

Overview of the Final Rule and the Quality Management System Regulation

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30

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 4th 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

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.

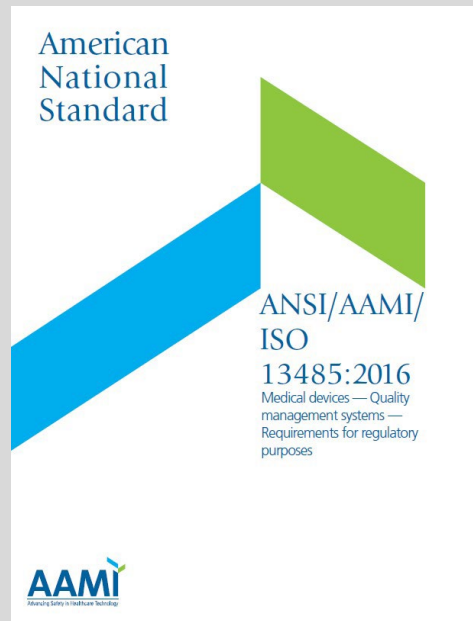
QMSR Overview – Incorporation by Reference

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

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	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments
12	Quality Management System Regulation	Will eventually be updated in the www.ecfr.gov/
13-15	Where to view only (read) ISO 13485 and ISO 9000 standards	ibr.ansi.org/standards/iso1.aspx
13-15	Where to purchase a copy of the ISO 13485 and ISO 9000 standards	ibr.ansi.org/

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.