

Materials and GMPs

Introduction

Regulations

- ◆ Predicate Rule
- ◆ Subpart E

Suppliers

- ◆ Supplier Qualification
- ◆ Audit Areas
- ◆ Periodic Review

Specifications

- ◆ Sources
- ◆ Limits
- ◆ Labels and Labeling

Receipt

- ◆ Incoming Inspection

Material Controls

- ◆ System Purpose
- ◆ Lot Numbers
- ◆ Expiration Dates
- ◆ Re-containerization
- ◆ Location
- ◆ Status
- ◆ Quarantine
- ◆ Rejected
- ◆ Approved
- ◆ Experimental

Sampling

- ◆ Defined
- ◆ Schedule
- ◆ Rules
- ◆ Protecting Samples
- ◆ Documentation

Storage

- ◆ Protect from Adulteration
- ◆ Types of Adulteration

Testing

- ◆ QC Roles
- ◆ Certificate of Analysis

Materials Use

- ◆ Oldest Approved Stock First
- ◆ Charge-in of Components
- ◆ Amount of Active Ingredient
- ◆ On Line Testing

Accountability

- ◆ Calculation of Yield
- ◆ Reconciliation of Components

Wrap Up

Course Length: 74 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 a detailed look at the rules for handling materials from purchase to use and testing.

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