Corrective Action Preventive Action (CAPA)

This course summarizes the cGMP requirements for Corrective Action Preventive Action (CAPA) and prepares participants to complete CAPA investigations on their own. Participants will learn what it means to have control over deviations so that failures can be prevented before they happen. They will learn how to write CA reports that will be used as written. Participants will learn how a well maintained CAPA system will save the company time and money.

Who Should Attend: Supervisors, managers & technicians in Production, Engineering, Quality Control & Assurance, and any personnel who perform investigations, write or revise deviations.

Class Length: one day

Maximum Class Size: 20

Course Prerequisites: None

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The Regulatory Requirements and draft guidelines
- The purpose of documentation
- Definitions of Correction, Corrective Action, Preventive action, Failure Investigations, Deviations- Process, Laboratory, Root Cause Analysis (RCA) and a Corrective Action Preventive action (CAPA) system, Non-Conformance vs. Non-compliance
- What is an appropriate trigger system for CAPAs?
- The role of Risk Assessment
- Containment actions
- Verification of effectiveness
    - What kind of evidence is needed?
    - Is a reduction of the root cause good enough?
    - Did the actions address problem causes, instead of just symptoms?
    - Establishment of monitoring and measuring
    - Are products or outcomes improved?
- Suggested timelines for closing out CAPAs
- Dealing with ineffective solutions
- What reports must be written during a CAPA process?
- How to determine if a non-conformance requires a CA
- Detection of recurring Product or Quality anomalies
- Training requirements
- CAPA case studies

VALIDATION & COMPLIANCE INSTITUTE

537 Fort Dearborn St.

Dearborn, MI 48124