

209: Change Control

Pharmaceutical and Biotechnology

(Course length: 1.5 Hours, 3 Graphics, 35 Pages, \$750)

Purpose: The purpose of this program is to learn about the necessity of a change control procedure and the requirements of the system.

Objectives

1. List the components of a change control procedure
2. State the goals of the quality unit review
3. Evaluate whether a change requires pre-market notification or regulatory submission
4. List the documents that may be requested during an inspection



Topics and Activities

1. Introduction and GMP opener activity

2. Regulatory citations

3. What is a change

- ◆ Definition
- ◆ Changes
- ◆ Planned versus unplanned

5. Change control procedures

- ◆ Identification of the change
- ◆ Effective date
- ◆ Responsibility
- ◆ Revision level
- ◆ Validation of changes
- ◆ Validation exceptions
- ◆ Communication
- ◆ Updating documentation
- ◆ Documentation distribution
- ◆ Remedial actions
- ◆ Regulatory submissions
- ◆ Submission not required
- ◆ Business factors
- ◆ Exhibits

6. Quality Assurance

- ◆ QA Review

7. Wrap up

- ◆ Common mistakes
- ◆ Flow chart
- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer activity
- ◆ GMP wrap up activity
- ◆ Change history
- ◆ Printing instructions

8. Glossary