

204: Quality Assurance

Pharmaceutical and Biotechnology

(Course length: 2.0 Hours, 32 Graphics, 49 Pages \$1050)

Purpose: To understand the role of QA in the manufacture of drug products

Objectives

1. Explain the QU role in assuring a CGMP compliant source for raw materials
2. Describe the QU role in receiving materials
3. Explain the QU role in sampling
4. Describe the QU role in inspections
5. Explain the QU role in handling nonconforming materials
6. Describe the QU role in documentation review and archive
7. Explain the QU role in audits and inspections
8. Explain the QU role in recalls



Topics and Activities

1. Introduction and GMP opener activity

2. Introduction

- ◆ Definitions
- ◆ Regulations
- ◆ Roles and direct reports

3. Suppliers and contractors

- ◆ Purpose
- ◆ Outsourcing
- ◆ Outsourcing checklist
- ◆ Activity: *Audit Team*

4. Materials and products

- ◆ Purpose
- ◆ Responsibilities
- ◆ Approves or rejects
- ◆ Incoming materials
- ◆ Materials inspection
- ◆ Material testing
- ◆ Label specification
- ◆ Control of labeling use
- ◆ Non-conforming materials definitions
- ◆ Non conforming materials

5. Investigations

- ◆ Purpose
- ◆ Investigations and reviews
- ◆ Structure of a problem and investigation
- ◆ Investigations must include
- ◆ Returned product investigation
- ◆ Complaint investigations

6. Documentation

- ◆ Standard operating procedures
- ◆ Process control records
- ◆ Document review
- ◆ Signature log
- ◆ Audit
- ◆ Deviation from standards
- ◆ Annual product review
- ◆ Annual product review required content
- ◆ Annual product review recommended content
- ◆ Annual product review reminders
- ◆ Scale up and post approval changes
- ◆ Post approval change analytical testing laboratory site

7. Recall procedure

- ◆ Purpose
- ◆ Product recall strategy
- ◆ Depth of recall
- ◆ Product recall classification

8. Qualstar pharmaceutical case study

9. Wrap up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer and wrap up activities
- ◆ GMP wrap up activity