Overview of the Quality Management System Regulation

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"Quality is never an accident; it is always the result of intelligent effort."

~John Ruskin

Quality Management System Regulation

- **Part 1: Overview of the Quality Management System Regulation**

- Part 2: Navigating the Quality Management System Regulation

Learning Objectives

- Discuss 2024 Final Rule: Medical Devices; Quality System Regulation Amendments
- Provide an overview of the Quality Management System Regulation (QMSR)
- Identify definitions and their hierarchy
- Review FDA implementation activities

2024 Final Rule: Medical Devices; Quality System Regulation Amendments

2024 Final Rule

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

www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments

2024 Final Rule: Framework and Preamble

- **Final rule explains:**
  - FDA's current regulatory framework
  - how public was engaged in rule making process
- **Preamble to final rule contains:**
  - 83 comments from public
  - FDA's responses to these public comments

2024 Final Rule: 21 CFR Part 820 Revision

- Revises Part 21 Code of Federal Regulations (CFR) Part 820
  - established October 1996
  - referred to as QS regulation

2024 Final Rule: 21 CFR Part 820 Revision

- New title “Quality Management System Regulation”
  - referred to as QMSR
  - established February 2024
- Harmonizes 1996 Quality System (QS) regulation for medical devices
  - converges its requirements with international quality management system requirements

2024 Final Rule: Transition Period

- 2 years
- QMSR effective date is February 2, 2026

Overview of QMSR

QMSR Overview

- Revises most requirements from 1996 Part 820
- Retains scope and some definitions from 1996 Part 820
- Includes conforming edits to Part 4 (cGMPs for combination products)
  - Doesn't impact cGMP requirements for combination products

cGMP = current good manufacturing practice

Listing of Regulation 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

21 CFR 820.7

- Incorporates by reference *International Standard, ISO 13485:2016, Medical devices-Quality management systems – Requirements for regulatory purposes*
- Calls out provisions to ensure consistency with other applicable FDA requirements

21 CFR 820.7

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

Where to Find Standards

- Available for viewing (read only) in ANSI Incorporated by Reference (IBR) Portal:

ibr.ansi.org/standards/iso1.aspx

ANSI = American National Standards Institute

Future Changes to Standards

- Evaluate potential changes to determine impact to the 2024 Final Rule
- Address through rulemaking, if necessary

Definitions and their Hierarchy

Hierarchy of Definitions

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

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Federal Food, Drug, and Cosmetic Act (FD&C Act) 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 CFR 820.3(b)
Provides definitions which supersede those in ISO 13485 and Clause 3 of ISO 9000

21 CFR 820.3(a)
Defines five additional terms which are not defined in ISO 13485 and Clause 3 of ISO 9000

Hierarchy of Definitions

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

Quality Management System Regulation (QMSR) 21 CFR 820.3 Definitions

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ISO 13485:2016
Clause 3: Terms and Definitions

ISO 9000:2015
Clause 3: Terms and Definitions

Definitions: 820.3(b)

- All definitions in Section 201 of FD&C Act apply, except as stated in the rule
- Certain terms defined in other regulations supersede correlating terms in ISO 13485 or ISO 9000, Clause 3:
  - Implantable medical device/“implant”
  - Manufacturer
  - Organization
  - Rework
- “Safety and Performance” is utilized instead of “safety and effectiveness”

Additional Definitions: 820.3(a)

- Terms that are not used or defined in ISO 13485 or ISO 9000, Clause 3:
  - Federal Food, Drug and Cosmetic Act
  - Component
  - Finished device
  - Human Cells, Tissues Based/Products regulated as a device
  - Remanufacturer

FDA Implementation Activities

FDA Inspections

- FDA retains inspectional authority:
  - FDA will not issue certificates of conformance to ISO 13485:2016 as a result of an FDA inspection
  - Manufacturers with certificate of conformance to ISO 13485:2016 are not exempt from FDA inspections
  - FDA will not require ISO 13485 certificates

FDA Implementation Activities

- Update technology systems
- 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

FDA Implementation Activities

- Train FDA personnel
- Issue public communications
- Conduct external education

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
15	Where to view only (read) ISO 13485 and ISO 9000 standards	ibr.ansi.org/standards/iso1.aspx
15	Where to purchase a copy of the ISO 13485 and ISO 9000 standards	ibr.ansi.org/

Summary

- FDA has issued 2024 Final Rule: **Medical Devices; Quality System Regulation Amendments**
- QMSR incorporates by reference ISO 13485:2016 and Clause 3 of ISO 9000:2015
- Final Rule includes a hierarchy of definitions
- FDA has developed implementation activities

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

CDRH Learn

Device Advice

Email DICE

Your Call to Action

- Read the 2024 Final Rule, including preamble
- Review the QMSR and use all the available educational resources
- Watch the follow-up CDRH Learn module: “Navigating the Quality Management System Regulation”

"Success is the sum of small efforts, repeated day-in and day-out."

~Robert Collier


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