
GLPs for Manufacturing Supporting Laboratories

Purpose

Students learn to apply 21 CFR 211 to the laboratory setting.

Objectives

At the completion of the class, students will be able to:

1. Summarize the content of 21 CFR 58.
2. Relate the GMP subparts to the laboratory environment.
3. Explain the expectations for specific laboratory practice such as; Out-of-Specification investigations, laboratory notebook review, review of analytical results, method development, and sampling and testing
4. State the consequences of not following GMPs in the laboratory.

Prerequisite

Attends should have at least a general understanding of basic CGMPs.

Who should attend this class?

This class is intended for those working in a laboratory that supports manufacturing.

About the class

1. This class uses a teams and competitive to challenge students knowledge of 21CFR211 and to seek new understandings for the GMP rules.
2. The optional final exam is approximately 15 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 4.0 Hours.

Topics Covered

Introduction

1. Preparation
2. Purpose
3. Objectives
4. Agenda
5. *Activity: Opener*

Regulatory Requirements

1. 21 CFR 58
2. 21 CFR 211

Organization and Personnel

1. The laboratory
2. Personnel qualification

Receipt of Materials

1. Regulatory requirements
2. Receiving and storing materials
3. Reagent storage containers

Sampling

1. Regulatory requirements
2. Statistical, random and representative sampling
3. Sampling from drums
4. Sample timing
5. Sampling guidelines
6. Sample container identification
7. Composite samples
8. *Activity: Sampling*
9. Sampling plans

Analytical Methods

1. Testing concepts
2. Validation
3. Skip lot testing
4. Test method development considerations
5. Test method development flow chart
6. Test method issues

Review of Analytical Results

1. Review of analytical results
2. Reviewer's responsibility
3. Testing results
4. Atypical results
5. Out-of-Specification definition
6. Out-of-Specification categories
7. When an Out-of-Specification occurs
8. Laboratory OOS investigations
9. Laboratory supervisor's role in the investigation
10. Investigation documentation
11. Written record includes
12. Laboratory errors detected
13. Typical laboratory errors
14. Laboratory errors not detected
15. Re-testing guidelines
16. Re-testing outcomes

17. Re-testing rules
18. Re-sampling and the courts
19. Re-sampling
20. Averaging and the courts
21. Averaging
22. Outlier testing

Out-of-Specification Investigations

1. Concluding OOS investigations
2. Laboratory investigations
3. Test outcomes
4. Quality Assurance role in OOS investigations

Stability Testing

1. Regulatory requirements
2. Stability sample size
3. Stability chamber
4. Same container closure system
5. Determining expiration date
6. Accelerated stability
7. Reconstitution
8. Documentation

Reserve Samples

1. Regulatory requirements
2. Reserve sample labeling
3. Retention times

Certificate of Analysis

1. Regulatory requirements
2. Purpose of a C of A
3. What's in a C of A
4. Identity test requirement

Laboratory Notebook Practices

1. Regulatory requirements
2. Definitions
3. Proper documentation
4. Computer printouts
5. Raw data
6. Correcting errors
7. Unacceptable habits
8. Data and specimen storage and facilities

Facilities and Equipment

1. Standard operating procedures
2. Equipment preventive maintenance
3. Glassware cleaning and storage
4. Waste removal from facilities

Wrap Up

1. GMP Challenge: GLPs or
2. Inspection Detection: GLPs