Calibration schedule misses
2. Documentation

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Human Errors

Do all human errors require investigation?

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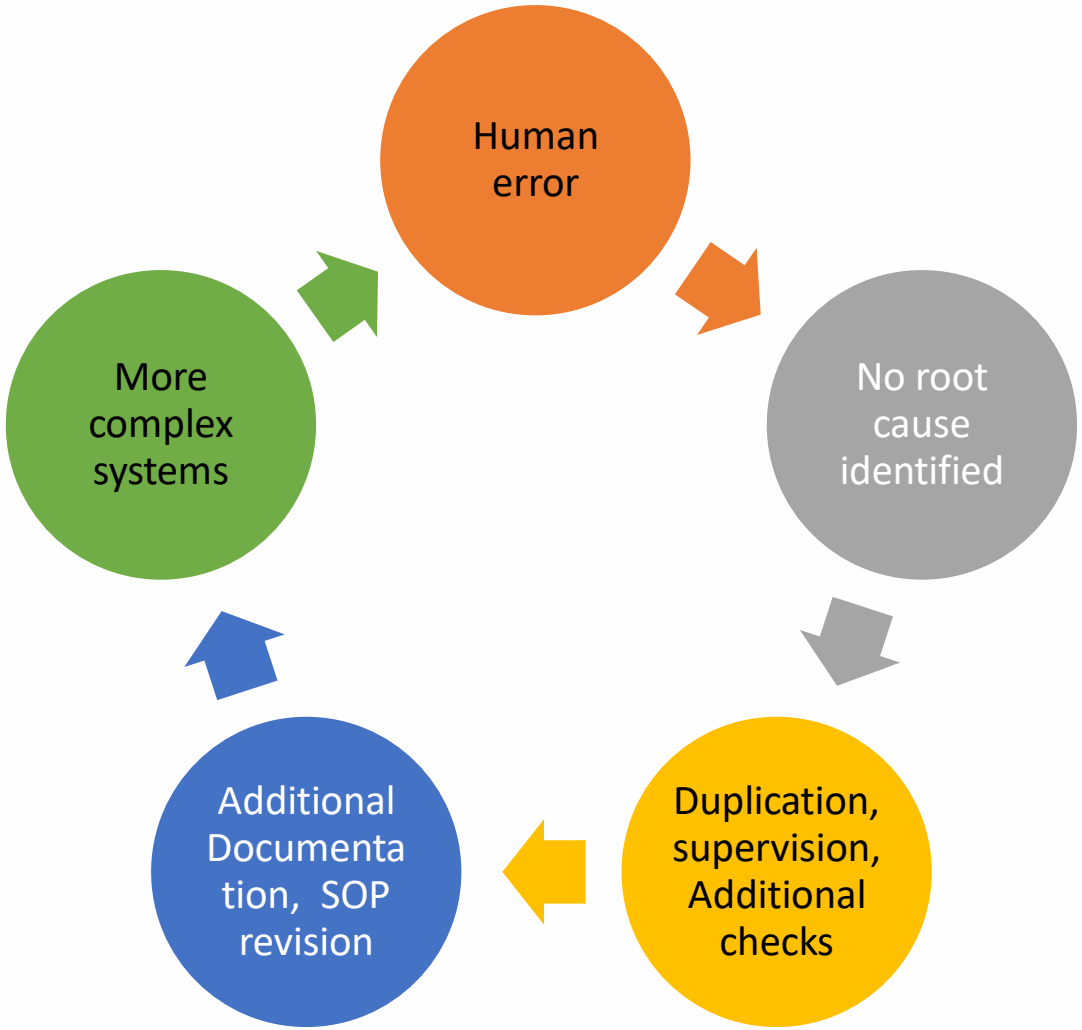
- Does all human errors be investigated and CAPA implemented?
  E.g. Skips, Lapses

