



QA ✓ RA Compliance Connection, Inc.
presents

FDA QSR Training

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FDA QSR Overview

A Two-Day Comprehensive Review

The FDA QSR?

The FDA Quality System Regulation includes the requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of all finished medical devices intended for human use. The QSR is designed to provide manufacturer's of finished medical devices with a framework of **basic** requirements to use in establishing a quality management system appropriate to the devices designed and manufactured and the manufacturing processes employed. The principles embodied by the regulation have been accepted worldwide as a means of ensuring that acceptable products are produced.

This Course is for you if:

- You manufacture or would like to manufacture medical devices for sale in the U.S. and you need to understand the quality system regulations affecting these devices.
- You are responsible for developing, implementing, maintaining or adhering to a quality management system compliant with the FDA Quality System Regulation.
- You would like to understand the quality system regulation requirements.

COURSE OUTLINE

Introduction

What is CGMP or FDA QSR?

- History
- Scope

Internal Company Benefits

Key Terms and Definitions

QSIT Approach/Technique

QSIT Program Results

In-Depth Requirement Review

Interrelation Between Sections

Establish & Maintain Procedures

Where Appropriate

1998 FDA Statistics

Helpful hints for:

- Procedure Development
- Procedure Formatting
- Process Flowcharting

COST

\$700 per person (5 person min)

\$495 each additional over 5

FDA QSR Executive Overview

A One-Day Primer

The FDA QSR?

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This Course is for you if:

- You manufacture or would like to manufacture medical devices for sale in the U.S. and you need to understand the quality system regulations affecting these devices.
- You are responsible for managing, implementing, and/or adhering to a quality management system compliant with the FDA Quality System Regulation.
- You would like to understand the quality system regulation requirements and their significant impact on your organization.

COURSE OUTLINE

Introduction

What is CGMP or FDA QSR?

- History
- Scope

Internal Company Benefits

Key Terms and Definitions

QSIT Approach/Technique

QSIT Program Results

Four Major Themes

- Management
- Design Controls
- Production & Process Controls
- Corrective & Preventive Action

Company-Wide Activities

Specific Requirements

Interrelation Between Sections

Establish & Maintain Procedures

Where Appropriate

Executive Management's Role

1998 FDA Statistics

COST

\$400 per person (5 person min)

\$350 each additional over 5

FDA QSR Employee Overview

A One-Day Primer

The FDA QSR?

The FDA Quality System Regulation includes the requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of all finished medical devices intended for human use. The QSR is designed to provide manufacturer's of finished medical devices with a framework of **basic** requirements to use in establishing a quality management system appropriate to the devices designed and manufactured and the manufacturing processes employed. The principles embodied by the regulation have been accepted worldwide as a means of ensuring that acceptable products are produced.

This Course is for you if:

- You are responsible for developing, implementing, maintaining or adhering to a quality management system compliant with the FDA Quality System Regulation.
- You would like to understand the quality system regulation requirements.
- You have been asked to become part of the internal audit team and need to understand the Quality System Regulation requirements.

COURSE OUTLINE

Introduction

What is CGMP or FDA QSR?

- History
- Scope

Internal Company Benefits

Key Terms and Definitions

Three Basic Categories

- Management Responsibilities
- Company-Wide Activities
- Specific Requirements

Interrelation Between Sections

Establish & Maintain Procedures

Where Appropriate

What to Expect From Auditors

Generic Auditor Questions

Wrap-Up Video

COST

\$2000 for up to 12 persons

\$250 each additional