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

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 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 SISPQ?
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?

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