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



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Human Errors
Investigation

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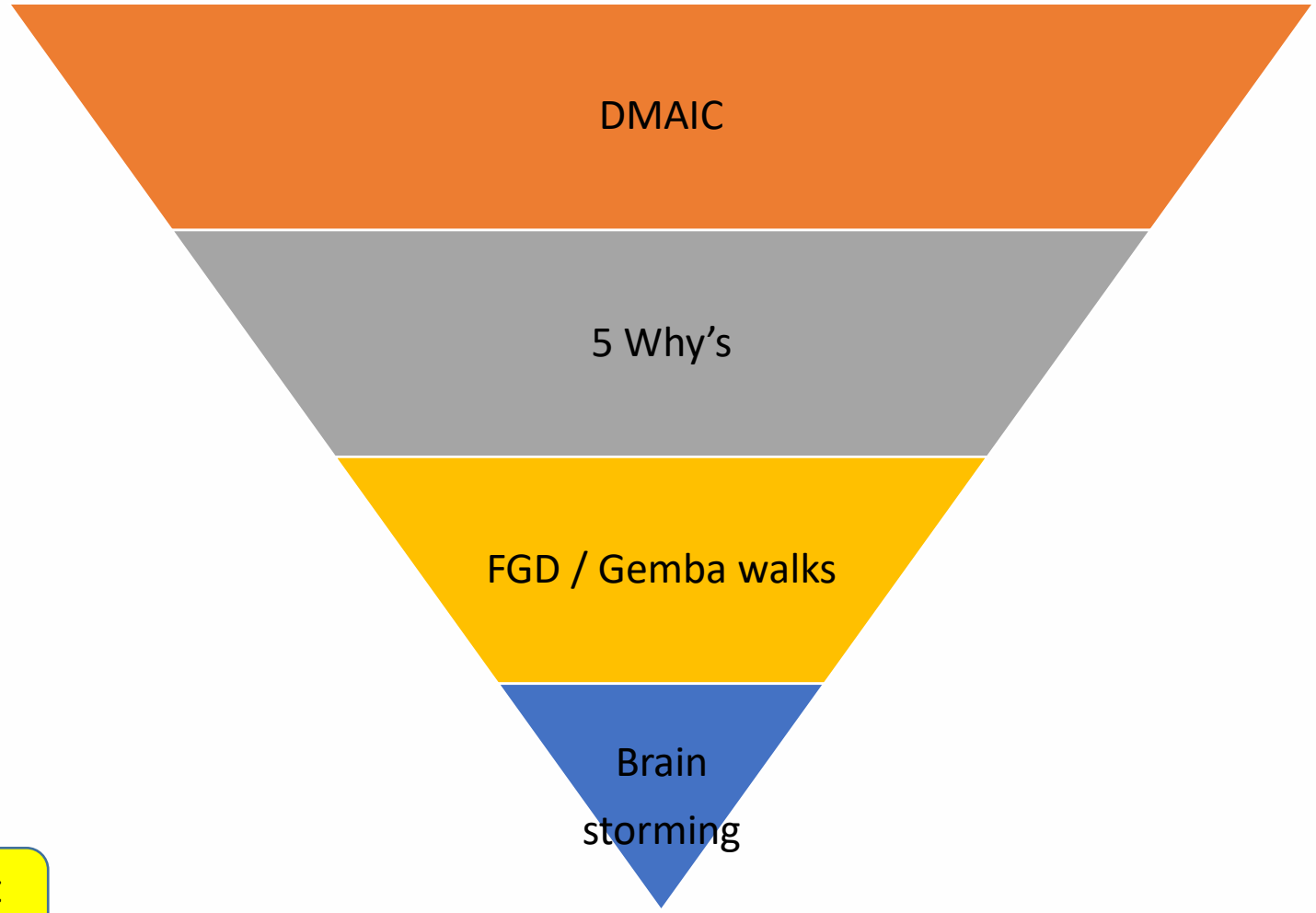
Complex human error



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

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Human Errors Categorization: Human Factor

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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

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Human Errors Categorization: Systems Factor

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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-suffient 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

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Human Errors
Investigation

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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

