



cGMP TRAINING



Fundamentals of Current Good Manufacturing Practices: Drugs

FDA Parts 11, 210 and 211

1-DAY
Interactive Training
Program



WHO SHOULD ATTEND

- U.S. and Canadian manufacturers and packagers in the pharmaceutical and biotechnology industry
- New employees, those who have production experience with no formal training in cGMP
- Personnel with training who need to stay current with cGMP

PURPOSE OF THE WORKSHOP

- Identifies regulatory expectations
- Shows you how to implement cGMP to avoid surprises in government audits
- Greatly reduces the risk of failing an audit or self-inspection
- Enables you to gain a working knowledge of cGMP in one day
- Shows you how to apply cGMP principles
- Provides a methodical approach to cGMP that simplifies the regulations and helps you understand why you need to comply and what you need to do to comply
- Helps you prepare an action plan for implementing cGMP immediately on your return to the workplace
- Provides documented effectiveness of learning (completed quiz)
- Gives you plenty of practice so you'll leave with proven skills
- Employs interactive exercises, industry-based case studies, hands-on tasks designed to involve and engage the participant
- Emphasizes adult learning principles
- Answers your questions based on the most current interpretations of the cGMP regulations
- Gives you a participant binder, marked quiz, course certificate, indexed cGMP pocket booklet, and The Personal Action Plan™. The Blue Book™ will be an indispensable reference for your day-to-day activities in the workplace.

WORKSHOP OBJECTIVES

- Apply the basic concepts of cGMP
- Understand the importance of cGMP compliance
- Understand and support the role of the Quality Control Unit
- Develop The Personal Action Plan™ to ensure compliance at your company

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Fundamentals of cGMP: 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

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Fundamentals of cGMP: Drugs ...continued



WHAT YOU WILL LEARN (continued)

13. The Production Process

- a. What aspects of cGMP apply to your daily work?
- b. What are some specific cGMP controls?
- c. Consequences of poor controls

14. Audits

- a. What is supporting cGMP evidence?
- b. How to prepare for a successful audit
- c. What do FDA inspectors look for?