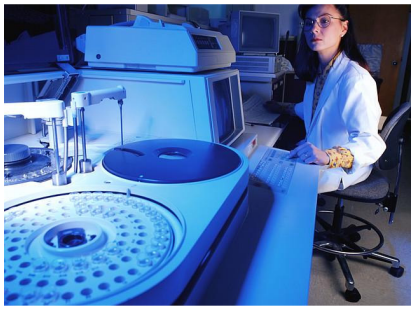
cGMP Basics for QA and QC personnel

This course provides the basic understanding of cGMP's that everyone supporting pharmaceutical manufacturing needs. It reinforces the concept that quality is everyone's responsibility and provides them with the tools to maintain compliance. This course will demonstrate how quality can be controlled and assured for API, pharmaceuticals and other related products. Participants will learn the 'why' behind cGMP's and how to apply its principles to specific situations.



Who Should Attend: laboratory technicians, managers, scientists, and engineers.

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:

- History of cGMP's
- The Code of Federal Regulations, Pharmacopoeias, and Guidance Documents as source information
- Who is the FDA and what power do they have?
- How employees should act during an FDA inspection
- How FDA communicates with the company
- Why FDA considers all products not made by cGMP's to be adulterated
- Roles and responsibilities of Manufacturing, Quality Assurance, Quality Control Employees
- Review the 21 CFR 210 & 211sections that pertain directly to the Quality functions
- Define Control and discuss examples
    - Specifications
    - Sampling
    - Testing
    - Out-Of-Specification results
    - Out-of-Trend results
    - Calibration
    - Standards
    - Laboratory records
    - Documentation practices
    - Computer Data
    - Change Control
    - Deviations
    - Record Review
- Validation of methods and laboratory software
- Requirements for employee training
- The Top Ten Items FDA cites in 483's

VALIDATION & COMPLIANCE INSTITUTE
537 Fort Dearborn St.
Dearborn, MI 48124
734-274-4680