An Innovative Approach to Navigating the Quality Management System Regulation

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QMSR
QUALITY
MANAGEMENT
SYSTEM
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Learning Objectives

- Discuss the purpose and scope of the Quality Management System Regulation (QMSR)
- Review the key requirements of the QMSR
  - Include referencing ISO 13485 and Clause 3 of ISO 9000
- Identify the similarities and differences between the current and the future 820
- Identify ways to adapt to the regulatory changes

Purpose and Scope of the QMSR

QMSR Purpose

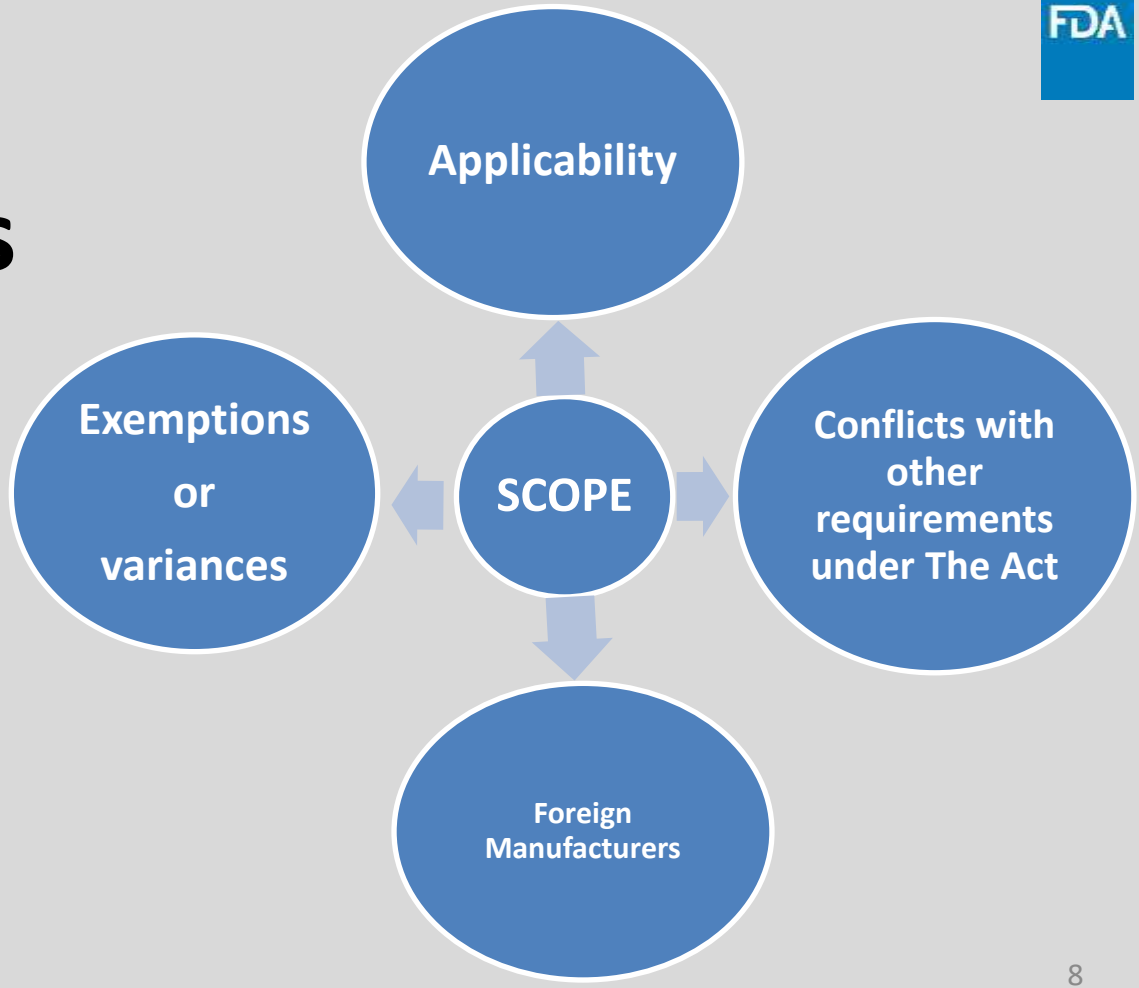
- Ensure ability to consistently manufacture devices that meet applicable requirements and specifications
- Provide a framework for achieving quality
- Assure that finished devices will be safe and effective
- Assure that finished devices comply with Federal Food, Drug, and Cosmetic Act

- Govern the methods used in, and the facilities and controls used for:
  - all finished devices intended for humans

QMSR Requirements

QMSR Requirements

- 820.1 Scope.



