

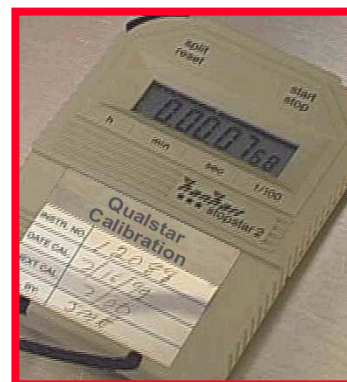
201: Production and Process Controls **Medical Devices**

(Course length: 1.5 Hours, 10 Graphics, 40 Pages, \$600)

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

Objectives:

- Describe the role of procedures in production controls
- Describe how changes in manufacturing are controlled
- List your responsibilities for cleanliness, and contamination control
- Explain the purpose of building and equipment Controls
- Explain the purpose of validating automated systems
- Explain the importance of controlling manufacturing material
- Explain the role of the Device Master Record and Device History Record in manufacturing and QA



Topics and Activities

1. Introduction

- ◆ GMP opener activity

2. Regulations

Subparts F and G

3. Procedures

- ◆ Conformance with specifications
- ◆ Production and process changes
- ◆ Planned deviations and non-conformances
- ◆ Unplanned deviations and non-conformances

4. Personnel and Contamination Controls

5. Buildings, Equipment, and Maintenance

- ◆ General
- ◆ Equipment
- ◆ Processing controls

6. In Process Sampling and Testing

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

7. Automated Processes

- ◆ Validated assembly steps and computer validation

8. Manufacturing Material

- ◆ Control of manufacturing material

9. Reprocessing and rework

- ◆ Guidelines

10. Documentation

- ◆ Work tickets, the DMR and DHR
- ◆ Retention time

11. Wrap-up