Webinar Overview

In February 2024, the FDA introduced new Quality Management System (QMS) regulations that closely align with ISO 13485:2016. This change is part of the FDA's transition from the current Quality System Regulations (QSR), which have been in place since 1978, to a more globally recognized and consistent framework. As manufacturers, it's essential to understand the changes and plan your transition strategy to remain compliant by February 2026.

Key Webinar Insights

1. **Regulatory History and Transition to QMSR**
    a. Before 1978, medical devices were regulated under pharmaceutical rules. The FDA introduced medical device-specific amendments in 1976, leading to the creation of the first Quality System Regulations (QSR) in 1978.
    b. In 1996, the FDA updated these regulations to include design control requirements, aligning with ISO 9001 and ISO 13485.
    c. The latest update in February 2024 incorporates the ISO 13485:2016 standard into the FDA's regulations, marking a significant shift towards global alignment.
2. **Key Changes in the FDA QMSR:**
    a. The FDA's new QMSR applies to manufacturers involved in the design, manufacturing, packaging, labeling, storage, installation, or servicing of finished medical devices.
    b. The regulations now call for compliance with ISO 13485, but manufacturers are not required to be certified in ISO 13485—compliance is sufficient for FDA regulations.
    c. The new rules simplify the structure of the regulations, focusing on key areas like medical device reporting, corrections, removals, and unique device identification.

Quality System Regulations (QSR) (obsolete 2 Feb 2026)	Quality Management System Regulations (QSR) (effective 2 Feb 2026)
Subpart A: General provisions (CFR 820.1 – 820.5)	Subpart A: General Provisions (CFR 820.1 – 820.10) **(QMSR)** ISO 13485:2016 Clause 1, Clause 3, Clause 4 ISO 9000:2015 Clause 3
Subpart B: Quality system requirements (820.20)	ISO 13485:2016 Clause 4, Clause 5, Clause 6, Clause 8
Subpart C: Design controls (820.30)	ISO 13485:2016 Clause 7
Subpart D: Document controls (820.40)	ISO 13485:2016 Clause 4 Subpart B: Supplemental Provisions (CFR 820.35) **(QMSR)**
Subpart E: Purchasing controls (820.50)	ISO 13485:2016 Clause 7
Subpart F: Identification and traceability (820.60)	ISO 13485:2016 Clause 7
Subpart G: Production and process controls (820.70)	ISO 13485:2016 Clause 4, Clause 6, Clause 7
Subpart H: Acceptance activities (820.80)	ISO 13485:2016 Clause 7, Clause 8
Subpart I: Nonconforming product (820.90)	ISO 13485:2016 Clause 8
Subpart J: Corrective and preventive action (820.100)	ISO 13485:2016 Clause 8
Subpart K: Labeling and packaging control (820.120 - 820.130)	ISO 13485:2016 Clause 7 Subpart B: Supplemental Provisions (CFR 820.45) **(QMSR)**
Subpart L: Handling, storage, distribution, and installation (820.140 – 820.170)	ISO 13485:2016 Clause 7
Subpart M: Records (820.180 – 820.198))	ISO 13485:2016 Clause 4 Subpart B: Supplemental Provisions (CFR 820.35) **(QMSR)**
Subpart N: Servicing (820.200)	ISO 13485:2016 Clause 7 Subpart B: Supplemental Provisions (CFR 820.35) **(QMSR)**
Subpart O: Statistical techniques (820.250)	ISO 13485:2016 Clause 7, Clause 8

3. **Scope and Definitions:**
    a. The QMSR applies to finished medical devices for human use and specific products such as human cells, tissues, and cellular/tissue-based products. It does not apply to manufacturers of device components or blood products.
    b. The FDA has adopted definitions from ISO 13485 and ISO 9000:2015 to ensure consistency in terms of quality management.
4. **Risk Management and Post-Market Surveillance:**
    a. Emphasis has shifted towards integrating risk management into all stages of product design, with more specific requirements for handling design changes and post-market surveillance.
    b. Post-market surveillance now involves assessing risks based on collected information from complaints and product modifications, ensuring ongoing safety and compliance.
5. **Key Compliance Areas:**
    a. **Design Control**: Manufacturers must ensure their design processes are compliant with ISO 13485 and FDA requirements.
    b. **Record Control**: Documentation requirements have been enhanced, with additional stipulations on complaint handling and product labeling and packaging controls.

c. **FDA Inspections**: The FDA's authority to inspect and review records has expanded under the new QMSR, including management reviews and internal audit records, which were previously excluded from inspection.

6. **Challenges and Solutions for Transition:**
    a. The transition to QMSR will require thorough gap analysis, updates to procedures, and additional training. Companies should start preparing today to meet the February 2026 deadline.
    b. Key areas to focus on include updating your quality system documentation, ensuring that design controls are aligned with ISO 13485, and conducting internal audits to verify compliance.

Next Steps for Manufacturers:

- **Review the QMSR Regulations**: Start by reading the full QMSR regulations and the preamble published by the FDA. This will help you understand the FDA's rationale and the changes you need to implement.
- **Conduct a Gap Assessment**: Compare your current quality management system against the ISO 13485:2016 requirements to identify any gaps that need to be addressed.
- **Update Procedures**: Based on the gap assessment, update your quality system documentation and develop new procedures where necessary.
- **Training and Internal Audits**: Ensure your team is well-informed about the changes. We recommend conducting an internal audit and bringing in external auditors for impartiality.
- **Stay Informed**: Regularly check the FDA's website and our company blog for updates and additional guidance on the transition.

Q&A Highlights

During the Q&A session, several important questions were raised and addressed, including:

1. **Will the FDA provide formal guidance on integrating ISO 13485 into U.S. regulations?**
    a. Yes, the FDA will continue to provide guidance as manufacturers transition to the new regulations. Stay updated by checking the FDA's resources on their website.
2. **How does the increased emphasis on risk management affect post-market surveillance?**

    a. Risk management is now integral to post-market surveillance, as manufacturers must continuously assess and manage the risks associated with their devices even after they've been released to the market.

3. **What are the potential consequences of not transitioning to QMSR by the deadline?**
    a. Manufacturers who do not transition to QMSR by the February 2026 deadline risk non-compliance, which could result in FDA inspection findings, warning letters, or issues with device submissions (e.g., 510(k) or PMA).

Additional Resources:

- For further information and resources on FDA compliance, please visit our website here.