cGMP's for Dietary Supplements

This course provides the understanding of cGMP's that everyone supporting Dietary Supplement manufacturing needs. This seminar is highly interactive so that participants can understand how the concepts are used in practice. It includes many real life examples that our facilitators have experienced on the job. 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: Two days

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
- Organization and Personnel
    - Roles and responsibilities of Manufacturing, Quality Assurance, Management and Employees
    - Prevention of microbial contamination
    - Personnel qualifications and training
- Buildings and facilities
    - Cleaning & maintenance
    - Design and construction
    - Facility Records
- Procedures. What SOP's do the finalized rules require?
- Equipment
    - selection, design, size, and location
    - calibration & maintenance

    - automatic, mechanical, and electronic
    - Cleaning
- Control of Components, Containers, and Closures
    - Receipt and Storage
    - Testing and approval/rejection
    - Use of approved components, containers, and enclosures
    - Retesting
    - Rejected components, containers, and enclosures
- Production and process control
    - Design requirements
    - Charging components
    - Yield calculation
    - Specifications for in-process and finished product; how to determine if specifications have been met
    - In-process sampling and testing
    - Control of microbiological contamination
    - Reprocessing
- Packaging and Labeling Control
    - Materials usage criteria
    - Label issuance
    - Packaging and labeling operations
    - Inspection
    - Expiration dating
- Holding and distribution
    - Warehousing and Distribution procedures
    - Recalls
- Laboratory Controls
    - Testing and release
    - Stability
    - Special testing requirements
    - Reserve samples
    - What FDA means by 'scientifically valid analytical method'
    - Out-of-Specification results
- Records and Reports
    - Equipment cleaning and use log
    - Component, container, closure, and labeling
    - Master production and control
    - Batch production and control

    - Production record review
    - Laboratory
    - Distribution
    - Customer complaints
    - Document management systems
- Returned and Salvaged Products
- Quality Systems
    - Change management
    - Corrective Action/Preventive Action
    - Deviation control. What FDA means by 'material review'
    - Management review
    - Preventive maintenance
- The Role of the Manager in a cGMP Organization
    - Enforcing standards while leading productivity
    - Cultural transformation

VALIDATION & COMPLIANCE INSTITUTE
835 Asa Gray Dr.
Ann Arbor MI 48105
734-274-4680