



# GMP TRAINING



## Good Manufacturing Practices Overview for Management: Drugs

Health Canada HPFBI Good Manufacturing Practices (GMP)

2 HOURS  
Management Overview



### WHO SHOULD ATTEND

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

### PURPOSE OF THE WORKSHOP

- Provides a compact learning package that enables you to gain a working knowledge of GMP
- Shows you how to apply GMP 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 GMP 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 GMP regulations
- Gives you a participant binder, course certificate, and indexed GMP 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 GMP
- Recognize the importance of GMP compliance
- Understand the role of Quality Control

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## GMP Overview for Management: Drugs ...continued

### WHAT YOU WILL LEARN

1. What is GMP?
  - a. Brief history of GMP
  - b. Why is GMP 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 SISPO?
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?