



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
- Root Cause Analysis techniques plus
 - Investigation- asking the right questions
 - Assignable cause –testing & verification
 - The difference between fixing the symptom and correcting the root cause
 - Contributing causes
 - The importance of an open, honest, and self correcting culture
- The reports which must be written and followed during a CAPA process
 - Out Of Specification result reports (OOS)
 - Non-conformance reports (NCR)
 - Deviation reports
 - Change Control reports
 - Calibration and Maintenance Records
- The purpose of signatures and initials of individuals
- How to determine if a non-conformance requires a CA
- Detection of recurring Product or Quality anomalies
- What constitutes verification/validation of effectiveness?
- Training requirements
- CAPA case study

