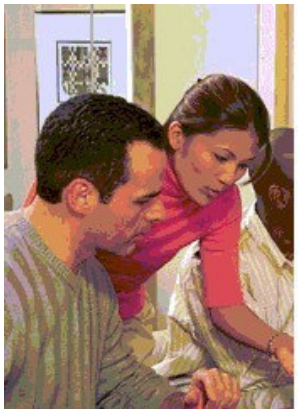
Controlling Process Deviations

Duration: one half day



Course Description: This course gives an overview of the reporting of Process Deviations in order to meet cGMP requirements.

Course Objectives:
Review the cGMP requirements for Process Deviations.
Learn how to conduct a step by step investigation of a Process Deviation and write reports that will satisfy FDA expectations.
Learn how to use lessons from Process Deviations to improve your systems.
Understand why there must be a maintained system
Learn what it means to have control over your deviations and so that you can prevent failures before they happen.

Target Audience: Supervisors and managers in Production, Quality Control & Assurance Personnel, and any personnel, who perform investigations, write or revise deviations.

Course content:
- Review of Regulatory Requirements and draft guidelines
- Review the purpose of documentation
- Definitions of Corrective Action, Preventive action, Failure Investigations, Deviations- Process & Laboratory, Root Cause Analysis (RCA) and a Corrective Action Preventive action (CAPA) system -critical parameters
- Picking the right investigative team.
- Define all the causes including root and contributing.
- How to drill down to find the root cause and then sideways to find similar potential problems.
- How to institutionalize the information learned and make sure that the deviation never happens again.
- Review 483's that have been issued for improper Process Deviation investigations.
- Auditing the process deviation investigation to ensure follow-through and completion
- Tracking systems.
- Detection of recurring Product or Quality anomalies
- Training requirements
- Process Deviation case study