U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Event

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

Today's Topic:
Quality Management System Regulation (QMSR):
Risk & Design and Development

January 14, 2026

U.S. FOOD & DRUG ADMINISTRATION

Quality Management System Regulation (QMSR): Risk & Design and Development

Panelists

Keisha Thomas
Associate Director for Compliance & Quality
Compliance and Quality Immediate Office
Office of Product Evaluation and Quality

Karen Masley-Joseph
Senior Advisor
Office of Medical Devices & Radiological Health
Inspectorate
Office of Inspections and Investigations

Tonya Wilbon
Assistant Director for Postmarket Industry
Education and Consumer Education
Division of Industry and Consumer Education

CAPT Kimberly Lewandowski-Walker
Regulatory Officer
FDA Inspections and Regulatory Audits Team
Office of Regulatory Programs
Office of Product Evaluations and Quality

U.S. Food and Drug Administration

Tonya Wilbon
Assistant Director for Postmarket Industry
Education and Consumer Education
Division of Industry and Consumer Education

Today's Discussion Topics

- 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

Discussion Topics

- **December 16, 2025 CDRH Webinar addressed:**
  - QMSR Key Takeaways:
    - Overview of Quality Management System Regulation
    - Navigating the Quality Management System Regulation

QMSR Risk & Design and Development

- **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

Key Risk Terms

- ***Risk***: combination of the probability of occurrence of harm and the severity of that harm

- ***Risk management:*** systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

ANSI/AAMI/ISO 13485:2016; SOURCE: ISO 14971:2007

Key Risk Terms

- **Risk-based approach:** identifying risks and opportunities and focusing on preventing or reducing undesired effects

- **Risk-based decision:** making a specific decision based on risk assessment and other criteria

ANSI/AAMI/ISO 13485:2016; Medical Device, A Practical Guide

QMSR Risk & Design and Development

- **Role of Risk Management**
  - Identifies, assesses, controls, communicates and reviews device risks to the quality management system processes

QMSR Risk & Design and Development

- Provide a framework for sound decision making-within a quality management system; for example:
  - Identifying design outputs that are essential for the proper functioning of the device
  - Continually updating based on postmarket surveillance data
  - Defining the extent of verification activities for purchased product
  - Defining the approach to quality management system software validation, or revalidation activities, in proportion to the risk associated with the use of the software

QMSR Risk & Design and Development

- Quality Culture: FDA Response to Comment 27

- "...FDA expects medical device manufacturers, led by individuals with executive responsibilities, to embrace a culture of quality as a key component in ensuring the manufacture of safe and effective medical devices..."

- "A culture of quality meets regulatory requirements through a set of *behaviors, attitudes, activities ,and processes."*

QMSR Risk & Design and Development

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	Title
Clause 4.1	General Requirements
Clause 6.2	Human Resources (NOTE, *for guidance and understanding*)
Clause 7.1	Planning of product realization
Clause 7.3	Design and Development
Clause 7.4	Purchasing

QMSR Risk & Design and Development

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	Title
Clause 7.5	Production and service provision
Clause 7.6	Control of monitoring and measuring equipment
Clause 8.2	Monitoring and Measurement
Clause 8.3	Control of nonconforming product
Clause 8.5	Improvement

Examples: Risk Documentation

EXAMPLES OF RISK DOCUMENTATION
Risk Management Plan: used at the start of product development
Risk Analysis Report: used during design & development
Risk Evaluation Summary: used during post-analysis, before mitigation
Risk Traceability Matrix: used after completing the previous documents to ensure risks are mitigated, where appropriate; continue to update throughout the device lifecycle
Risk Management File (RMF): maintained throughout device lifecycle
Design Review Meeting Minutes: used during formal design reviews
Benefit-Risk Analysis Report: used when residual risks remain after controls

QMSR Risk & Design and Development

- **Design and Development**
  - A set of *processes* that transform *requirements* for an object into more detailed requirements for that object.
  - The terms “design” and “development” and “design and development” are sometimes synonymous and used interchangeably.