QMSR Requirements

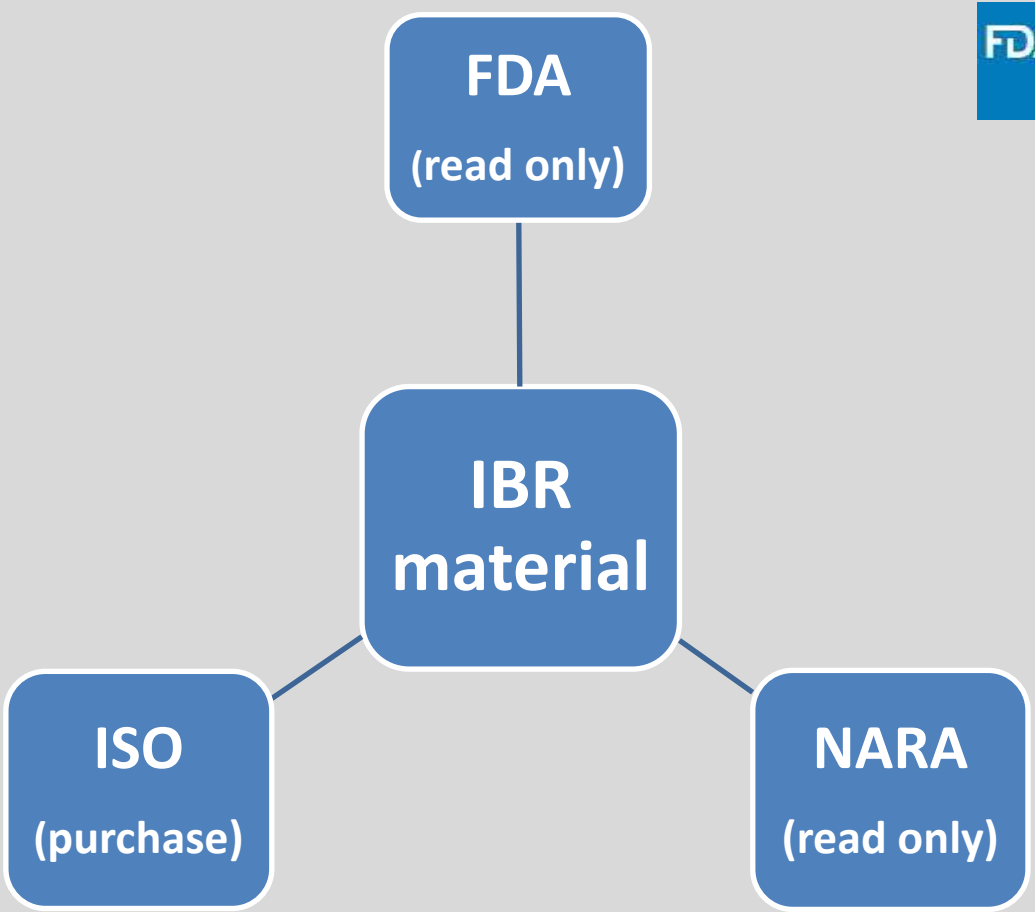
- **820.3 Definitions.**
  - Requirements specify that:
    - ➢ Definitions in ISO 13485 and Clause 3 of ISO 9000 apply
      - Except as specified in paragraph (b) of this section
      - Do not affect the meaning of similar terms defined
    - ➢ The 5 terms defined also apply and are either not used or not defined in ISO 13485 and Clause 3 of ISO 9000

QMSR Requirements

- **820.3 Definitions.**
  - — Requirements specify that:
    - All definitions in Section 201 of the FD&C Act supersede correlating definitions in ISO 13485
      - The 5 terms defined apply and supersede the definitions for correlating terms in ISO 13485 or ISO 9000

