U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Quality Management System Regulation (QMSR):
Key Takeaways

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Quality Management System Regulation (QMSR): Key Takeaways

Panelists

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Today's Discussion Topics

- Overview of Quality Management System Regulation (8/30/24); www.youtube.com/watch?v=Na-OF3OkqEg
- Navigating the Quality Management System Regulation (8/30/24); www.youtube.com/watch?v=CMnJw6G4hKo

QMSR Key Takeaways

- **Final Rule issued amends the Quality System regulation**
  - www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments

- **QMSR:**
  - Aligns with the international consensus standard for devices
  - Becomes effective February 2, 2026
  - Incorporates by Reference
    - **ISO 13485: 2016 (E)**
    - **Clause 3 of ISO 9000:2015(E)**

ISO = International Standards Organization

QMSR Key Takeaways

- **Final Rule includes a hierarchy of definitions**
  - QMSR definitions and certain terms defined in other FDA regulations supersede those in ISO 13485 and Clause 3 of ISO 9000
- **FDA will revise or develop relevant policies, procedures, inspection process and other documents impacted by this rulemaking**
  - Compliance Programs
  - Guidance Documents
  - Standard Operating Procedures, Work Instructions
  - Templates

QMSR Key Takeaways

- **QMSR applies to:**
  - All finished devices intended for human use
  - Manufacturers performing certain functions, including contract sterilization, installation, relabeling, and specification development

QMSR Key Takeaways

- **The key requirements of the QMSR are included in 6 Sections**
  - 820.1: Scope
  - 820.3: Definitions
  - 820.7: Incorporation by reference
  - 820.10: Requirements for a quality management system
  - 820.35: Control of records
  - 820.45: Device labeling and packaging controls

QMSR Key Takeaways

- **The scope of the QMSR addresses:**
  - The applicability of the QMSR
  - Conflicts with other requirements under the FD&C Act
  - Foreign Manufacturers
  - Exemptions or Variances

QMSR Key Takeaways

- **The scope of the QMSR:**
  - Governs methods used in, and facilities and controls used for all finished devices intended for humans

Activities	
Design	Manufacture
Packaging	Labeling
Storage	Installation
Servicing	

QMSR Key Takeaways

Purpose of QMSR:

Ensure ability to consistently manufacture devices that meet applicable requirements and specifications

Provide a framework for achieving quality

Assure that finished devices will be safe and effective

Assure that finished devices comply with FD&C Act

QMSR Key Takeaways

820.10 Requirements for a quality management system

- **Specifies requirements for:**
  - Documenting a quality management system
  - Complying with other applicable regulatory requirements:

21 CFR Part	Title
830	Unique Device Identification (UDI)
821	Medical Device Tracking Requirements
803	Medical Device Reporting
806	Medical Devices; Reports of Corrections and Removals

QMSR Key Takeaways

820.10 Requirements for a quality management system

- **Specifies requirements for:**
  - Complying with Design and Development requirements of Clause 7.3 in ISO 13485:2016
  - Complying with requirements in Traceability for Implantable devices, Clause 7.5.9.2 in ISO 13485:2016
- **Specifies that:**
  - That an adulterated device, as well as the person responsible for the adulteration, is subject to regulatory action

QMSR Key Takeaways

- **Additional requirements for:**
  - Control of records, ISO 13485, Clause 4.2.5
    - 820.35, Control of records
  - Control of production and service provision, ISO 13485, Clause 7.5.1
    - 820.45, Device labelling and packaging controls

Related Modules

- Quality Management System Regulation (QMSR) – Risk Management, Risk Based Approach, and Risk-Based Decisions (09/30/25); www.youtube.com/watch?v=QFNSAlfJaic
- Quality Management System Regulation (QMSR) – Design and Development (09/30/25); www.youtube.com/watch?v=btjL5Czsfyo


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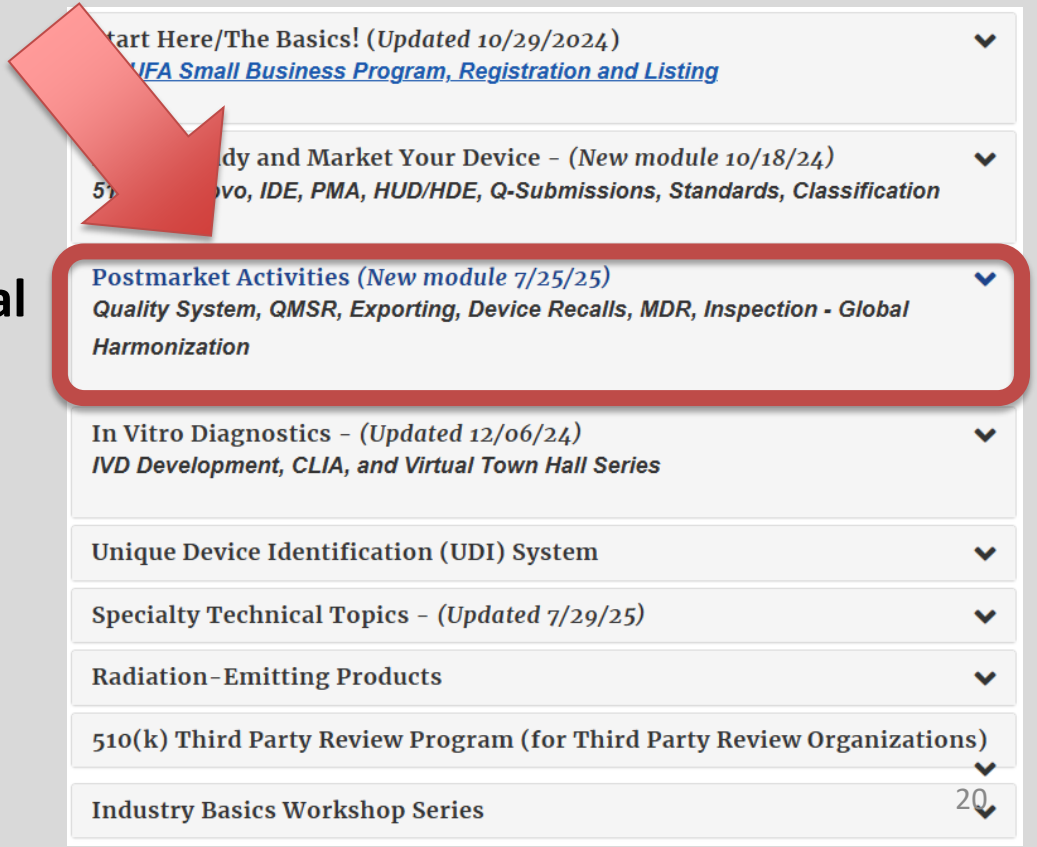
Panel Discussion

Closing Remarks

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Specific questions about the final rule**
  - Email: QMSR-Rule@fda.hhs.gov
- **General regulatory questions**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHEvents

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