

## 205: Quality Control

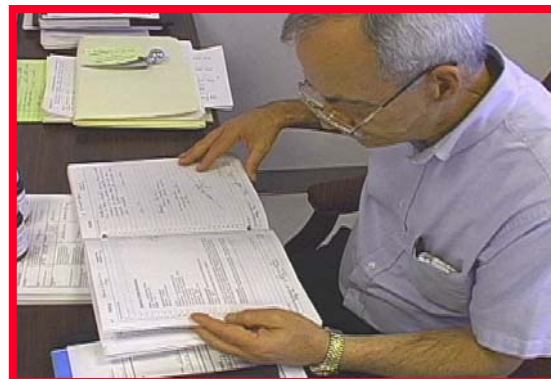
### Pharmaceutical and Biotechnology

(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 I - Laboratory controls</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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