

Industry Expert Training Series * HRD Corp Claimable Course Scheme

Navigating FDA's Quality Management System Regulation Training Brochure



Navigating FDA's Quality Management System Regulation

INTRODUCTION

The U.S. FDA Quality Management System Regulation (QMSR) represents a fundamental shift from the legacy 21 CFR Part 820 Quality System Regulation (QSR) to a harmonized, ISO 13485-based framework. While QMSR incorporates ISO 13485:2016 by reference, it retains critical U.S. statutory and regulatory requirements, creating both opportunities and compliance risks for medical-device manufacturers.

COURSE OBJECTIVES

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

- Understand the structure, intent, and scope of FDA QMSR.
- Clearly distinguish what changed vs what did not from 21 CFR Part 820.
- Interpret ISO 13485 clauses as enforceable FDA requirements.
- Identify and address QMSR gaps in existing QMS documentation.
- Implement risk-based, lifecycle-oriented compliance.
- Prepare for FDA inspections under QMSR.
- Develop a practical transition and remediation roadmap.

COURSE OUTLINE

Day 1 – Understanding QMSR & Structural Alignment

1. Module 1: FDA QMSR – Regulatory Context & Intent
 - Why FDA moved from QSR to QMSR
 - Harmonization with ISO 13485:2016
 - Legal status of ISO clauses under U.S. law
 - Effective date, enforcement expectations, and transition period
 - Impact on manufacturers vs contract manufacturers
2. Module 2: QMSR Structure & Scope
 - QMSR regulatory framework overview
 - Relationship between: QMSR / ISO 13485:2016
 - FDA statutory requirements
 - FDA's interpretation of "incorporation by reference"
3. Module 3: Clause-by-Clause Mapping – 21 CFR 820 vs. ISO 13485 vs. QMSR
 - Management Responsibility (820.20 vs. ISO 13485 Clause 5)
 - Design Controls (820.30 vs. ISO 13485 Clause 7.3)
 - Purchasing Controls (820.50 vs. ISO 13485 Clause 7.4)
 - Production & Process Controls (820.70 vs. ISO 13485 Clause 7.5)
 - CAPA (820.100 vs. ISO 13485 Clause 8.5)

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4. Module 4: Risk-Based Thinking under QMSR
 - Embedded risk-based approach across QMSR
 - ISO 14971 risk management
 - Process risk (PFMEA)
 - Software risk (CSV / GAMP 5)
 - Risk proportionality in controls and validation

5. Module 5: Documentation & Record Control under QMSR
 - Mandatory documented procedures
 - Records vs. documents under FDA expectations
 - Electronic records, data integrity, audit trails
 - Alignment with 21 CFR Part 11
 - Inspection-ready documentation structures

Day 2 – Implementation, Inspection Readiness & Transition

6. Module 6: Design Controls & Lifecycle Management
 - Design planning, inputs, outputs, verification & validation
 - Design transfer and changes
 - Design history file (DHF) expectations under QMSR
 - Software design & validation alignment

7. Module 7: Production, Process & Supplier Controls
 - Process validation & monitoring
 - Statistical techniques & sampling plans
 - Supplier qualification & monitoring
 - Contract manufacturer oversight under QMSR
 - Change management & revalidation triggers

8. Module 8: CAPA, Complaints & Post market Surveillance
 - CAPA system structure under ISO 13485 & QMSR
 - Complaint handling vs. MDR vs. vigilance
 - Trending, signal detection & escalation
 - Corrections & removals
 - FDA enforcement expectations

9. Module 9: FDA Inspection Readiness under QMSR
 - How FDA investigators will inspect under QMSR
 - Differences from traditional QSIT inspections
 - Inspection focus areas & common pitfalls
 - Inspection defense strategies
 - Responding to FDA 483s under QMSR

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10. Module 10: QMSR Transition & Action Planning

- Gap assessment methodology
- Transition roadmap (QSR to QMSR)
- SOP revision prioritization
- Training & competency updates
- Management review & governance

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	Module 1: FDA QMSR – Regulatory Context & Intent Module 2: QMSR Structure & Scope
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Module 3: Clause-by-Clause Mapping – 21 CFR 820 vs. ISO 13485 vs. QMSR Module 4: Risk-Based Thinking under QMSR Module 5: Documentation & Record Control under QMSR
2	9.00 am – 12.30 pm	Module 6: Design Controls & Lifecycle Management Module 7: Production, Process & Supplier Controls Module 8: CAPA, Complaints & Post market Surveillance
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Module 9: FDA Inspection Readiness under QMSR Module 10: QMSR Transition & Action Planning

CONTACT

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