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FDA QSR to QMSR: Understanding FDA's New Requirements & Inspection Expectation

Training Brochure

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FDA QSR to QMSR: Understanding FDA's New Requirements & Inspection Expectation

INTRODUCTION

The U.S. FDA has introduced the Quality Management System Regulation (QMSR) to modernize medical device quality system requirements and align them more closely with ISO 13485. This regulatory transition marks a significant shift from the traditional Quality System Regulation (QSR) framework and will directly impact how manufacturers design, implement, and demonstrate compliance during FDA inspections.

This training provides a structured and practical understanding of the QSR-to-QMSR transition, highlighting key regulatory changes, inspection focus areas, and compliance expectations. Participants will gain clarity on what has changed, what remains, and how to prepare their quality systems and organizations for FDA inspections under the new QMSR environment.

COURSE OBJECTIVES

After participating in the training, you will be able to:

- Understand the **regulatory intent and structure** of FDA's Quality Management System Regulation (QMSR).
- Explain the **key differences and alignments** between legacy QSR (21 CFR 820) and QMSR.
- Identify **new and modified FDA requirements** resulting from ISO 13485 incorporation.
- Interpret FDA **inspection expectations under QMSR.**
- Assess the **impact of QMSR on existing quality system processes.**
- Recognize common **inspection risks and compliance gaps** during the transition period.
- Prepare an effective **QMSR transition and inspection readiness strategy.**

COURSE OUTLINE

1. Introduction of US FDA
    - The US Food and Drug Administration (FDA)
    - The Federal Food, Drug, and Cosmetic Act (FD&C Act)
    - The Code of Federal Regulations (CFR)
    - Importance of compliance with US FDA QMSR

2. Quality Management System Regulation
    - Introduction
    - Overall highlight of main changes
    - Summary of key changes
    - QSR vs QMSR section comparison
    - QMSR section by section requirements interpretation

3. FDA inspection
    - Introduction
    - FDA inspection flow

- QSIT (Quality System Inspection Technique)- How FDA traditionally inspected (Pre-February 2026)
- The new QMSR inspection era: What replaced QSIT (Post-February 2026)
- What's changing in QMSR inspection
- Key QMSR requirements with inspection implications
- Expectation and preparation: Pre-inspection & during inspection (do's & don'ts)
- FDA inspection outcome
- Response to FDA observations/ Form 483

4. Executive summary for medical device manufacturer

5. Extra information
   - Gap analysis - Identification of current QSR documentation to be removed & maintained under the new QMSR framework.
   - Gap analysis - FDA QSR vs. FDA QMSR vs. ISO 13485:2016
   - FDA QMSR readiness checklist (For QSR to QMSR transition)

DURATION

Two (2) full days

MODE OF TRAINING

Remote Online Training or Classroom Training

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Introduction of US FDA • The US Food and Drug Administration (FDA) • The Federal Food, Drug, and Cosmetic Act (FD&C Act) • The Code of Federal Regulations (CFR) • Importance of compliance with US FDA QMSR
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Quality Management System Regulation • Introduction • Overall highlight of main changes • Summary of key changes • QSR vs QMSR section comparison • QMSR section by section requirements interpretation

2	9.00 am – 12.30 pm 12.30 pm – 1.45 pm 1.45 pm – 5.15 pm	FDA inspection • Introduction • FDA inspection flow • QSIT (Quality System Inspection Technique)- How FDA traditionally inspected (Pre-February 2026) • The new QMSR inspection era: What replaced QSIT (Post-February 2026) • What's changing in QMSR inspection • Key QMSR requirements with inspection implications Lunch break FDA inspection • Expectation and preparation: Pre-inspection & during inspection (do's & don'ts) • FDA inspection outcome • Response to FDA observations/ Form 483 Executive summary for medical device manufacturer Extra information

CONTACT

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