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# The QSR Essentials

## **Purpose**

Employees identify the essential elements of QSR for beginning work in the medical device industry.

**Objectives** At the completion of the class, students will be able to:

1. State the historical development of QSR regulations.
2. Explain the role and function of standard operating procedures.
3. Describe the personal role for contamination control.
4. Identify the sources of contamination.
5. List the common QSR documentation practices.
6. Explain material controls.
7. State the common practices of production and process controls.
8. Explain the importance of an adequate, appropriate, and sufficient building design.
9. State the requirements of equipment design and construction.
10. List the requirements for building, and equipment cleaning and maintenance.
11. Explain the role of the quality management system.
12. Explain the role of the laboratory.

## **Prerequisite**

None

## **About the Class**

1. This class uses group-facilitated discussion, problem solving activities and facilitator instruction to expand current knowledge of QSRs.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 8 hours.

*Learn the basics and have fun!*

## ***The Principles of QSR*** **Topics Covered**

Topics may change slightly and the order may be altered based on the needs of the client or individual instructor's preferences.

### **Past, Present, and Future**

1. Definitions
2. Perspectives 1900-1962
3. From 1962 to the present
4. Into the new millennium

### **Legal Issues**

1. Types of FDA investigations
2. Investigation documentation
3. Basic inspection behavior
4. Enforcement
5. Errors and consequences

### **Personnel Responsibilities**

1. Personnel
2. Management
3. Organization and personnel
4. Training
5. Consultants and contractors

### **Standard Operating Procedures**

1. QA responsibility
2. Writing, formatting and guidelines
3. Revisions and approval
4. Review frequency

### **Contamination**

1. Sources of contamination
2. Personal methods of contamination control
3. Penicillin controls

### **Personal hygiene**

1. Rest rooms and hand washing
2. Clothing to be worn
3. Cleanroom activities

### **Cleaning**

1. Requirements
2. Types of cleaning
3. Refuse and trash

### **Documentation**

1. Completion, checking, and correcting
2. Error descriptions
3. Non-compliant practices
4. Fraud and falsification policy

### **Materials**

1. Supplier qualification
2. Material specifications, controls and identification
3. Sampling
4. Receiving materials
5. Labels and labeling
6. Non-conforming materials

### **Process Control**

1. Identity, strength, quality, and purity
2. Deviations
3. Weighing of materials
4. Charge-in of active ingredients
5. Amount of active ingredient
6. Calculation of yield and values
7. Identification
8. Processing controls
9. Statistical, random, or representative
10. Finished product and in process testing
11. Time limitations on production
12. On line testing
13. Microbiological contamination control
14. Reprocessing
15. Documentation

### **Buildings and Facilities**

1. Design and construction features
2. Sufficient space defined
3. Product, equipment, material flow
4. Designated and defined spaces with examples
5. Environmental rationale
6. Methods and parameters
7. Demonstrated control
8. Penicillin contamination
9. Lighting
10. Air systems
11. Water
12. Facility alarms
13. Waste
14. Housekeeping

### **Equipment**

1. Appropriate and suitable
2. Equipment selection
3. Blue prints of process
4. Control devices
5. Equipment construction materials
6. Lubricants
7. Filters design and specifications
8. HEPA Filters
9. Procedures and training
10. Levels of cleaning
11. Equipment cleaning logs
12. Work orders and repair orders
13. Log requirements and exceptions

**Calibration**

1. Key elements
2. Measurement frequency
3. Timing, standards, and procedure
4. Logs for due dates
5. Consultants and outside firms
6. Out of calibration responsibilities
7. Out of service
8. Calibration documentation

**Laboratory**

1. Subpart I - Laboratory controls
2. Establishes control mechanisms
3. Testing and release for distribution
4. Certificate of analysis
5. When an OOS Occurs
6. Average laboratory results
7. Laboratory investigations
8. Procedural requirements
9. Recent citations
10. Stability chamber
11. Determining expiration date
12. Accelerated stability
13. Reconstitution
14. Procedural requirements
15. Retention times

**Quality Management System**

1. Purpose
2. Responsibilities
3. Incoming materials
4. Materials inspection
5. Materials testing
6. Label specification
7. Control of labeling
8. Non-conforming materials definitions
9. Documentation review
10. Non-conforming materials
11. Standard operating procedures
12. Process control records
13. Document review
14. Signature logs
15. Deviation from standards
16. Device master record
17. Device history record
18. Quality system record
19. All compliant records
20. Reportable complaint reports
21. Non-conformances and deviations
22. Internal audits
23. Activity: Audit Team
24. Supplier qualification
25. Outsourcing
26. Outsourcing checklist
27. Investigations and reviews
28. Structure of a problem and investigation
29. Investigations include
30. Returned product investigations
31. Complaint investigations

32. Complaints
33. Complaint procedures
34. Complaint files
35. Requirements for complaint investigations
36. Purpose
37. Recall strategy
38. Depth of a recall
39. Product recall classifications
40. Corrective and preventive actions
41. Management involvement