

FDA QSR TRAINING

© 2003 QARA Compliance Connection, Inc.

FDA QSR (21 CFR 820)



WHAT IS IT AND WHAT DOES IT MEAN?

The FDA QSR Training module is a **must** for any organization that manufactures medical devices and is mandated to implement and comply with the Quality System Regulation 21 CFR Part 820. Every organization's management team should be at least knowledgeable of the requirements that pertain to their area of responsibility and authority.

The FDA QSR Training module is designed to provide participants with a knowledge and understanding of the Food and Drug Administration's Quality System Regulation (QSR). The module includes an introduction to Current Good Manufacturing Practice (CGMP) history and discusses some key terms cited in the regulation. The organizational benefits associated with implementation and compliance with the regulation are also highlighted.

Additionally, the Quality System Inspection Technique (QSIT) used by FDA Inspectors during a facility inspection is outlined and results from some facility inspections using this technique are trended to show common areas of non-compliance.

The module includes a detailed review of each of the QSR sections presented in simple, easy to understand language. An interrelationship diagram shows how each of the QSR sections are related.

Wherever the Regulation indicates that procedures need to be established, a procedure needs to be documented. Wherever the QSR indicates "where appropriate", the requirement is appropriate unless you can give justification to the contrary. The FDA QSR Overview module identifies where procedures are required and where documentation is appropriate.

The FDA QSR module also provides some guidance as to what to expect from Auditors and the types of questions that may arise during an inspection/audit.

CGMP History

- Manufacturer's establish and follow quality systems to ensure products consistently meet requirements.
- 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.

Course Objectives



Review:

Current good manufacturing practice (cGMP) history
Key terms and definitions
Quality System Inspection Technique (QSIT)
Quality System Regulation (QSR) Sub-Parts

Key Terms & Definitions

Manufacturer = any person who designs, manufactures, fabricates, assembles, or processes a finished device.

Quality = the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Quality System = the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Course Outline

- QSR History/Introduction
- Terms & Definitions
- Internal Benefits
- QSIT Approach & Stats
- QSR Sections
- Section Interrelationships
- Establish Procedures
- Where Appropriate
- Concluding Remarks
- Audit Expectations
- Typical Auditor Questions

Key Terms & Definitions Notes Pages

Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, re-labeling, re-manufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Quality means a lot of things to a lot of people. It is not just defined by the manufacturer but is also defined by customer needs and expectations. Remember, what may be a desired or unanticipated need today may be a basic or expected need tomorrow. The customer's perception of quality is the single most important factor for market share and profitability.

A quality system is a type of management system where quality is the primary focus. It is the organization's responsibility as a whole to adopt this system of management, not just the QA Department.

**For more information, call today!
Phone: (813) 784-8457**