

201: Production and Process Controls

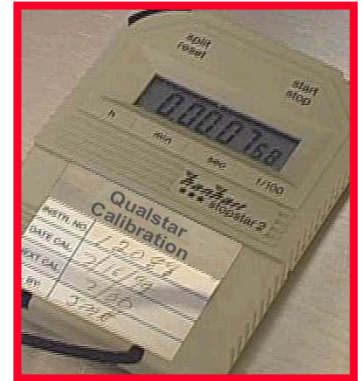
Pharmaceutical and Biotechnology

(Course length: 1.5 Hours, 16 Graphics, 39 Pages, \$600)

Purpose: To learn the methods used to control production processes in compliance with the Good Manufacturing Practices regulations.

Objectives:

1. Describe the role of procedures in production controls
2. Describe the methods of material controls
3. Describe processing controls
4. Explain the use of sampling as a means to control processes
5. Explain the importance of contamination control
6. Explain the requirements and role of documentation of production processes



Topics and Activities

1. Introduction and GMP opener activity

2. Regulations

3. Procedures

- ◆ Identity, strength, quality, and purity
- ◆ Planned deviations
- ◆ Unplanned deviations

4. Materials

- ◆ Weighing of materials
- ◆ Charge-in of active ingredients
- ◆ Amount of active ingredient
- ◆ Calculation of yield
- ◆ Yield values

5. Equipment

- ◆ Identification
- ◆ Processing controls

6. Sampling

- ◆ Statistical, random, or representative
- ◆ Finished product testing
- ◆ In-process testing
- ◆ Control chart action signals
- ◆ Activity: Sampling

7. Processing

- ◆ Time limitations on production
- ◆ On line testing

8. Contamination controls

- ◆ Microbiological contamination

9. Reprocessing and rework

- ◆ Guidelines

10. Documentation

- ◆ Batch records
- ◆ Retention times

11. Wrap up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer activity
- ◆ GMP wrap up activity
- ◆ Change history
- ◆ Printing instructions

12. Glossary