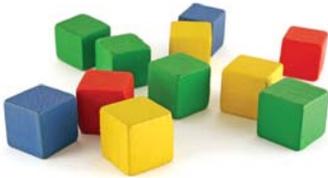




# GMP TRAINING



## Preparing for a Regulatory Inspection: Drugs

Health Canada Good Manufacturing Practices (GMP)  
FDA Current Good Manufacturing Practices (cGMP)

½ -DAY  
Interactive Training  
Program



### WHO SHOULD ATTEND

- Fabricators/manufacturers, packagers/labelers, testers, importers, distributors, and wholesalers in the pharmaceutical and biotechnology industries
- New employees and personnel with or without GMP training

### PURPOSE OF THE WORKSHOP

- As we are experienced auditors and we are often audited by government regulatory bodies, we are in a unique position to offer you a course that:
  - 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 interactive exercises, industry-based case studies, hands-on tasks designed to involve and engage the participant
  - Emphasizes adult learning principles
  - Gives you a participant binder, marked quiz, course certificate, and The Personal Action Plan™

### WORKSHOP OBJECTIVES

- Describe the reasons for regulatory inspections
- Explain the legal basis for inspections
- Discuss the potential outcomes of an inspection
- Distinguish between appropriate and inappropriate behaviors
- Identify proper ways of responding to an auditor's questions

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# GMP TRAINING



## Preparing for a Regulatory Inspection: Drugs ...continued

### WHAT YOU WILL LEARN

1. A close look at the inspection process
  - a. What is the investigator looking for?
  - b. What are the benefits and consequences of inspections?
  - c. What happens during the inspection?
  - d. What can you do to make an inspection go well?
2. Types of inspections (FDA, Health Canada)
3. What are the potential outcomes?
  - a. Observations
  - b. Findings
  - c. Could the government force your product to be withdrawn from the market?
  - d. Border detention
4. Answering an auditor's questions
  - a. What are some of the mistakes people make?
  - b. What will the investigator think?
  - c. How could the company be affected?
  - d. What should a person in your firm do?
5. Inspection "Do" and "Don'ts"
  - a. Proper responses
  - b. Attitude
  - c. What not to say