



GMP TRAINING

Drug Good Manufacturing Practices for Importers & Distributors

½ -DAY
Interactive
Training Program



Health Canada HPFBI Good Manufacturing Practices (GMP)



WHO SHOULD ATTEND

- Importers and distributors in the pharmaceutical 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

- Shows you how to implement GMP to avoid surprises in government audits
- Provides a compact learning package that enables you to gain a working knowledge of GMP specific to your activities as an importer and/or distributor
- Shows you how to effectively and efficiently apply GMP principles in your business
- 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
- Greatly reduces the risk of failing an audit or self-inspection
- 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 GMP regulations as they apply to you and your staff
- Gives you a participant binder, marked quiz, course certificate, indexed GMP 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

- Acquire basic knowledge of GMP
- Recognize the importance of GMP compliance
- Handle drug products in compliance with GMP
- Obtain a compliant GMP audit rating

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Drug GMP for Importers and Distributors ...continued

WHAT YOU WILL LEARN

1. What is GMP?
 - a. Why is GMP important?
 - b. Who is the HPFBI?
 - c. What is an EL?
2. Drugs
 - a. What is a DIN?
 - b. What is SISPO?
 - c. What doesn't apply to importers and distributors?
3. What does GMP require?
 - a. Premises
 - b. Equipment
 - c. Personnel
 - d. Sanitation
4. Manufacturing Controls
 - a. Procedures
 - b. Deviations
 - c. Recalls
 - d. Self-inspection
5. Quality Control
 - a. An independent department
 - b. Who is responsible for quality?
 - c. Qualifications
6. Finished Product Testing
 - a. Unique Identifiers
 - b. Testing requirements
 - c. Storage
7. Records and Documentation
 - a. What is a Record?
 - b. Good Documentation Practices (GDP)
 - c. Common documentation errors
8. Sampling and Stability
 - a. Regulatory requirements
 - b. Retention samples
9. Audits
 - a. Risk classifications
 - b. How to prepare for a successful audit
 - c. What do Health Canada inspectors look for?