cGMP's for Managers and Leaders

Managers play a special role in a cGMP environment. Managers must be prepared to lead employees to high productivity, yet maintain strict compliance with the regulations. This course provides the understanding of cGMP's that managers need to support the development of a compliant system within their organizations. Participants will learn the 'why' behind cGMP's. 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. The seminar reinforces the concept that quality is everyone's responsibility and provides managers with the tools to accomplish the behavior change necessary for compliance.

Who Should Attend: Executives and managers in production & laboratory, team leaders, first line supervisors, scientists, and engineers.

Class Length: three days

Maximum Class Size: 20

Course Prerequisites: None

Course Objectives: At the conclusion of the class participants 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: Form 482, Form 483, Establishment Inspection Report, Warning Letters, Consent Decrees
- 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
    - Personnel qualifications and training.
- Buildings and facilities
    - Cleaning & maintenance
    - Specialized systems & clean rooms
    - Facility Records
- Equipment
    - selection, design, size, and location
    - calibration & maintenance

    - automatic, mechanical, and electronic
    - filters
- 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
    - SOP's, deviations
    - Charging components
    - Yield calculation
    - Equipment identification
    - In-process sampling and testing
    - Time limitations
    - 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
    - Laboratory animals
    - 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
- Introduction to Validation
- Quality Systems
    - Change management
    - Corrective Action/Preventive Action
    - Deviation control
    - Management review
    - Preventive maintenance
- The Role of the Manager in a cGMP Organization
    - Enforcing standards while leading productivity
    - Cultural transformation

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