

21 CFR 211 – Good Manufacturing Practice Regulation

Introduction and Overview

- ◆ What are CGMPs

Subpart A General Provisions

Subpart B: Organization and Personnel

- ◆ Suppliers
- ◆ Training
- ◆ Personal Sanitation
- ◆ Consultants and Contractors

Subpart C: Buildings and Facilities

- ◆ Space
- ◆ Lighting
- ◆ HVAC
- ◆ Plumbing and Water
- ◆ Sewage and Refuse
- ◆ Toileting Facilities
- ◆ Cleaning and Maintenance

Subpart D: Equipment

- ◆ Design
- ◆ Construction
- ◆ Cleaning and Maintenance
- ◆ Calibration
- ◆ Filters

Subpart E: Control of Components, Drug Product Containers and Closures

- ◆ Receipt
- ◆ Testing
- ◆ Use
- ◆ Storage
- ◆ Rejected Materials
- ◆ Requirements

Subpart F: Production and Process Controls

- ◆ Charge in
- ◆ Calculation of Yield
- ◆ Equipment Identification
- ◆ Sampling

- ◆ Time Limitations
- ◆ Control of Microbiological Contamination
- ◆ Reprocessing

Subpart G: Packaging and Labeling Control

- ◆ Inspections
- ◆ Issuance
- ◆ Pre-use Inspection
- ◆ Tamper-resistant Packaging
- ◆ Drug Product Inspection
- ◆ Lot Numbers
- ◆ Expiration Dating

Subpart H: Holding and Distribution

- ◆ Storage
- ◆ Inventory Control
- ◆ Environmental Control

Subpart I: Laboratory Controls

- ◆ Testing
- ◆ Specifications
- ◆ Stability Testing
- ◆ Contamination Testing
- ◆ Reserve Sampling
- ◆ Laboratory Animals
- ◆ Penicillin Contamination

Subpart J: Records and Reports

- ◆ General Requirements
- ◆ Logs
- ◆ Traceability
- ◆ Lot Numbers
- ◆ Reconciliation
- ◆ Master Production and Control Record
- ◆ Batch Production and Control Record
- ◆ Production Record Review
- ◆ Laboratory Records
- ◆ Distribution Records
- ◆ Complaint Files

Subpart K: Returned and Salvaged Drug Products

- ◆ Returned Products
- ◆ Salvaging Drug Products
- ◆ Documentation

Summary

- ◆ Do It Right
- ◆ Document It
- ◆ Disclose Errors

Course Length: 35 Minutes includes time to take the final exam.

Times are estimates and vary depending on the speed of taking the course assessments. Quiz questions are presented twice, once for the practice quiz and once for the final exam. Quiz times are estimated at 0.75 minutes for each question. Individual student response times may vary.

Who should take this class? New employees or those who need an introduction to GMPs as it relates to 21 CFR 211, the Current Good Manufacturing Practice. This is also a great review for a quarterly refresher of GMPs

To purchase this program visit our on line shopping cart at:

<http://gallery.bcentral.com/GID5138385DD496508-CBT-Modules.aspx>

or,

Call: (415) 487-3500 to speak to a training consultant.