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Human Errors

Corrective and Preventive Actions

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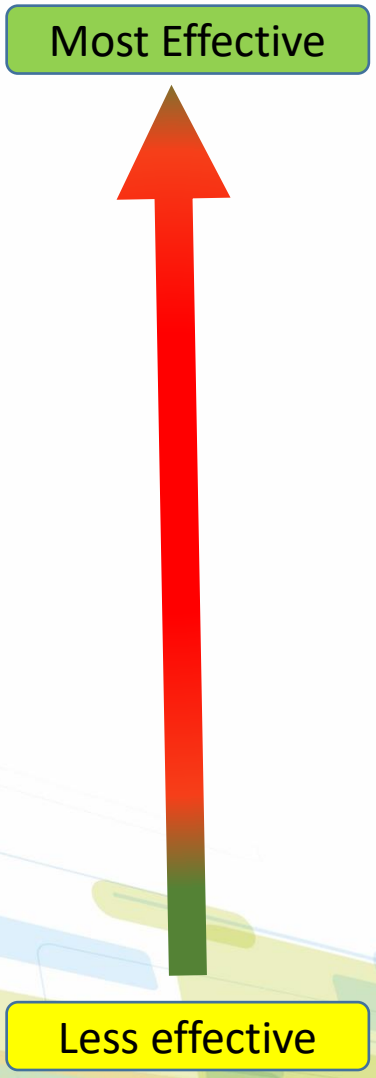

