



cGMP TRAINING



Current Good Manufacturing Practices Overview for Management: Drugs

U.S. FDA Current Good Manufacturing Practices (cGMP)

2 HOURS
Management
Overview



WHO SHOULD ATTEND

- Executives in the pharmaceutical and biotechnology industries
- Non-technical audience
- Managers with no formal training in cGMP

PURPOSE OF THE WORKSHOP

- Provides a compact learning package that enables you to gain a working knowledge of cGMP
- Shows you how to apply cGMP principles
- Simplifies the regulations and helps you understand why you need to comply and what you need to do to comply
- Identifies regulatory expectations
- Shows you how to implement cGMP to avoid surprises in government audits
- Greatly reduces the risk of failing an audit
- Employs interactive Mr. GMP Exercise™
- Answers your questions based on the most current interpretations of the cGMP regulations
- Gives you a participant binder, course certificate, and indexed cGMP pocket booklet. The Blue Book™ will be an indispensable reference for your day-to-day activities in the workplace.

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of cGMP
- Recognize the importance of cGMP compliance
- Understand the role of Quality Control

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cGMP Overview for Management: Drugs ...continued

WHAT YOU WILL LEARN

1. What is cGMP?
 - a. Brief history of cGMP
 - b. Why is cGMP important?
 - c. What are the FDA expectations?
2. Role of Quality Control Unit
 - a. What is SISPQ?
 - b. What are the responsibilities of the Quality Control Unit?
 - c. What does Quality Ownership mean?
3. Personnel and Training
 - a. Qualified personnel
 - b. Job-specific training
 - c. Documentation of training
4. Equipment
 - a. Cleaning requirements
 - b. Calibrate what and when?
 - c. Preventive maintenance
5. FDA Part 11
 - a. Computer security and audit trails
 - b. Electronic records
 - c. Electronic signatures
6. Validation
 - a. What is Validation?
 - b. What types of validation are required?
 - c. How do you perform validation?
7. Sanitation and Hygiene
 - a. Sanitation Program
 - b. How do you prevent contamination?
 - c. Personal hygiene
8. Production and Process Controls
 - a. Why is it important to document Deviations?
 - b. 1/10/100 Rule
 - c. What is Change Control?
9. Packaging and Labeling Control
 - a. What needs to be on a label?
 - b. Identifying product status
 - c. What does 'Quarantined' mean?
10. Laboratory Controls
 - a. Validating your test methods
 - b. What is stability testing?
 - c. What are reserve samples?
11. Procedures
 - a. SOPs
 - b. Regulatory requirements
 - c. How do you control these?
12. Records and Reports
 - a. What is a Record?
 - b. Good Documentation Practices (GDP)
 - c. Common documentation errors