Why Understanding How to Manage Human Error and Understand Human Factoring Application is Critical to Effective CAPA

Description: Date: April 5th, 2016
Time: 10:00 AM PDT, 01:00 PM EDT

Ineffective CAPA(s) results from a continued use of misleading approaches to conducting investigations, such as, root cause analysis instead of Causal Analysis. Causal Analysis provides an understanding of all contributing factors to a deviation. There is never just one cause for a deviation; therefore, root cause analysis doesn't provide the necessary data for a deviation to determine all needed CAPA(s). Furthermore, to ensure effective CAPA(s) are implemented requires understanding the science behind human system interaction, how to human factor systems and manage human error and a formal process to measure CAPA effectiveness must be a part of a quality system.

Failure is the “gold mine” for the opportunity to learn and improve. Consider what I heard in a presentation by a Duke University, Civil Engineer professor on the benefits of failure, “If the Titanic had gone a little slower or faster and hadn’t hit the iceberg, causing such a tragedy, how many more steel ships would have been built with the same structural flaw?”

Objectives of the Presentation:
- Be able to use a proven risk and science based approach to complete causal analysis
- Ways to mitigate human error through understanding human-system interaction (Human Factors)
- What types of changes need to be made to quality systems to complete causal analysis, implement and monitor CAPA effectiveness
- How to evaluate aspects of culture that are preventing the opportunity to learn from failure so CAPA effectiveness is achieved
- How do quality system process changes to achieve effective CAPA impact quality system software changes
- Create a shared responsibility culture that supports learning from failure in order to advance quality

Why Should you Attend:

Ineffective Corrective Action/Preventive Action (CAPA) systems have been noted repeatedly by regulatory agencies, particularly by the FDA as a significant quality system weakness. Ineffective CAPA leads to:
- Poor quality; repetitive quality deviations
- Product Recalls: Product Complaints
- Inefficiency
- Financial loss
- Employee frustration/reduced morale
- Employee turnover

Who can Benefit:
- CEO
- Quality President
- Quality Vice President
- FDA Auditor
- Quality Auditor
- Sr. Quality Director
- Quality Director
- Compliance Officer
- Quality Manager
- Quality Specialist (any level)
- HR Director
- HR Manager
- Quality System Software Validation Director
- Software Validation Director

Contents:

Areas Covered:

Key effective CAPA components:

- Regulatory compliant system
- Electronically compliant system with ability to monitor adverse trends (accessing data is crucial because you can’t fix what you don’t know about)
- Data / interview process of investigation (timing, culture)
- Risk assessment
- Human error management: understand conditions that promote human error / error prevention techniques
- Human Factors: human-system interaction (equipment, standard operating procedures (SOP), Forms and more)
- Causal Analysis (not Root Cause Analysis)

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