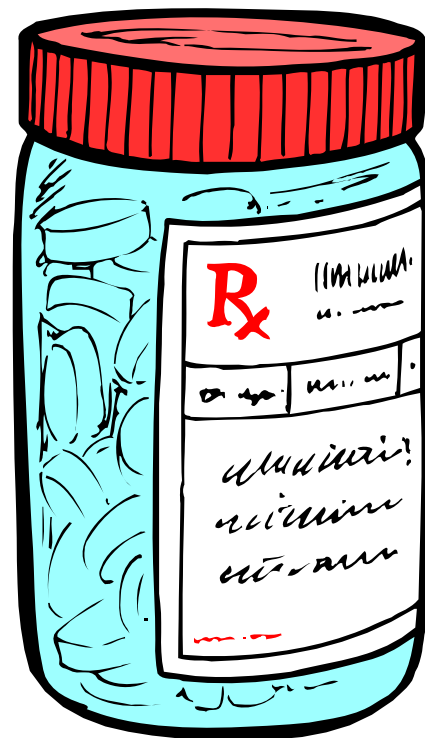


310: Drug Stability
Pharmaceutical and Biotechnology
(Course length: 3.0 Hours, 19 Graphics, 109 Pages, \$1200)

Purpose: To set up a stability program.

Objectives

1. Design a Stability Testing Program for New Drug Substances and New Drug Products
2. Design a Stability Testing Program for New Dosage Forms
3. Design a Stability Testing Program for an Abbreviated New Drug
4. Design a Stability Testing Program for an Investigational New Drug
5. Design a Stability Testing Program for Biotechnological Products
6. Design a Stability Testing Program for Post Approval Changes
7. Design Full and Reduced Stability Studies
8. Evaluate Stability Data
9. Write a Stability Protocol and Report
10. Validate a Stability Chamber



Topics and Activities

1. Introduction

- ◆ Purpose
- ◆ Objectives
- ◆ Agenda
- ◆ Activity: Opener

2. Regulatory Requirements

3. Organization and Personnel

- ◆ The laboratory
- ◆ Personnel qualification

4. Receipt of Materials

- ◆ Regulatory requirements
- ◆ Receiving and storing materials
- ◆ Reagent storage containers

5. Sampling

- ◆ Regulatory requirements
- ◆ Statistical, random and representative sampling

- ◆ Sampling from drums
- ◆ Sample timing
- ◆ Sampling guidelines
- ◆ Sample container identification
- ◆ Composite samples
- ◆ Activity: Sampling
- ◆ Sampling plans

6. Analytical Methods

- ◆ Testing concepts
- ◆ Validation
- ◆ Skip lot testing
- ◆ Test method development considerations
- ◆ Test method development flow chart
- ◆ Test method issues

7. Review of Analytical Results

- ◆ Review of analytical results
- ◆ Reviewer's responsibility
- ◆ Testing results
- ◆ Atypical results
- ◆ Out-of-Specification definition
- ◆ Out-of-Specification categories
- ◆ When an Out-of-Specification occurs
- ◆ Laboratory OOS investigations
- ◆ Laboratory supervisor's role in the investigation
- ◆ Investigation documentation
- ◆ Written record includes
- ◆ Laboratory errors detected
- ◆ Typical laboratory errors
- ◆ Laboratory errors not detected
- ◆ Re-testing guidelines
- ◆ Re-testing outcomes
- ◆ Re-testing rules
- ◆ Resampling and the courts
- ◆ Re-sampling
- ◆ Averaging and the courts
- ◆ Averaging
- ◆ Outlier testing
- ◆ Concluding OOS investigations
- ◆ Laboratory investigations
- ◆ Test outcomes
- ◆ Quality Assurance role in OOS investigations

8. Stability Testing

- ◆ Regulatory requirements
- ◆ Stability sample size
- ◆ Stability chamber
- ◆ Same container closure system
- ◆ Determining expiration date
- ◆ Accelerated stability
- ◆ Reconstitution
- ◆ Documentation

9. Reserve samples

- ◆ Regulatory requirements
- ◆ Reserve sample labeling
- ◆ Retention times

10. Certificate of Analysis

- ◆ Regulatory requirements
- ◆ Purpose
- ◆ What should be included
- ◆ Identity test requirement

11. Laboratory Notebook Practices

- ◆ Regulatory requirements
- ◆ Definitions
- ◆ Proper documentation
- ◆ Computer printouts
- ◆ Raw data
- ◆ Correcting errors
- ◆ Unacceptable habits
- ◆ Data and specimen storage and facilities

12. Facilities and Equipment -

- ◆ Standard operating procedures
- ◆ Equipment preventive maintenance
- ◆ Glassware cleaning and storage
- ◆ Waste removal from facilities

13. Wrap Up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer activity
- ◆ Wrap up activity
- ◆ Key learning points activity