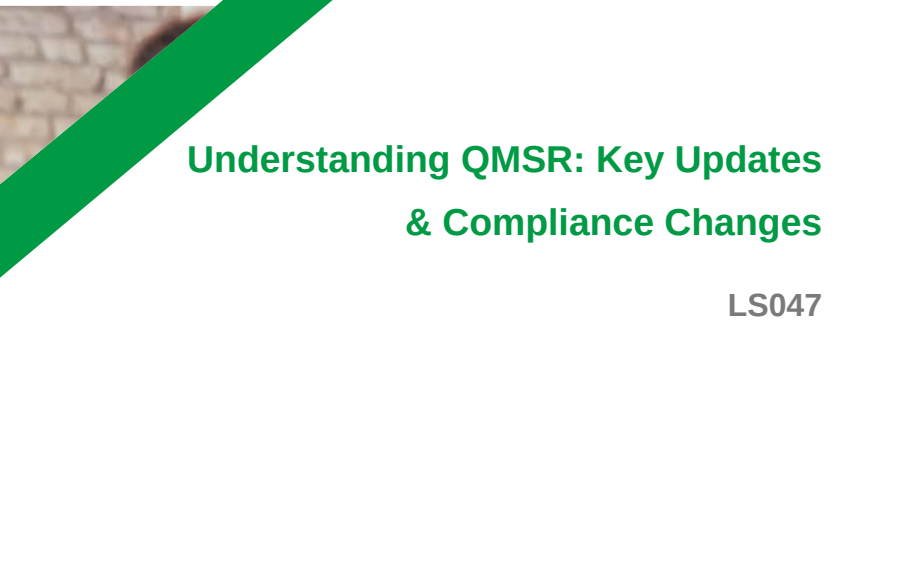
SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY



Understanding QMSR: Key Updates & Compliance Changes

LS047

Understanding QMSR: Key Updates & Compliance Changes

Manufacturers of medical devices intending to market their products in the United States are currently required to comply with the U.S. FDA's 21 CFR Part 820: Quality System Regulation (QSR). Non-compliance with any applicable provision of the QSR renders a device adulterated under Section 501(h) of the Food, Drug, and Cosmetic Act, and may result in regulatory action against both the product and the responsible individuals.

On February 2, 2024, the FDA issued a final rule that replaces the QSR with a new regulation—the Quality Management System Regulation (QMSR)—which harmonises U.S. requirements with ISO 13485:2016. The QMSR will officially come into effect on February 2, 2026. Organisations already certified or aligned with ISO 13485:2016 are expected to experience minimal disruption. However, manufacturers currently operating solely under 21 CFR Part 820 and not aligned with ISO 13485 will be more significantly impacted.

This course provides a detailed overview of the QMSR structure and highlights the key updates and additional requirements beyond ISO 13485:2016. A working knowledge of ISO 13485:2016 is assumed. If further knowledge on the ISO 13485:2016 is required please see more details on ISO 13485:2016 training programme.

Duration & Price

Duration: 0.5 day
Public Virtual Training: €250
Delivery mode: This programme is available In-Company

Dates & Locations

Date	Venue	
15 Sept 2025	Virtual	Book Date
20 Oct 2025	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

- Introduction to the FDA Quality Management System Regulation (QMSR)
- Key QMSR timelines and transition expectations
- Overview of the QMSR structure and layout
- Discussion of individual QMSR elements
- Comparison of QMSR with ISO 13485:2016:
    - What's new under QMSR
    - How QMSR requirements fit within an ISO 13485:2016-compliant system

As further updates are released by the FDA (including a revised QSIT guide and compliance communications), the course content will be refreshed accordingly to reflect current guidance.

Who should participate?

This course is ideal for all personnel involved in the development, implementation, and maintenance of Quality Management Systems, including:

- Quality Professionals
- Regulatory Affairs Personnel
- Engineers
- Internal Auditors
- QMS Implementation Leads

What will I learn?

Participants achieve the following learning outcomes from the programme:

- A clear understanding of the layout, structure, and key timelines of the QMSR
- Insight into the new requirements introduced by QMSR
- The ability to begin planning their organisation's transition strategy from QSR to QMSR
- A practical understanding of how QMSR fits into an ISO 13485:2016 quality framework

As more information and documents are released by FDA e.g. updated QSIT document, this course will be updated accordingly.

What are the entry requirements?

It is advised that participants have some knowledge of ISO 13485:2016 when attending this course. If further knowledge on ISO 13485 is required, please see our the ISO 13485 training programme.

How do we train and support you?

In-House Courses

Course tutor will contact your organisation in advance. In-house courses can be customised to meet your organisation's specific requirements.

Course Manual

Delegates will receive a very comprehensive course manual.

Tutors

John Lafferty
View Profile

Kevina O’Donoghue
View Profile

What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.

Click Here

SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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