

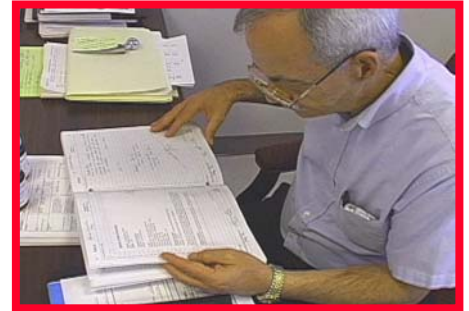
207: Design Control **Medical Devices**

(Course length: 2.0 Hours, 15 Graphics, 57 Pages, \$550)

Purpose: To learn about the role of QC in the support of manufacturing drug products

Objectives

- Describe the purpose and regulatory reasons for design control
- Describe the relationship between change control and design control
- List the elements of the design control process
- List documents that are required to show that design controls are in place



Topics and Activities

1. Introduction

2. Opener activity

3. Why Design Control?

4. Regulations

- ◆ Who has to do design Control?

5. Change Control and Design Control

6. Planning

- ◆ Design and development planning
- ◆ Critical elements

7. Inputs and Outputs

- ◆ Definitions
- ◆ Design input
- ◆ Design input marketing
- ◆ Design input R&D
- ◆ Design input – product developers
- ◆ Design input – incorrect assumptions
- ◆ Design input – requirements
- ◆ Design input – assessment
- ◆ Design output

- ◆ Design output – components

8. Design Review, Verification, Validation

- ◆ Design review
- ◆ Verification
- ◆ Validation
- ◆ Design review
- ◆ Design review intent
- ◆ Design review – procedures
- ◆ Design verification
- ◆ Design verification – definition
- ◆ Design verification – methods
- ◆ Design verification documentation

9. Design validation

- ◆ Design validation – planning
- ◆ Design validation review
- ◆ Design validation method

10. Design Transfer

- ◆ Design transfer
- ◆ Design transfer production specifications

11. Design Changes

- ◆ Design changes
- ◆ Design change elements
- ◆ Documentation control system components
- ◆ Risk assessment
- ◆ Design validation documentation

12. Design history file

- ◆ Documentation

13. Session Closing