



Root Cause Analysis

This course provides the participants with a foundation for effective root cause analysis (RCA). Participants will learn cGMP requirements and how to effectively address non-conformances, failures, deviations and complaints by identifying root causes and implementing corrective and preventive actions. They will discover how structured problem solving speeds the process of identifying root causes and contributing factors. They will learn how to write and maintain procedures for Root Cause Analysis. Participants will learn how a well-maintained RCA system will save the company time and money. Through the use of an in-class example, participants will learn how and when to use problem solving tools to collect and analyze data, determine the root cause for a problem, and recommend improvements to reduce the potential for future occurrences.



- 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 a understanding of the following:
- The Regulatory Requirements and draft guidelines
 - The benefits of conducting an investigation using a systematic, documented approach
 - The definitions of terms commonly associated with Investigations and root cause analysis such as correction, corrective action, and preventive action
 - Root Cause Analysis components
 - Investigation: ask the right questions
 - Data collection: structured interviews, document review, field observation. How to generate a timeline of events preceeding and following the incident.
 - Data and Trend analysis to determine the common underlying factors
 - Establish why the event happened through identification of both active and latent failures in the sequence.
 - Identification of assignable cause: testing & verification
 - Clarification of the difference between fixing the symptom and correcting the root cause
 - Analysis of contributing factors and causes
 - The importance of an open, honest and self correcting culture
 - The value of a team approach
 - Analysis of FDA Warning Letters and common citations
 - Case study

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