

# Overview of the Final Rule and the Quality Management System Regulation

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# Thirty Years In The Making

## The Year 1996

- Gallon of Gas \$1.23
- Dow Jones Tops 6,000
- Quality System Regulation publishes
- ISO 13485 publishes for the first time
- GHTF is in its 4<sup>th</sup> Year

ISO = International Organization for Standardization  
 GHTF = Global Harmonization Task Force

## The Year 2024

- Gallon of Gas \$3.22
- Dow Jones Tops 40,000
- Quality Management System Regulation publishes
- Current ISO 13485:2016
- IMDRF over a decade old

IMDRF = International Medical Device Regulators Forum

# Learning Objectives

- Introduce the Final Rule, Medical Devices; Quality System Regulation Amendments and Preamble
- Describe the Quality Management System Regulation (QMSR) and the incorporation by reference of ISO 13485:2016 and ISO 9000:2015, clause 3
- Highlight and explain definitions, and note FDA future activities and plans

# **Final Rule, Medical Devices; Quality System Regulation Amendments and Preamble**

# Final Rule

- The U.S. Food and Drug Administration (FDA) published the final rule **Medical Devices; Quality System Regulation Amendments** on **February 2, 2024.**

[www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments](https://www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments)

# Final Rule

- Rule explains the FDA's current regulatory framework and how the public was engaged in the rule making process
- Preamble to final rule has 83 comments from the public and the FDA's responses to them

# Final Rule

- Rule revises name of 21 CFR part 820 to **The Quality Management System Regulation (QMSR)**
- Harmonizes current Quality System regulation for medical devices by converging its requirements with international quality management system requirements

# Final Rule

- Transition period from Quality System Regulation (“Current” 820) to Quality Management System Regulation (“Future” 820) is two (2) years
- QMSR effective date is February 2, 2026

# Knowledge Check

**It is important to read the preamble, including the comments and responses, to the final rule.**

1. True
2. False

# Quality Management System Regulation (QMSR) Overview

# Overview of Quality Management System Regulation (QMSR)

- Withdraws most requirements in current Part 820
- Retains scope and some definitions from Quality System Regulation
- Includes conforming edits to Part 4 (cGMPs for combination products).
  - Does not impact the cGMP requirements for combination products

**cGMP = current good manufacturing practice**

# Overview of Quality Management System Regulation (QMSR)

- 820.1 Scope.
- 820.3 Definitions.
- 820.7 Incorporation by reference.

# Overview of Quality Management System Regulation (QMSR)

- 820.10 Requirements for a quality management system.

Links additional FDA requirements such as MDR, UDI, Corrections and Removals, and Tracking; applicability of Design and Development activities

MDR = medical device reporting

UDI = unique device identification

# Overview of Quality Management System Regulation (QMSR)

- 820.35 Control of records.  
Supplements record keeping activities, complaint/servicing records, UDI, and confidentiality
- 820.45 Device labeling and packaging controls.

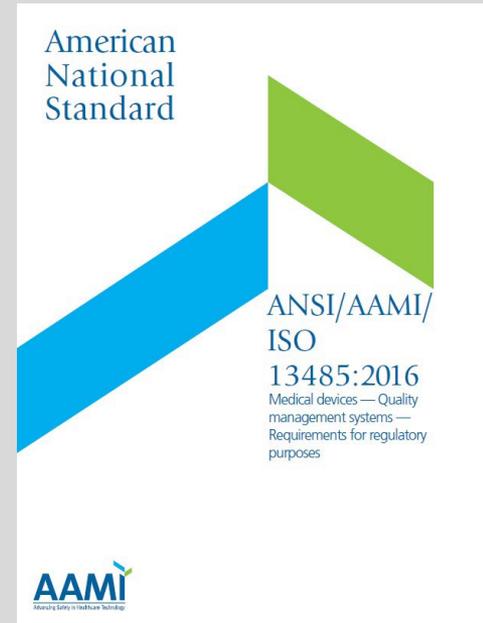
# QMSR Overview – Incorporation by Reference

Incorporates by reference the *International Standard, ISO 13485:2016, Medical devices-Quality management systems –Requirements for regulatory purposes,*

- Minimal called out provisions to ensure consistency with other applicable FDA requirements.
- Includes definitions and requirements

# QMSR 820.7-ISO 13845 Incorporation

- Establishes requirements for a Quality Management System (QMS) that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including:
  - Design and development
  - Production
  - Storage
  - Distribution
  - Installation
  - Servicing and
  - Final decommissioning/disposal of medical devices



