

## QMSR Transition Training Adapting to the New FDA Regulation

Rev.1

Half-day seminar | 09:15-13:00 | 4.5 academic hours

**Location:** Gsap Training Facilities, Haifa MTAM

**Trainer:** Dr. Sivan Luder

*Including Certificate of Completion*

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### Training Introduction

This training provides a comprehensive overview of the U.S. FDA's new Quality Management System Regulation (QMSR), which replaces the existing Quality System Regulation (21 CFR Part 820) and incorporates ISO 13485:2016 by reference. The course explains the regulatory background, structure, and intent behind the QMSR, including its alignment with international quality standards.

Participants will learn how the regulation impacts core QMS elements such as design controls, supplier management, and risk-based processes. The course will highlight both harmonized ISO clauses and unique FDA requirements.

By the end of the course, attendees will be equipped with the knowledge and tools to assess their current QMS, identify required updates, and plan a smooth and compliant transition to QMSR by the 2026 deadline.

### How will I benefit?

- Understand the full scope and implications of the QMSR final rule
- Learn to conduct a gap analysis between QSR, ISO 13485, and QMSR
- Gain practical tools for updating SOPs, forms, and quality documentation
- Receive guidance on integrating risk management throughout your QMS
- Prepare for FDA inspections under the QMSR framework
- Reduce duplicate regulatory efforts across markets

### Who Should Attend

Professionals working in the medical device industry including Quality, Regulatory, R&D, Manufacturing, Engineering, and Clinical teams.

## Basic Requirements

- No prior knowledge is required. However, familiarity with ISO 13485 and ISO 14971 is a significant advantage, as it will enhance comprehension and engagement with the training content.
- For those unfamiliar with these standards, follow-up learning can be completed afterward to reinforce understanding and fully benefit from the QMSR transition training. (Ask us about completion training sessions)

## Training Agenda and Syllabus

Module	Details
<b>Introduction &amp; Background</b>	Brief history of 21 CFR Part 820 and rationale for transitioning to QMSR;
<b>What is QMSR?</b>	Overview of the QMSR Final Rule (Feb 2024), incorporation by reference of ISO 13485,
<b>ISO 13485:2016 Essentials</b>	Overview of ISO 13485:2016 Explanation of ISO 13485 clauses relevant to QMSR, including risk management, product realization, training, and design
<b>Key Differences: QSR vs. QMSR</b>	Side-by-side breakdown of terminology, risk integration, and documentation
<b>FDA-Specific Requirements Beyond ISO</b>	Review of FDA-specific requirements and their integration into QMSR (UDI, tracking, AE reporting, complaints)
<b>Scenario-Based Transition Planning</b>	Case-based analysis of 3 scenarios: QSR only, ISO only, both compliant; step-by-step transition actions
<b>Implementation Roadmap</b>	How to build a QMSR transition plan, assign responsibilities, update SOPs, perform audits, and train staff
<b>Preparing for FDA Inspections</b>	What to expect in an FDA inspection post-QMSR, how to document compliance, CAPA alignment
<b>Q&amp;A / Case Discussion</b>	Open Q&A, lessons learned from mock audits, and previous transitions



### Meet the Trainer: Dr. Sivan Luder

Regulatory, Clinical, and Quality Expert with a PhD in Molecular Biology and over 12 years of experience across various industries, with a strong focus on the medical device sector.

Possesses a deep scientific background and extensive experience in leading the development and implementation of medical devices from concept to commercialization, managing regulatory projects, and preparing international submissions. Skilled in establishing, implementing, and maintaining Quality Management Systems (QMS) and in preparing for and supporting audits, with a proven track record of leading and successfully managing QMS and ISO 13485 and MDSAP audits.



**Contact today to secure your place**

