Diagnosis of Personnel Errors and Implementation of an Effective CAPA for GLP Compliance

Dr. Labhu Sanghani, Director Global QA, Jai Research Foundation, Gujarat, India

JAI RESEARCH FOUNDATION

Abstract

➡ Appropriately trained and well organized laboratory staff are key to the successful operation of a GLP facility. Personnel working in a GLP facility must receive direct and detailed training for a flawless performance. Competencies, covering the requisite components of an employee's training and functional responsibilities must be assessed periodically and recorded. A laboratory imparting training, adequate enough, to meet needs of all personnel must be documented, and evidence of adherence to the ongoing requisite practices by every laboratory personnel must be readily available.

➡ Human beings are inclined to error. Personnel commit mistake either they are unaware of it or are under a tight grip of misconception. This can be addressed by system-centric and person-centric ways.

➡ Under the system-centric way, individual works and tries to avert error and or mitigate its effect. The person-centric ways focuses on errors of concerned individuals, holding them responsible for forgetfulness, inattention, or moral weakness. Occurrence of mistakes in daily work is governed by factors such as age, state of mind, physical health, attitude, and emotions. The key factors causing personnel error are: low alertness, high stress, high confusion, overconfidence, and low compliance. These factors needs detailed diagnosis identifying the reason, an effective proactive corrective and preventive action for identified errors. The very first step to overcome human error is to discard unnecessary illusion and ignorance.

Low Alertness

Illness
• Mental or physical weakness
• Distraction due to illness
• Excessive work schedule

Fatigue (Lethargy)
• Inadequate sleep
• Post meal-mid-afternoon
• Repeated error at certain time

Boredom
• Poor work planning
• Poor motivation
• Goal confusion

High Stress

Low Morale
➤ Job Danger
➤ Lack of Confidence
➤ Poor teamwork

Poor Supervision
➤ Job assignment error
➤ Staffing error
➤ Poor communication

Fear of Failure
➤ Task confusion
➤ Poor accountability
➤ Poor supervision

High Confusion

High Complexity:
Inadequate knowledge
Not familiar with task
Poor procedures

Cognitive Overload:
Multi-tasking
Inadequate training or procedures
Distractive environment

Information deficiency:
Lack of teamwork
Information not available
Not enough information

Underestimated complexity
➤ Long time on same job
➤ Low management standards
➤ Poor teamwork

Tunnel vision
➤ Poor supervision
➤ Poor accountability
➤ Perceived time pressure

Shortcuts
➤ Task outside of procedure
➤ Poor teamwork
➤ Perceived time pressure

Mindset
➤ Task outside of procedure
➤ Tribal knowledge
➤ Assumptions

Low Compliance

Inadequate Motivation
➤ Low Consequence
➤ Wrong Assumptions

Habit Intrusion
➤ Reflex
➤ Poor supervision
➤ Perceived time pressure

Embarrassed
➤ Too complex task
➤ Lack of procedure
➤ Poor training

Human Error Causal Factors

➤ **Knowledge Based**: Error based on the absence of knowledge of the procedure, regulation or need

➤ **Cognition Based**: Error based on the lack of ability to apply the knowledge necessary to fulfill the requirement

➤ **Value Based**: Error based on the lack of willingness to accept the requirement of regulations and procedures

➤ **Reflexive Based**: Error based on the absence of ability to immediately respond to the requirements

➤ **Condition Based**: Error based on the lack of ability to counteract the error-inducing condition

➤ **Skill Based**: Error based on the absence of required skill and competency

➤ **Lapse Based**: Error based on the absence of attention to the task

Conclusion

Human beings are inclined to error. Personnel commit mistake either they are unaware of it or are under a tight grip of misconception Occurrence of mistakes in daily work is governed by factors such as age, state of mind, physical health, attitude, and emotions. These factors needs detailed diagnosis identifying the reason, an effective proactive corrective and preventive action for identified errors. The very first step to overcome human error is to discard unnecessary illusion and ignorance.