QMSR Risk & Design and Development

- Design and Development is important to medical device quality and safety
- Organizations must maintain a design and development file for each medical device type or medical device family

21 CFR 820.10 (c)
Design and Development

QMSR Design and Development requirements apply to manufacturers of:

- *All* **Class II** and **Class III** medical devices
- AND these **Class I** medical devices:
  - Devices automated with computer software
  - Tracheobronchial suction catheters
  - Non-powdered Surgeon's gloves
  - Protective restraints
  - Manual radionuclide applicator system
  - Radionuclide teletherapy source

QMSR Risk & Design and Development

- Begin Design and Development:
  - When research is ending
  - After Feasibility/“Proof of Concept”
  - Prior to start of clinical evaluation

Design and Development Stages

- Planning
- Input
- Output
- Review
- Verification
- Validation
- Transfer
- Changes

QMSR Risk & Design and Development

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	Title
Clause 7.1	Planning of product realization
Clause 7.3.1 and 7.3.2	General and Design and development planning
Clause 7.3.3	Design and development inputs
Clause 7.3.4	Design and development outputs
Clause 7.3.5	Design and development review

QMSR Risk & Design and Development

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	Title
Clause 7.3.6	Design and development verification
Clause 7.3.7	Design and development verification
Clause 7.3.8	Design and development transfer
Clause 7.3.9	Control of design and development changes
Clause 7.3.10	Design and development files

Related Modules

- 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

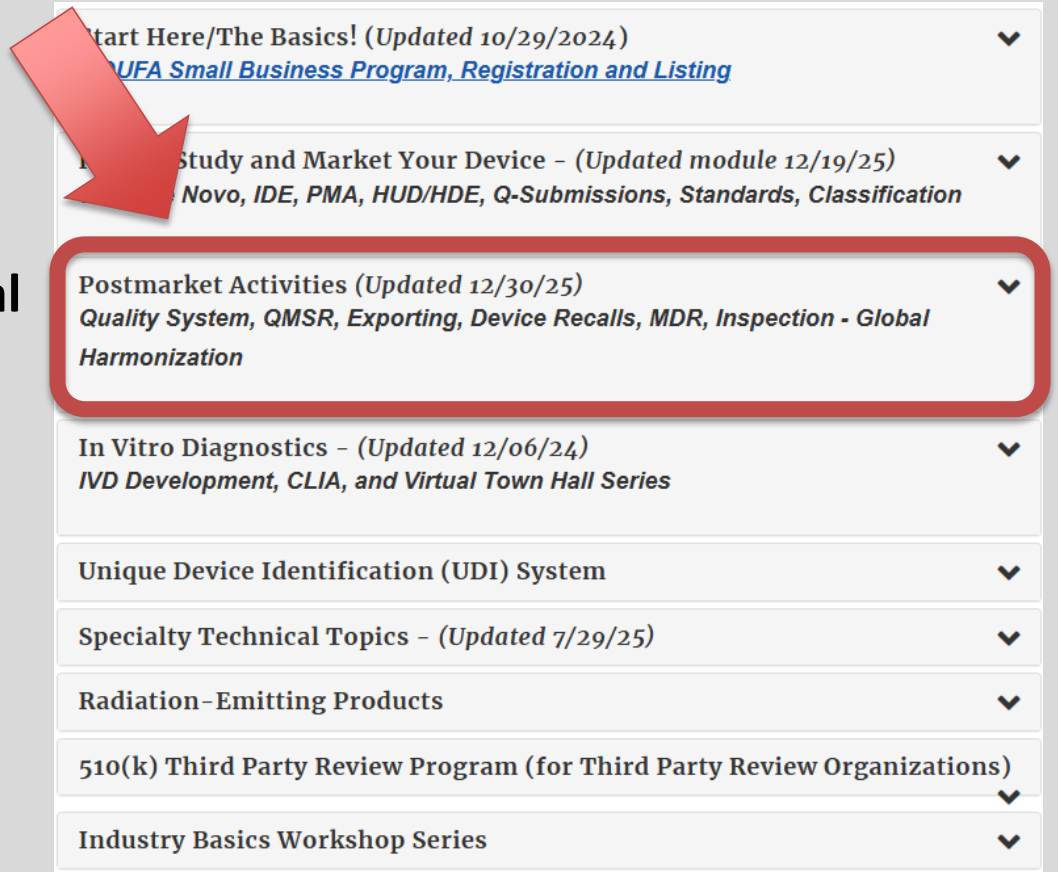

FDA
U.S. FOOD & DRUG
ADMINISTRATION

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 CDRH Events**
  - www.fda.gov/CDRHEvents




FDA
U.S. FOOD & DRUG
ADMINISTRATION