

Quality System Requirements & Industry Practice



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Course Outline - Quality System Requirements & Industry Practice

Day 1

08:00 - 12:00 Instruction (two ten minute breaks)
12:00 - 13:00 Lunch
13:00 - 17:00 Instruction (one twenty minute break)

Topics Covered:

1. Introduction

2. Overview

820.1 Scope
820.3 Definitions

3. Management

820.5 Quality System
820.20 Management Responsibility
820.22 Quality Audit
820.25 Personnel

4. Document Controls & Records

820.40 Document Controls
820.180 General Requirements
820.181 Device Master Record
820.184 Device History Record
820.186 Quality System Record

Case Studies

5. Design Controls

820.30 Design Controls

Day 2

08:00 - 12:00 Instruction (two ten minute breaks)
12:00 - 13:00pm Lunch
13:00 - 17:00pm Instruction (one twenty minute break)

Topics Covered:

5. Design Controls (continued)

820.30 Design Controls

Case Study

6. Acceptance Activities and Purchasing Controls

820.50 Purchasing Controls

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Day 3

08:00 - 12:00 Instruction (two ten minute breaks)
12:00 - 13:00 Lunch
13:00 - 17:00 Instruction (one twenty minute break)

Topics Covered:

6. Acceptance Activities and Purchasing Controls (continued)

820.60 Identification
820.65 Traceability
820.86 Acceptance Status
820.80 Receiving, In-Process and Finished Device Acceptance
820.250 Statistical Techniques

7. Production & Process Controls

820.70 Production and Process Controls
820.75 Process Validation

Case Study

7. Production & Process Controls (continued)

820.72 Inspection, Measuring and Test Equipment

Day 4

08:00 - 12:00 Instruction (two ten minute breaks)
12:00 - 13:00 Lunch
13:00 - 17:00 Instruction (one twenty minute break)

Topics Covered:

7. Production & Process Controls (continued)

820.120 Device Labeling
820.130 Device Packaging
820.140 Handling
820.150 Storage
820.160 Distribution
820.170 Installation

8. Monitoring & Feedback

820.90 Non-Conforming Product
820.100 Corrective & Preventive Action
820.198 Complaint Files
820.200 Servicing

Case Studies Conclusion

Day 5

08:00 - 10:45 Optional Examination