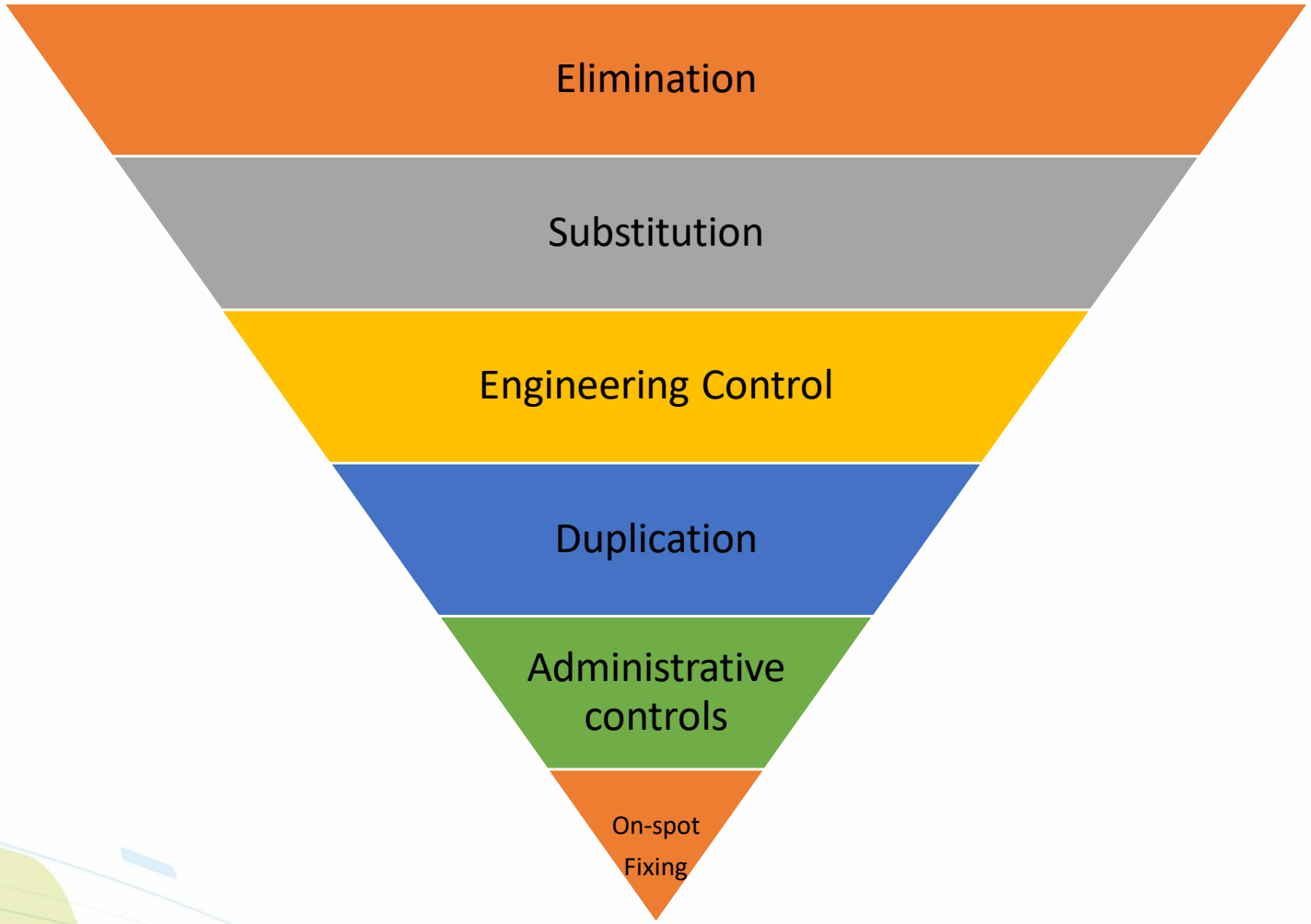

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Human Errors
Case Study

ILLUSTRATIVE

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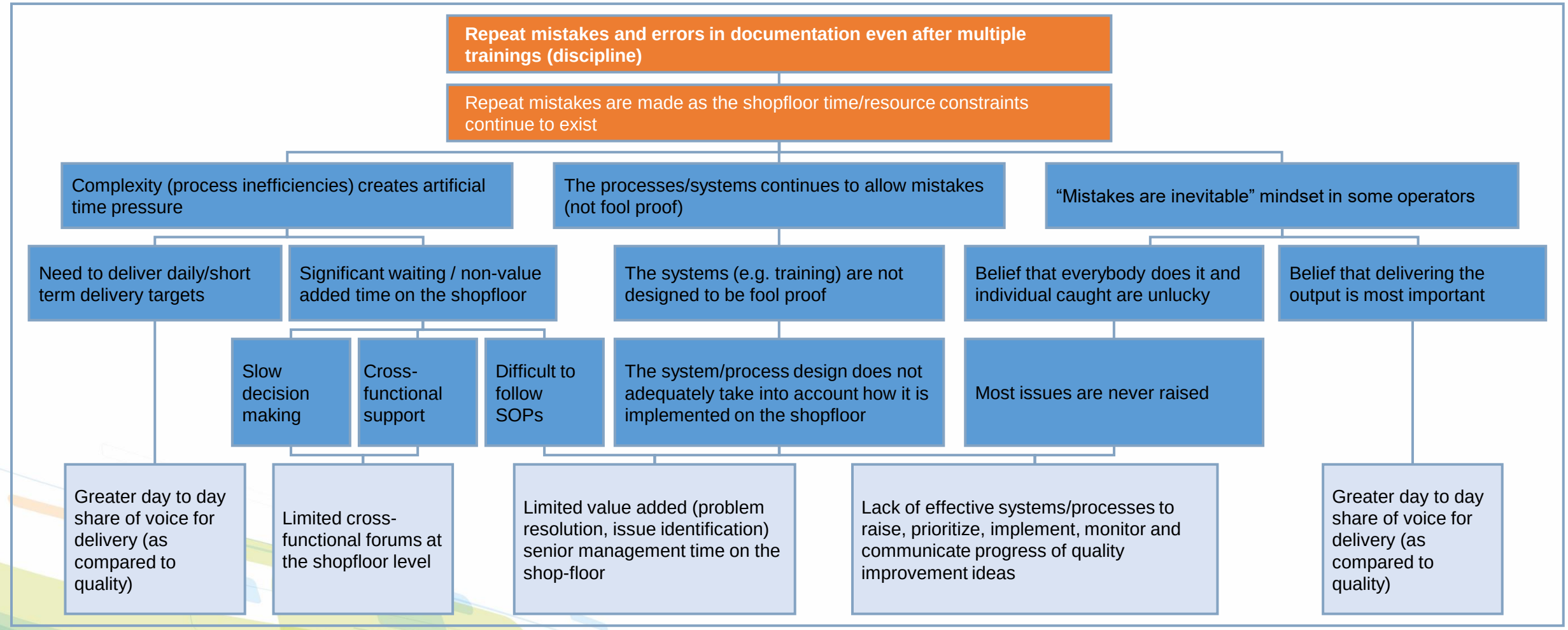

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Human Errors
Summary

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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.

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Questions

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Thank You