

204: Quality Management Systems **Medical Devices**

(Course length: 3.5 Hours, 30 Graphics, 96 Pages \$1150)

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

- ◆ CGMP opener activity

2. QSR Introduction

- ◆ Subparts A to O Summary

3. Quality Functions: Materials and Product Release

- ◆ Purpose
- ◆ Responsibilities
- ◆ Incoming materials
- ◆ Materials inspection
- ◆ Materials testing
- ◆ Label specification
- ◆ Control of labeling
- ◆ Non-conforming materials definitions
- ◆ Documentation review
- ◆ Non-conforming materials

3. Documentation and Records

- ◆ Standard operating procedures
- ◆ Process control records
- ◆ Document review
- ◆ Signature logs
- ◆ Deviation from standards
- ◆ Device master record
- ◆ Device history record
- ◆ Quality system record
- ◆ All compliant records
- ◆ Reportable complaint reports
- ◆ Non-conformances and deviations

4. Audits and Supplier Qualification

- ◆ Internal audits
- ◆ Activity: Audit Team
- ◆ Supplier qualification
- ◆ Outsourcing
- ◆ Outsourcing checklist

5. Investigations

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

6. Customer Complaints and Recalls

- ◆ Complaints
- ◆ Complaint procedures
- ◆ Complaint files
- ◆ Requirements for complaint investigations
- ◆ Recalls
- ◆ Purpose
- ◆ Recall strategy
- ◆ Depth of a recall
- ◆ Product recall classifications

7. CAPA and Management Reporting

- ◆ Corrective and preventive actions
- ◆ Management involvement

8. Quality Systems: Summary

- ◆ Qualstar medical device case study