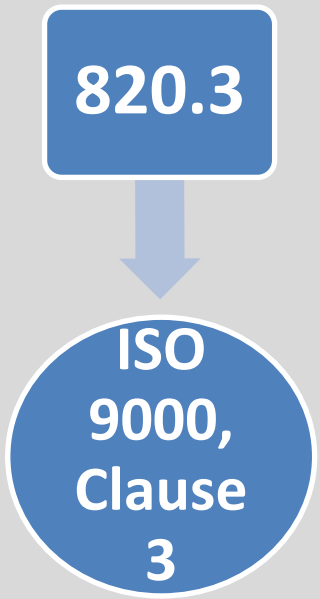
QMSR Requirements

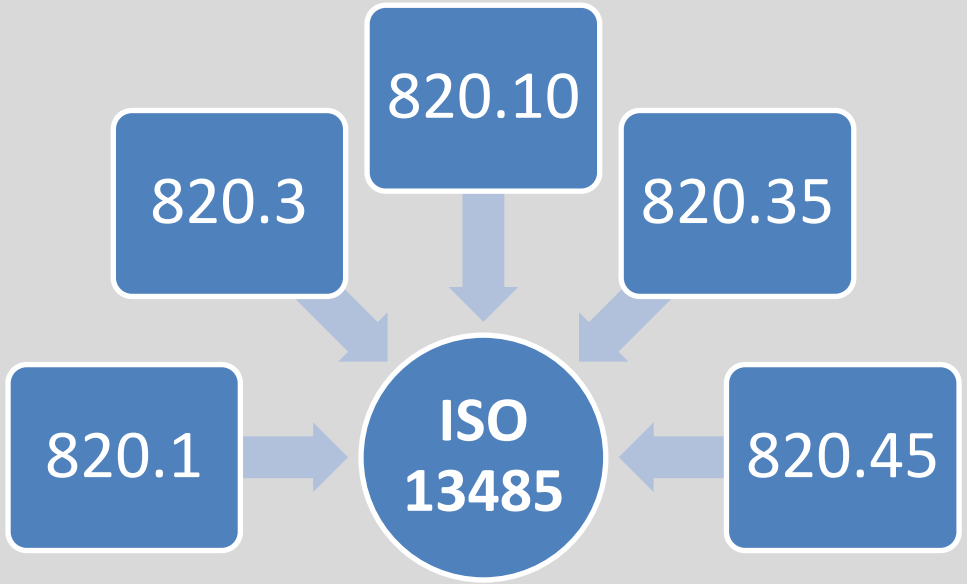
- **820.7 Incorporation by reference.**
  - All approved incorporation by reference (IBR) material is available



QMSR Requirements

- **820.7 Incorporation by reference.**





QMSR Requirements

- **820.10 Requirements for a quality management system.**
  - — Specifies requirements for:
    - ➢ Documenting a quality management system
    - ➢ Complying with other applicable regulatory requirements
      - ○ Part 830
      - ○ Part 821
      - ○ Part 803
      - ○ Part 806

QMSR Requirements

- **820.10 Requirements for a quality management system**.
  - Specifies requirements for:
    - Complying with Design and Development requirements of Clause 7.3 in ISO 13485
    - Complying also with requirements in Traceability for Implantable devices, Clause 7.5.9.2 in ISO 13485
  - Specifies that adulterated device, as well as person responsible for the adulteration is subject to regulatory action

QMSR Requirements

- **820.35 Control of records.**
  - Specifies requirements for specific information to be included in certain records:
    - Records of complaints
    - Records of servicing activities
    - Records for each Medical device or batch of medical device (include Unique Device Identification)
    - Confidential records

QMSR Requirements

- **820.45 Device labeling and packaging controls**
  - Specifies requirements for:
    - Documenting and maintaining procedures for labeling and packaging
    - Examining labeling and packaging for accuracy prior to release or storage

QMSR Requirements

- **820.45 Device labeling and packaging controls**
  - Specifies requirements for:
    - Documenting the release of the labeling for use per Clause 4.2.5 of ISO 13485
    - Establishing and maintaining labeling and packaging operations to prevent mix-ups
      - Document results of labeling inspection per Clause 4.2.5 of ISO 13485

Navigating the QMSR Requirements

Familiarize	• Familiarize yourself with FDA regulations and applicable standards
Conduct	• Conduct Gap Analysis
Implement	• Implement robust documentation
Foster	• Foster a Culture of Compliance

Knowledge Check

Which applicable FDA regulations are you required to comply with, as appropriate, to fully comply with the listed ISO 13485 clauses?

