



GMP TRAINING



Fundamentals of Good Manufacturing Practices

Health Canada HPFBI Good Manufacturing Practices (GMP)

Health Canada NHPD GMP

FDA 21 CFR 111 Current GMP (cGMP)

1-DAY
Drugs, NHPs &
Dietary Supplements
Interactive Training



WHO SHOULD ATTEND

- Fabricators, packagers/labelers, testers in the pharmaceutical, natural health product and dietary supplement industries
- 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

- Provides a compact learning package that enables you to gain a working knowledge of GMP in one day
- Shows you how to apply GMP principles
- 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 drug, NHP and FDA dietary supplement regulatory expectations
- Shows you how to implement GMP to avoid surprises in government audits
- Greatly reduces the risk of failing an audit
- Helps you prepare an action plan for implementing GMP immediately on your return to the workplace
- 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, and Personal Action Plan™
- Gives each participant The Green Book™ which includes the FDA 21 CFR Part 111 regulations and Health Canada NHPD regulations, as well as The Blue Book™ which includes the FDA cGMP, Title 21, Parts 11, 210 and 211 and Health Canada HPFBI GMP. These booklets will be an indispensable reference for your day-to-day activities in the workplace.

9-6975 Meadowvale Town Centre Circle
Suite 410 Mississauga Ontario
L5N 2V7 Canada

TOLL FREE: 1-877-877-5152

PHONE: 905-363-1182

FAX: 905-542-7981

info@qualityandcompliance.com

www.qualityandcompliance.com

www.validapharm.com

www.nhpcompliance.com



GMP TRAINING



Fundamentals of GMP ...continued

Health Canada HPFBI Good Manufacturing Practices (GMP)

Health Canada NHPD GMP

FDA 21 CFR 111 Current GMP (cGMP)

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of GMP
- Recognize the importance of GMP compliance
- Understand the role of Quality Control
- Develop The Personal Action Plan™ to ensure compliance at your company

WHAT YOU WILL LEARN

1. What is GMP/cGMP?
 - a. Brief history of GMP
 - b. Why is GMP/cGMP important?
 - c. What are the basic expectations?
 - d. What regulations are in effect?
2. Natural Health Products
 - a. Health Canada and the NHPD
 - b. NHP Regulations
 - c. Canadian GMP review
3. Dietary Supplements
 - a. 21 CFR 111 FDA cGMP Regulations
 - b. cGMP review
4. Definitions
 - a. Health Canada definitions
 - b. FDA definitions
 - c. SISPO
 - d. Prohibition (21 CFR 21 Part III Subpart A)
5. Comparison of the Canadian and US GMP
 - a. Places
 - b. People
 - c. Process
 - d. Products
6. Places
 - a. Premises
 - b. Equipment
 - c. Personnel
7. People
 - a. Personnel
 - b. Quality assurance
8. Process
 - a. Sanitation program
 - b. Operations
9. Product
 - a. Specifications
 - b. Stability
 - c. Samples
 - d. Records
 - e. Recall reporting
10. Good Documentation Practices
 - a. Requirements
 - b. Errors
 - c. Common documentation mistakes