cGMP Basics

This course provides the understanding of cGMP's that everyone supporting manufacturing needs. 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 cGMP's and how to apply its principles to specific situations.

Who Should Attend: production & 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, Management and Employees
- Buildings and facilities
    - Cleaning & maintenance
    - Specialized systems & clean rooms
    - Equipment selection, calibration & maintenance
    - Facility Records
- Manufacturing.
    - Production and process control
    - Holding and distribution
    - Batch Production Records
- Packaging and labeling
- Quality Control and Quality Assurance.
    - Sampling
    - Testing
    - Out-of-Specification results
    - Laboratory records
- Shipping and Receiving.
- Requirements for employee training.
- The Ten Commandments of cGMP's.

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