



GMP TRAINING



Preparing for a Regulatory Inspection

1/2-DAY
Overview Training
Program



WHO SHOULD ATTEND

- Intended for fabricators/manufacturers, packager/labellers, testers, importers, distributors, and wholesalers in the pharmaceutical and biotechnology industry
- Appropriate for new employees and for 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 GMPs 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 behaviours
- Identify proper ways of responding to an auditor's questions

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Preparing for a Regulatory Inspection ...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 - c. Could the government force your product to be withdrawn from the market?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 "Do Nots"
 - a. Proper responses
 - b. Attitude
 - c. What not to say