

FDA QSR EMPLOYEE OVERVIEW

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FDA QSR (21 CFR 820)



The FDA QSR Employee Overview module is **ideal** for training employees who work in the medical device industry and who are responsible for implementing and/or complying with FDA's Quality System Regulation - 21 CFR Part 820.

The FDA QSR Employee Overview module is designed to provide employees with a basic knowledge and understanding of the Food and Drug Administration's Quality System Regulation (QSR) in simple, easy to understand language. It is imperative that employees not only understand their particular job function but also the GMP requirements that pertain to that function. Employees should also understand how their particular job function relates to the overall quality system.

Four Key Themes

Three Distinct Areas:

- Management Responsibilities
- Company-Wide Activities
- Specific Requirements

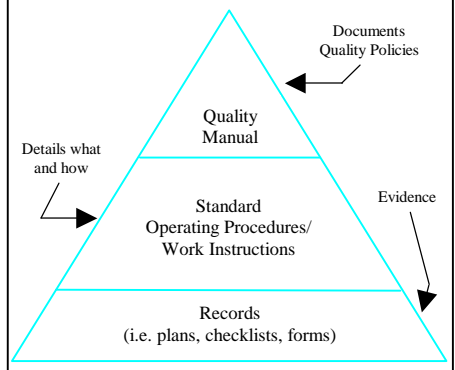
Course Outline

- QSR History/Introduction
- Internal Company Benefits
- Key Terms & Definitions
- QSIT Approach/4 Themes
- Company-Wide Requirements
- Specific Requirements
- Interrelation btw Sections
- Establish & Maintain Procedures
- Where Appropriate
- Your Role
- Concluding Remarks

The module includes an introduction to Current Good Manufacturing Practice (CGMP) history and discusses some key terms cited in the regulation. The benefits associated with implementation and compliance with the regulation are also highlighted.

The module includes an overview of each of the QSR sections broken down into three categories: Management responsibilities, company-wide activities and department or function specific requirements. The inter-relationships between the requirements is also illustrated.

Management Responsibility Outline Documentation Structure



CGMP History

- Manufacturer's establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications.
- The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as CGMP's.
- CGMP= Current Good Manufacturing Practice
- CGMP's were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) as a result of the Medical Device Amendment of 1976.

The FDA QSR Employee Overview module identifies where procedures are required by the regulation and where documentation is appropriate unless justification is given to the contrary.

The module also provides employees with insight as to what they might expect from FDA Inspectors or Auditors and what type of questions might be asked during an inspection or audit of the facility.

Documents vs. Records

Documents:

Quality Manual
Procedures
Work Instructions

Records:

Forms
Reports
Meeting Minutes

For more information, call today!

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