

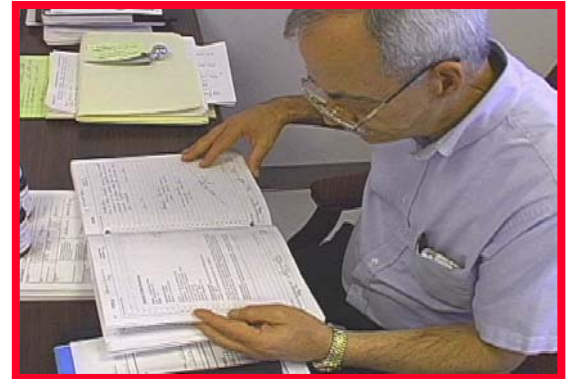
## **205: Quality Control** **Medical Devices**

(Course length: 2.0 Hours, 19 Graphics, 57 Pages, \$600)

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

### **Objectives**

1. Explain the role of quality control
2. Explain what we do with analytical results
3. Describe the actions to take when presented with out-of-specification results
4. Explain the process of conducting a deviation investigation
5. Explain what we look for when reviewing a Certificate of Analysis
6. Describe the requirements for laboratory notebooks and the associated review



### **Topics and Activities**

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| <ol style="list-style-type: none"><li>1. <b>Introduction and GMP opener activity</b></li><li>2. <b>Regulations</b><ul style="list-style-type: none"><li>◆ Subpart H – Acceptance activities</li><li>◆ Establishes control mechanisms</li></ul></li><li>3. <b>Specifications and standards</b><ul style="list-style-type: none"><li>◆ What to check for</li></ul></li><li>4. <b>Sampling plans</b><ul style="list-style-type: none"><li>◆ Choosing a sampling plan</li><li>◆ Steps to using a sampling plan</li><li>◆ Types of sampling plans</li></ul></li><li>5. <b>Testing procedures</b><ul style="list-style-type: none"><li>◆ Requirements</li><li>◆ Testing concepts</li><li>◆ Testing and release for distribution</li></ul></li></ol> | <ol style="list-style-type: none"><li>6. <b>Roles and responsibilities</b><ul style="list-style-type: none"><li>◆ Review of analytical results</li><li>◆ Analytical reviewer responsibility</li></ul></li><li>7. <b>Analytical results</b><ul style="list-style-type: none"><li>◆ When an OOS Occurs</li><li>◆ Average laboratory results</li><li>◆ Test outcomes</li><li>◆ Deviations</li></ul></li><li>8. <b>Investigations</b><ul style="list-style-type: none"><li>◆ Laboratory investigations</li><li>◆ Written records include</li></ul></li><li>9. <b>Certificate of analysis</b><ul style="list-style-type: none"><li>◆ Purpose</li><li>◆ Report content</li></ul></li><li>10. <b>Stability testing</b><ul style="list-style-type: none"><li>◆ Procedural requirements</li><li>◆ Recent citations</li><li>◆ Stability chamber</li><li>◆ Determining expiration date</li><li>◆ Accelerated stability</li><li>◆ Reconstitution</li><li>◆ Documentation</li></ul></li></ol> | <ol style="list-style-type: none"><li>11. <b>Reserve samples</b><ul style="list-style-type: none"><li>◆ Procedural requirements</li><li>◆ Retention times</li></ul></li><li>12. <b>Other types of samples</b><ul style="list-style-type: none"><li>◆ Terminology</li></ul></li><li>13. <b>Documentation</b><ul style="list-style-type: none"><li>◆ Definitions</li><li>◆ Proper documentation</li><li>◆ Computer printouts</li><li>◆ Correcting errors</li><li>◆ Unacceptable habits</li></ul></li><li>14. <b>Wrap up</b><ul style="list-style-type: none"><li>◆ GMP quiz</li><li>◆ Company problems</li><li>◆ GMP closer and wrap up activities</li></ul></li></ol> |
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