



GMP TRAINING



Fundamentals of Good Manufacturing Practices: Drugs

Health Canada HPFBI Good Manufacturing Practices (GMP)

1-DAY
Interactive Training
Program



WHO SHOULD ATTEND

- Fabricators, packagers/labelers, testers in the pharmaceutical and biotechnology industry
- New employees, those who have production experience with no formal training in GMP,
- Personnel with training who need to stay current with GMP

PURPOSE OF THE WORKSHOP

- Provides a compact learning package that enables you to gain a working knowledge of GMP in one day
- Shows you how to apply GMP principles
- Provides a methodical approach to GMP that 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 GMP to avoid surprises in government audits
- Greatly reduces the risk of failing an audit or self-inspection
- Helps you prepare an action plan for implementing GMP 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 (e.g., Mr. GMP Exercise™), 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 GMP regulations
- Gives you a participant binder, marked quiz, course certificate, indexed GMP pocket booklet, and Personal Action Plan™. The Blue Book™ will be an indispensable reference for your day-to-day activities in the workplace.

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Fundamentals of GMP: Drugs ...continued

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of GMP
- Recognize the importance of GMP compliance
- Apply the GMP regulations to the Manufacturing and Distribution Cycles
- Understand the role of Quality Control
- Develop The Personal Action Plan™ to ensure compliance at your company

WHAT YOU WILL LEARN

- 1. What is GMP?**
 - a. Brief history of GMP
 - b. Why are GMPs important?
 - c. What is a DIN?
- 2. Role of Quality (QA/QC)**
 - a. Quality Assurance vs. Quality Control
 - b. What does Quality Ownership mean?
 - c. What is SISPQ?
- 3. Equipment**
 - a. Cleaning requirements
 - b. Calibrate what and when?
 - c. PM programs
- 4. Validation**
 - a. What is Validation?
 - b. What types of validation are required?
 - c. How do you perform validation?
- 5. Sanitation and Hygiene**
 - a. Sanitation Programs
 - b. How do you prevent contamination?
 - c. Personal hygiene
- 6. Labeling**
 - a. What needs to be on a label?
 - b. Identifying product status
 - c. What does 'Quarantined' mean?
- 7. Records and Documentation**
 - a. What is a Record?
 - b. Good Documentation Practices (GDP)
 - c. Common documentation errors
- 8. Procedures**
 - a. SOPs
 - b. Regulatory requirements
 - c. How do you control these?
- 9. Deviations/Change Control**
 - a. Why is it important to document Deviations?
 - b. 1/10/100 Rule
 - c. What is Change Control?
- 10. The Manufacturing Cycle**
 - a. Pre-Manufacturing Activities
 - b. What are some specific GMP controls?
 - c. Consequences of poor controls
- 11. Audits**
 - a. Risk classifications
 - b. How to prepare for a successful audit
 - c. What do Health Canada inspectors look for?