



GMP TRAINING



Fundamentals of Drug Good Manufacturing Practices: 2009 Update

3 hrs
Overview Training Program



WHO SHOULD ATTEND

- Drug fabricators, packagers/labelers, distributors, importers, wholesalers, and testers of radiopharmaceutical, biological, veterinary, and disinfectant drugs
- Quality personnel with basic GMP training who need to stay current with Health Canada's HPFBI GMP

PURPOSE OF THE WORKSHOP

- Provides a compact learning package enabling you to gain a working knowledge of the changes in the 2009 GMP
- Answers your questions based on the most current interpretations of the GMP regulations
- Fulfills your requirement for on-going GMP training
- Gives you a copy of the Q&C QuickNote™, HPFBI GMP Guidelines, presentation handouts, and an indexed GMP pocket booklet
- 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
- Provides documented effectiveness of learning (completed quiz)
- Employs the interactive Mr. GMP Exercise™ to involve and engage the participant

WORKSHOP OBJECTIVES

- Identify the 2009 changes to the GMP guidelines
- 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

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Fundamentals of Drug GMP: 2009 Update ...continued

WHAT YOU WILL LEARN

1. Overview of the Guidelines

- Industry news
- Regulatory trends and findings
- Regulatory inspection hot topics
- Glossary
- Appendices

2. Changes to the Regulations

- Overview of HPFBI expectations and interpretations
- Quality management
- Premises
- Equipment
- Personnel
- Sanitation
- Raw material testing

2. *Changes to the Regulations (cont'd)*

- Manufacturing control
- Quality control department
- Packaging material testing
- Finished product testing
- Records
- Samples
- Stability
- Sterile products

3. Emerging Regulations – March 2010

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