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ISO 13485:2016 Internal Auditor with FDA QMSR (USA/Canada) — 2026 Update

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COURSE DESCRIPTION

Why now? On Feb 2, 2026, FDA enforced the QMSR, modernizing 21 CFR 820 by incorporating ISO 13485:2016 and ISO 9000:2015 Clause 3. Internal audits must therefore use ISO 13485 clauses as the baseline while verifying the FDA-retained requirements that remain outside ISO—particularly UDI, MDR, Corrections & Removals, and Device Tracking. Terminology matters. The QMSR adopts ISO terminology, consolidating legacy FDA record types (DMR, DHF, DHR) into the ISO-defined Medical Device File (MDF). We show you how to audit MDFs effectively and how to maintain clear cross-references to legacy structures during the transition. Risk and traceability are elevated. Under QMSR, FDA emphasizes risk-based thinking across the entire QMS, not just product design risk. You'll practice auditing a risk-based approach to supplier controls, software validation, CAPA effectiveness, and internal audit planning—plus bidirectional design traceability and production identification/traceability (ISO 13485 §§7.3, 7.5.8, 7.5. What remains uniquely FDA? You'll use actionable checklists to evaluate labeling & packaging controls that FDA retains to strengthen label verification, and you'll learn the updated inspection posture for management review, internal quality audits, and supplier audit records under QMSR. Canada readiness. Finally, you'll align internal audits to ISO 13485 + CMDR and the MDSAP process so your teams are audit-ready for U.S. FDA inspections and Canadian MDSAP AO surveillance.

AUDIENCE PROFILE

- Professionals in the medical device industry across the U.S. and Canadian markets, including:
- Internal auditors seeking to deepen or broaden their auditing expertise
- Quality managers, senior quality personnel, and Quality Management Officers
- Regulatory Affairs and Quality Affairs specialists
- Supplier Quality Engineers and compliance professionals
- Manufacturing, operations, and production leads responsible for quality system execution
- Product Managers and Project Managers involved in device lifecycle and compliance activities
- Medical device manufacturers, operators, and supplier organizations upgrading their audit programs to align with the QMSR baseline for February 2026
- Executives, specialists, and industry professionals aiming to develop or formalize their capabilities as medical device auditors

PREREQUISITES

- Basic knowledge of ISO 13485 is highly recommended for this training course.
- Not sure which ISO 13485 training course you need?

- Progress from ISO 13485 fundamentals to advanced auditing expertise through this comprehensive medical device quality management learning pathway.
- !Medical Device Quality Management Learning Pathway
- Participants begin with an introduction to ISO 13485 and FDA QMSR requirements in the ISO 13485 Quality Management Systems for Medical Device Manufacturers with FDA QMSR (USA/Canada) — 2026 Update \[eg-46-11-26-0019\] training course, gaining a clear understanding of the regulatory and quality management expectations for medical device manufacturers.
- They then advance to implementation techniques with the ISO 13485:2016 – Introduction & Implementation with FDA QMSR (USA/Canada) — 2026 Update \[eg-46-43-26-0001\] training course, learning how to establish, maintain, and improve a compliant Quality Management System that supports product quality, patient safety, and regulatory readiness.
- Once a strong implementation foundation has been established, learners develop practical auditing competencies through the ISO 13485:2016 Internal Auditor \[eg-46-43-26-0051\] course, where they learn to assess QMS effectiveness and drive continual improvement.
- This pathway culminates with the ISO 13485:2016 Lead Auditor Training Program for Medical Devices with FDA QMSR & MDSAP Regulatory Requirements (USA/Canada) — 2026 Update \[eg-46-43-26-0052\], providing the advanced audit leadership skills needed to conduct and lead audits against ISO 13485, FDA QMSR, and MDSAP requirements. This structured progression is ideal for quality professionals, regulatory specialists, implementation teams, internal auditors, and future lead auditors seeking a complete development path from compliance awareness to auditing excellence.

