



# GMP TRAINING



## Drug Good Manufacturing Practices for Wholesalers

### Health Canada HPFBI Good Manufacturing Practices (GMP)

½ -DAY  
Interactive Training  
Program



#### WHO SHOULD ATTEND

- Wholesalers 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
- Greatly reduces the risk of failing an audit or self-inspection
- 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 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™ booklet 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 Wholesalers ...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 wholesalers?
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. Records and Documentation
  - a. What is a Record?
  - b. Good Documentation Practices (GDP)
  - c. Common documentation errors
7. Audits
  - a. Risk classifications
  - b. How to prepare for a successful audit
  - c. What do Health Canada inspectors look for?