# QMSR Overview – Incorporation by Reference

- Incorporates by reference Clause 3 of *ISO 9000:2015, Quality management systems--Fundamentals and vocabulary*, contains terms and definitions necessary for the application of ISO 13485

# QMSR Overview – Incorporation by Reference

- Both standards are available for viewing (read only) in the ANSI Incorporated by Reference (IBR) Portal, [ibr.ansi.org/standards/iso1.aspx](http://ibr.ansi.org/standards/iso1.aspx)

**ANSI = American National Standards Institute**

# QMSR Overview – Incorporation by Reference



- Any future changes to the standard would need to be evaluated to determine impact to the rule and, if necessary, addressed through rulemaking

# Knowledge Check

**The Quality Management System Regulation does which of the following?**

1. Transitions to ISO 13485:2016
2. Incorporates by reference ISO 13485:2016
3. Requires I hire a notified body

# Definitions and FDA Activities

# Understanding Definitions

Food Drug and Cosmetic Act (FD&C) Section 201

## Quality Management System Regulation (QMSR) 21 CFR 820.3 Definitions

“The definitions in ISO 13485 apply to this Part, except as specified in subsection (b)...

**21 CFR820.3(b)**  
Provides definitions which superseded those in ISO 13485 and ISO 9000

**21 CFR820.3(a)**  
Defines five additional terms which are not defined in ISO 13485 and ISO 9000

**ISO 13485:2016**  
Clause 3: Terms and Definitions

**ISO 9000:2015**  
Clause 3: Terms and Definitions

# Superseding Definitions 820.3(b)

- All definitions in Section 201 of FD&C Act apply and supersede correlating terms (for example, “device” and “labeling”)
- Implantable medical device/“implant” 860.3
- Manufacturer
- Organization
- Rework
- Safety and Performance means the same as “safety and effectiveness”

# Additional Definitions 820.3(a)

- Component
- Federal Food, Drug and Cosmetic Act
- Finished device
- Human Cells, Tissues Based/Products regulated as a device
- Remanufacturer

# Other Key Terms from Preamble

- Replaces term “establish” with “document”
- Replaces “management with executive responsibility” to “top management”
- Uses ISO definitions for “nonconformity” and “verification”
- Adopts ISO terms for “customer” and “product”

# Knowledge Check

**What is the order of superseding definitions?**

1. FD&C Act, QMSR, ISO 13485 and ISO 9000
2. ISO 9000, ISO 13485, FD&C Act, QMSR
3. Whatever DICE tells you when you call them

# FDA Activities - Inspections

- FDA retains its inspectional authority
  - FDA inspections will not result in issuance of certificates of conformance to ISO 13485:2016
  - Manufacturers with a certificate of conformance to ISO 13485:2016 are not exempt from FDA inspections
  - FDA will not require ISO 13485 certificates

# FDA Activities – Implementation Plans

- Update technology systems
- Revise [and/or develop] relevant policies, procedures, inspection process and other documents impacted by this rulemaking
  - Compliance Program
  - Guidance Documents
  - Standard Operating Procedures, Work Instructions, Templates, etc.

# FDA Activities – Implementation Plans

- Train internal personnel
- Issue external communications
- Conduct external education, for example, presentations like this one

# Knowledge Check

**FDA will issue a Certificate of Conformance to ISO 13485.**

1. True
2. False

# Resources

Slide Number	Cited Resource	URL
6	Medical Devices; Quality System Regulation Amendments Final Rule	<a href="https://www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments">www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments</a>
12	Quality Management System Regulation	Will eventually be updated in the <a href="https://www.ecfr.gov/">www.ecfr.gov/</a>
13-15	Where to view only (read) ISO 13485 and ISO 9000 standards	<a href="https://ibr.ansi.org/standards/iso1.aspx">ibr.ansi.org/standards/iso1.aspx</a>
13-15	Where to purchase a copy of the ISO 13485 and ISO 9000 standards	<a href="https://ibr.ansi.org/">ibr.ansi.org/</a>

# Summary

- FDA has issued the Final Rule, Medical Devices; Quality System Regulation Amendments and its preamble
- The QMSR incorporates by reference ISO 13485:2016 and ISO 9000:2015
- The final rule includes a hierarchy of definitions
- FDA has an implementation plan of activities for future rollout

# Questions



# Your Call to Action

- Read the Final Rule, including the preamble.
- Then read it again.
- Learn about the QMSR and use all the available educational resources.
- Prepare your quality management system so you are ready by February 2, 2026.