COURSE OBJECTIVES

By the end of this course, participants will be able to:

- Explain the QMSR effective date, its incorporation by reference of ISO 13485:2016 and ISO 9000:2015 Clause 3, and the resulting implications for internal audits.
- Plan, prepare, and conduct internal audits using ISO 13485:2016 as baseline criteria in alignment with ISO 19011:2018.
- Verify FDA-retained requirements, including UDI (830), MDR (803), Corrections & Removals (806), and Device Tracking (821).
- Audit the Medical Device File (MDF) and map legacy DMR/DHF/DHR records into QMSR-aligned documentation structures.
- Assess risk-based controls across the QMS, including supplier management, CAPA effectiveness, and QMS software validation.
- Evaluate design & development traceability (7.3) and production identification/traceability (7.5.8/7.5.9), including UDI data integrity considerations.
- Verify labeling and packaging inspection controls retained under QMSR and understand access expectations for management review, internal audit, and supplier audit records.
- Recognize CMDR and MDSAP requirements and integrate them into internal audits for full North American compliance readiness.

COURSE OUTLINE

Module 1: Day 1 — QMSR Alignment, ISO 13485 Integration & Audit Fundamentals

Regulatory & Normative Framework

- FDA QMSR Overview: effective date, scope, incorporation of ISO 13485:2016 and ISO 9000:2015 Clause 3.
- Implications for internal audits and compliance programs under QMSR.

- Legal and normative foundations: ISO 13485 requirements, key audit-relevant clauses, and comparison with EU expectations.

ISO 19011:2018 & Audit Program Essentials

- Principles of auditing; risk-based audit program planning.
- Audit types, frequency, and planning of internal audits.
- Auditor competence and requirements for internal auditors.
- Sampling strategies and documentation expectations.

Practical Audit Preparation & Execution

- How to prepare audits in a practical, structured way.
- Audit questions, audit procedures, checklists, and documentation.
- Conducting audits: opening meeting, interviewing techniques, communication with auditees, and closing meeting.
- Audit trails for risk-based QMS topics: supplier controls, software validation, CAPA effectiveness.

Documentation Auditing Under QMSR

- MDF vs. DMR, DHF, DHR: how to audit design & production documentation in a QMSR environment.
- Design & production traceability (ISO 13485 7.3, 7.5.8, 7.5.9).
- UDI foundations and their impact on traceability audits.

Module 2: Day 2 — FDA Retained Requirements, Canada Regulations & Applied Audit Skills

FDA-Retained Requirements Under QMSR

- UDI (21 CFR 830), MDR reporting (803), Corrections & Removals (806), Tracking (821).
- Labeling & packaging controls retained by FDA.
- How to audit retained requirements using checklist-driven approaches.
- Access expectations: internal audits, supplier audits, and management review under the QMSR framework.

Canada CMDR & MDSAP Essentials for Internal Auditors

- Canadian licensing, labeling/IFU bilingual requirements, and PMS obligations.
- MDSAP expectations: scope, Audit Objectives (AOs), and practical implications for internal audits.
- Integration of CMDR/MDSAP checkpoints into internal audit programs.

Managing Audit Results & Post-Audit Activities

- Evaluation of audit findings, grading, documentation.
- Determination and tracking of corrective actions.
- Effective follow-up strategies to ensure closure and continuous improvement.

Extensive Workshops, Case Studies & Final Assessment

- Scenario-based case studies covering QMSR, ISO 13485, FDA retained items, and CMDR/MDSAP.
- Role-play exercises: interviewing, evidence gathering, communication challenges.
- Full audit simulation from planning to reporting.
- Final knowledge assessment

DELIVERY NOTE

- Instructor-led virtual classroom format, combining live expert teaching, demonstrations, case studies, group exercises, and guided practice—mirroring the methodology used in TÜV SÜD's accredited programs.
- Participants engage in scenario-based audit simulations to apply ISO 13485:2016 and QMSR requirements to realistic audit situations.
- Interactive sessions include discussions, audit evidence review, traceability walkthroughs, supplier evaluation scenarios, and document-review mini workshops.
- Learners must access the ISO 13485:2016 standard during the course; references are built into exercises and learning materials.
- Course delivered by one of TÜV SÜD's leading industry experts
- Small class sizes enhance trainer-delegate relationship
- Receive globally recognised TÜV SÜD certificate upon completion