



GMP TRAINING



Fundamentals of Good Manufacturing Practices (GMP)

1-DAY
Overview Training
Program



WHO SHOULD ATTEND

- Intended for fabricators, packagers/labellers, testers in the pharmaceutical and biotechnology industry
- Appropriate for new employees, for those who have production experience with no formal training in GMPs, and for personnel with training who need to stay current with GMPs

PURPOSE OF THE WORKSHOP

- As we've been working in the compliance field for many years, and are current with the GMP regulations, we've developed a course that:
 - Provides a compact learning package that enables you to gain a working knowledge of GMPs 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 regulatory expectations
 - Shows you how to implement GMPs to avoid surprises in government audits
 - Greatly reduces the risk of failing an audit or self-inspection
 - Helps you prepare an action plan for implementing GMPs 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, indexed GMP pocket booklet, and Personal Action Plan™. The GMP booklet will be an easy 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.nhpcpliance.com



GMP TRAINING



Fundamentals of Good Manufacturing Practices (GMP) ...continued

WORKSHOP OBJECTIVES

- Acquire and apply the basic concepts of GMP
- Recognize the importance of GMP compliance
- Apply the GMP regulations to the Manufacturing and Distribution Cycle
- 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?
 - a. Brief history of GMP
 - b. Why are GMPs 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 programmes
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 Programmes
 - b. How do you prevent contamination?
 - c. Personal hygiene
6. Labelling
 - 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?