

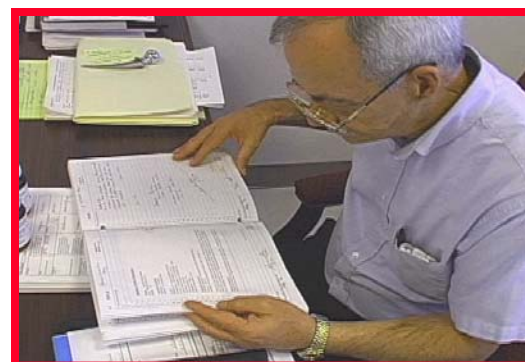
304: GLPs for Manufacturing Supporting Laboratories Pharmaceutical and Biotechnology

(Course length: 4.0 Hours, 60 Graphics, 118 Pages, \$1100)

Purpose: To learn about the role of the laboratory in the testing of raw materials, in-process materials, and finished drug products.

Objectives

1. Cite the regulatory requirement for GLPs
2. State the basic requirements for analysts and chemists in the laboratory
3. Explain the role of quality control
4. List the requirements of laboratory materials handling
5. Explain what we do with analytical results
6. Describe the actions to take when presented with out-of-specification results
7. Explain the process of conducting a deviation investigation
8. Explain what we look for when reviewing a Certificate of Analysis
9. Describe the requirements for laboratory notebooks and the associated review
10. Explain the role of stability and reserve samples
11. Define basic concepts in test method development



Topics and Activities

1. Introduction

- ◆ Preparation
- ◆ Purpose
- ◆ Objectives
- ◆ Agenda
- ◆ *Activity: Opener*

2. Regulatory Requirements

- ◆ 21 CFR 58
- ◆ 21 CFR 211

3. Organization and Personnel

- ◆ The laboratory
- ◆ Personnel qualification

4. Receipt of Materials

- ◆ Regulatory requirements
- ◆ Receiving and storing materials
- ◆ Reagent storage containers

5. Sampling

- ◆ Regulatory requirements
- ◆ Statistical, random and representative sampling
- ◆ Sampling from drums

- ◆ Sample timing and guidelines
- ◆ Sample container identification
- ◆ Composite samples
- ◆ *Activity: Sampling*
- ◆ Sampling plans

6. Analytical Methods

- ◆ Testing concepts
- ◆ Validation
- ◆ Skip lot testing
- ◆ Test method development considerations
- ◆ Test method development flow chart
- ◆ Test method issues

7. Review of Analytical Results

- ◆ Review of analytical results
- ◆ Reviewer's responsibility
- ◆ Testing results
- ◆ Atypical results
- ◆ Out-Of-Specification definition
- ◆ Out-Of-Specification categories
- ◆ When an Out-Of-Specification occurs

- ◆ Laboratory OOS investigations
- ◆ Laboratory supervisors role in the investigation
- ◆ Investigation documentation
- ◆ Written record includes
- ◆ Laboratory errors detected
- ◆ Typical laboratory errors
- ◆ Laboratory errors not detected
- ◆ Re-testing guidelines
- ◆ Re-testing outcomes
- ◆ Re-testing rules
- ◆ Re-sampling
- ◆ Averaging
- ◆ Outlier testing
- ◆ Concluding OOS investigations
- ◆ Laboratory investigations
- ◆ Test outcomes
- ◆ Quality Assurance role in OOS investigations

8. Stability Testing

- ◆ Regulatory requirements
- ◆ Stability sample size
- ◆ Stability chamber
- ◆ Same container closure system
- ◆ Determining expiration date
- ◆ Accelerated stability
- ◆ Reconstitution
- ◆ Documentation

9. Reserve samples

- ◆ Regulatory requirements
- ◆ Reserve sample labeling
- ◆ Retention times

10. Certificate of Analysis

- ◆ Regulatory requirements
- ◆ Purpose
- ◆ What to include in C of A
- ◆ Identity test requirement
- ◆ Laboratory Notebook Practices
- ◆ Regulatory requirements
- ◆ Definitions
- ◆ Proper documentation
- ◆ Computer printouts
- ◆ Raw data
- ◆ Correcting errors
- ◆ Unacceptable habits
- ◆ Data and specimen storage and facilities

11. Facilities and Equipment

- ◆ Standard operating procedures
- ◆ Equipment preventative maintenance
- ◆ Glassware cleaning and storage
- ◆ Waste removal from facilities

12. Wrap Up

- ◆ GMP quiz
- ◆ *Activity: Company problems*
- ◆ *Activity: GMP closer activity*
- ◆ *Activity: Wrap up activity*
- ◆ *Activity: Key learning points activity*