



cGMP Review for QA and QC Personnel

This class reviews Current Good Manufacturing Practices for Quality Assurance and Quality Control personnel. It reinforces the concept that quality is everyone's responsibility and provides them with the tools to maintain compliance. Participants will learn the "why" behind cGMPs and how to apply them to their everyday activities. They will also understand the special role they play during an FDA inspection. Employees will leave with an understanding of their role in assuring compliance in an FDA regulated environment.



Who Should Attend: QA and QC employees

Class Length: half day

Maximum Class Size: 20

Course Prerequisites: cGMP History

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

- What the FDA is and its role in the regulated industries
- The FDA's options for enforcing compliance with regulations
- Where the cGMPs are written and which ones apply to them
- How the relevant cGMPs relate to QA and QC employee's everyday activities
- Examples of how employees can directly affect their facilities, regulatory compliance.
- How the decisions employees make each day can affect the quality of the products they produce
- The roles of the different functional units such as Quality, Manufacturing, etc as defined in the Code of Federal Regulations
- What to expect during an FDA inspection
- The role of the Quality Control unit during an FDA inspection
- How to act during a FDA inspection
- Training requirements