

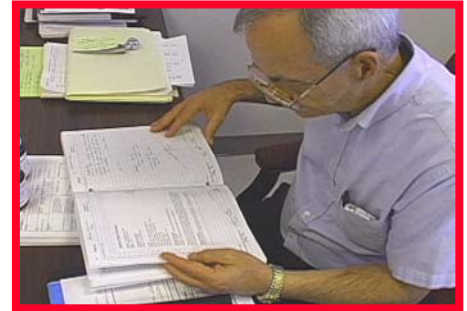
207: Design Control **Medical Devices**

(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

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| <p>1. Introduction</p> <p>2. Opener activity</p> <p>3. Why Design Control?</p> <p>4. Regulations</p> <ul style="list-style-type: none">◆ Who has to do design Control? <p>5. Change Control and Design Control</p> <p>6. Planning</p> <ul style="list-style-type: none">◆ Design and development planning◆ Critical elements <p>7. Inputs and Outputs</p> <ul style="list-style-type: none">◆ 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 | <ul style="list-style-type: none">◆ Design output – components <p>8. Design Review, Verification, Validation</p> <ul style="list-style-type: none">◆ Design review◆ Verification◆ Validation◆ Design review◆ Design review intent◆ Design review – procedures◆ Design verification◆ Design verification – definition◆ Design verification – methods◆ Design verification documentation <p>9. Design validation</p> <ul style="list-style-type: none">◆ Design validation – planning◆ Design validation review◆ Design validation method <p>10. Design Transfer</p> <ul style="list-style-type: none">◆ Design transfer◆ Design transfer production specifications | <p>11. Design Changes</p> <ul style="list-style-type: none">◆ Design changes◆ Design change elements◆ Documentation control system components◆ Risk assessment◆ Design validation documentation <p>12. Design history file</p> <ul style="list-style-type: none">◆ Documentation <p>13. Session Closing</p> |
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