A. Part 830

B. Part 821

C. Part 803 and 806

D. All of the above

Knowledge Check

Material from which standard(s) is being incorporated into the QMSR by referencing?

A. ISO 14971

B. ISO 13485

C. ISO 9000, Clause 3

D. B and C

Current 820 and Future 820: Similarities and Differences

Current 820 and Future 820

Current 820	Future 820
Quality System Regulation (QS Reg)	Quality Management System Regulation (QMSR)
Issued October 7, 1996	Issued February 2, 2024
Effective June 1, 1997	Effective February 2, 2026

Current 820 and Future 820

Current 820 requirements	Future 820 requirements
Subpart A-General Provisions 820.1, 820.3, 820.5	Substantively similar and IBR*
Subpart B- Quality System Requirements 820.20, 820.22, 820.25	IBR*
Subpart C- Design Controls 820.30	Substantively similar and IBR*
Subpart D- Document Controls 820.40	IBR* w/Differences addressed in 820.35
Subpart E- Purchasing Controls 820.50	IBR*

* IBR- incorporation by reference

Current 820 and Future 820

Current 820 requirements	Future 820 requirements
Subpart F- Identification and Traceability 820.60, 820.65	IBR* with links to other regulations
Subpart G- Production and Process Controls 820.70, 820.72, 820.75	IBR*
Subpart H- Acceptance Activities 820.80, 820.86	IBR*
Subpart I- Nonconforming Product 820.90	IBR*
Subpart J- Corrective and Preventive Action 820.100	IBR*

* IBR- incorporation by reference

Current 820 and Future 820

Current 820 requirements	Future 820 requirements
Subpart K- Labeling and Packaging Control 820.120, 820.130	IBR* w/Differences addressed in 820.45
Subpart L-Handling, Storage, Distribution, and Installation 820.140, 820.150, 820.160, 820.170	IBR*
Subpart M- Records 820.180, 820.181, 820.184, 820.186, 820.198	IBR* w/Differences addressed in 820.35/links to other regulations
Subpart N-Servicing 820.200	IBR* w/Differences addressed in 820.35
Subpart O- Statistical Techniques 820.250	IBR*

* IBR- incorporation by reference

Ways to Adapt to Regulatory Changes

Ways to Adapt to Regulatory Changes

- Identify and understand the regulatory changes
- Conduct Gap Analysis
- Identify Differences
- Revise processes and procedures to incorporate changes

Ways to Adapt to Regulatory Changes

- Train employees on revised processes and procedures
- Implement new processes and procedures
- Monitor implementation of revised processes and procedures

Resources

Slide Number	Cited Resource	URL
1	Final Rule: Medical Devices; Quality System Regulation Amendments	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments#sectno-reference-820.3
5	ISO 13485: 2016- Medical Devices- Quality management systems- Requirements for regulatory purposes	ibr.ansi.org/Standards/iso1.aspx
13	ISO 9000: 2015-Quality management systems- Fundamentals and vocabulary	www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en
11	21 CFR 4: Regulation of Combination Products	www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-4

Knowledge Check

What is IBR an acronym for in the QMSR?

1. Investigative branch review
2. Institutional board review
3. Incorporation by reference
4. None of the above

Summary

- The Quality Management System Regulation (QMSR) specifies requirements that provide assurance that devices are safe and effective
- The QMSR incorporates by reference ISO 13485:2016 and Clause 3 of ISO 9000:2015 standards
- All definitions in 201 of the FD&C Act and the QMSR supersede correlating definitions in ISO 13485 and Clause 3, ISO 9000

Questions

Your Call To Action

- Embrace these continuous efforts of harmonization.
- Familiarize yourself with the following documents: Final Rule, QMSR, ISO 13485:2016, and Clause 3, ISO 9000:2015.
- Conduct a gap analysis of your current procedures to identify any gaps in meeting the regulatory requirements.
- Engage in continuous training on implementing the QMSR.