

FDA QSR EXECUTIVE OVERVIEW

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FDA QSR (21 CFR 820)



WHAT IS IT AND WHAT DOES IT MEAN?

The FDA QSR Executive Overview module is **ideal** for training executives who work in the medical device industry and who are mandated to implement a quality management system that complies with the Quality System Regulation 21 CFR Part 820. Every organization's management team needs to understand the requirements that pertain to their area of responsibility and authority. Executives need to also understand the QSR's impact on the organization.

The FDA QSR Executive Overview module is designed to provide executives with a basic knowledge and understanding of the Food and Drug Administration's Quality System Regulation (QSR). FDA has placed increased emphasis on top management to take a more active role in ensuring their company's compliance with the Quality System Regulation.

The module discusses the medical device classes and associated regulatory requirements and includes some history regarding Current Good Manufacturing Practice (CGMP) regulation and the current Quality System Regulation (QSR). FDA's Quality System Inspection Technique (QSIT) is also discussed and key terms and definitions associated with implementation and compliance with the regulation are reviewed.

This module helps executives understand the FDA Investigator's approach during a facility inspection by presenting FDA's Management Controls Subsystem Inspection plan and focusing on the subparts essential to Management for ensuring an effective quality management system is established and maintained. Results from FDA's QSIT pilot program are illustrated to show common problem areas.

The module includes a detailed review of the Quality System Requirements and Corrective and Preventive Action subparts, and provides an overview of the remaining sections broken down by company-wide activities and specific department related activities. The module presents the information in simple, easy to understand language.

The FDA QSR Executive Overview module also identifies where procedures are required; where documentation is required; and the various types of FDA enforcement actions inclusive of examples and statistics.

Each module includes a CR ROM of the Adobe Acrobat® formatted presentation, an Instructor's manual, a comprehension exam and a 3-per-page master presentation handout. The instructor's manual is an invaluable resource for anyone responsible for understanding and implementing the QSR requirements and training company executives. Completion of the exam provides a record of training.

Specific Record Requirements

- Device Master Record (DMR)** = How to make the device
- Device History Record (DHR)** – Proof that made the device correctly
- Quality System Record** – Records not specific to a device
- Complaint Files** – Records related to reports of product deficiencies or product performance

FDA Enforcement Activities

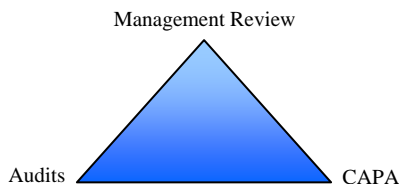
Types of FDA enforcement activities:

- Warning letters and untitled letters
- Seizures
- Injunctions
- Recalls
- Prosecutions/Convictions
- Civil Money Penalties

Course Outline

- Device Classes & Requirements
- CGMP History/QSR Intro
- Why Compliance & Benefits
- QSIT Program & Results
- Key Terms & Definitions
- Specific Management Requirements
 - Quality System Requirements
 - Corrective & Preventive Action
- Company-Wide Requirements
- Department Specific Requirements
- QSR Miscellaneous
- Management's Role
- FDA Enforcement Actions & Statistics
- What to Expect From Investigators

How does Management assure an effective Quality System?



For only \$695 you save the time, money and headache associated with developing an internal training program to meet mandated FDA QSR requirements.

FDA QSR EXECUTIVE OVERVIEW

Process Validation Section 820.75

- Validate processes which cannot be fully verified by subsequent inspection and test
- Establish procedures for monitoring and control of process parameters to ensure continued compliance
- Re-validate process changes as needed

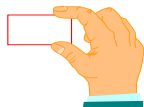


Each presentation page has an Instructor's notes page. (See Figure 1 & 2) Where needed, the notes page further clarifies and/or emphasizes the slide contents and may suggest an example of how a particular requirement may be met. The notes are included in the Instructor's Manual and serve as a train-the-trainer type tool.

Quality Policy

Overall business goals, quality objectives and the quality policy are all interrelated and must work together to achieve business improvement. As a result:

- The quality policy should be documented, communicated and understood by all employees
- The quality policy should provide a framework for reviewing the company's quality objectives
- Objectives must be measurable
- QMS processes must be designed to meet objectives and maintain QMS integrity



Process Validation Notes Pages

Some products are the result of processes that have a unique attribute – the results are not able to be verified through subsequent inspection and testing or deficiencies become apparent only after the product is in use or has been distributed. Also included in this category are those processes that can only be verified by destructive testing. Processes typically requiring validation include: sterilization, welding, soldering, heat-treatment, injection molding, packaging, etc.

These types of processes require qualification of the process, materials, and operators to give confidence in the results – i.e. to show that pre-determined specifications can consistently be met.

Procedures must be developed for validated processes to show how process parameters will be monitored and controlled to ensure that the specified requirements will continue to be met after validation. e.g. mfg sop's, work instructions, etc.

Where appropriate, statistical techniques may be used to control and verify the acceptability of processes.

Revalidation may be necessary if there are changes in the actual process that may affect quality or its validation status; negative trends in quality indicators are observed; there are changes in the product design which affects the process; there is a transfer of processes from one facility to another; there is a change in the application of the process.

Figure 1

Quality Policy Notes Pages

If the organization wants to truly implement an effective quality management system, Executive Management needs ensure quality goals and objectives are relevant to business goals and objectives. Executive Management is responsible for defining the Quality Policy and quality objectives however, the translation of quality objectives into actual methods and procedures, and the implementation of the quality system may be delegated.

- Once defined and documented, Executive Management needs to communicate the policy. They need to find a way to tell everyone in the organization what the policy is and how it affects each of them. Furthermore, management needs to demonstrate their commitment to the policy both visibly and actively on a continuing basis. (e.g. provide resources, training, QP cards, review periodically, customer and employee feedback, etc.)
- The organization's quality policy should provide an overall direction for the company and its quality objectives should follow in that direction. The quality objectives established should include those needed to meet product and customer requirements.
- Quality objectives should be established at all relevant functions and levels within the organization. Objectives need to be measurable and consistent with the quality policy.
- Processes must be designed such that the integrity of the QMS is maintained when changes to the system are planned and implemented.

Figure 2