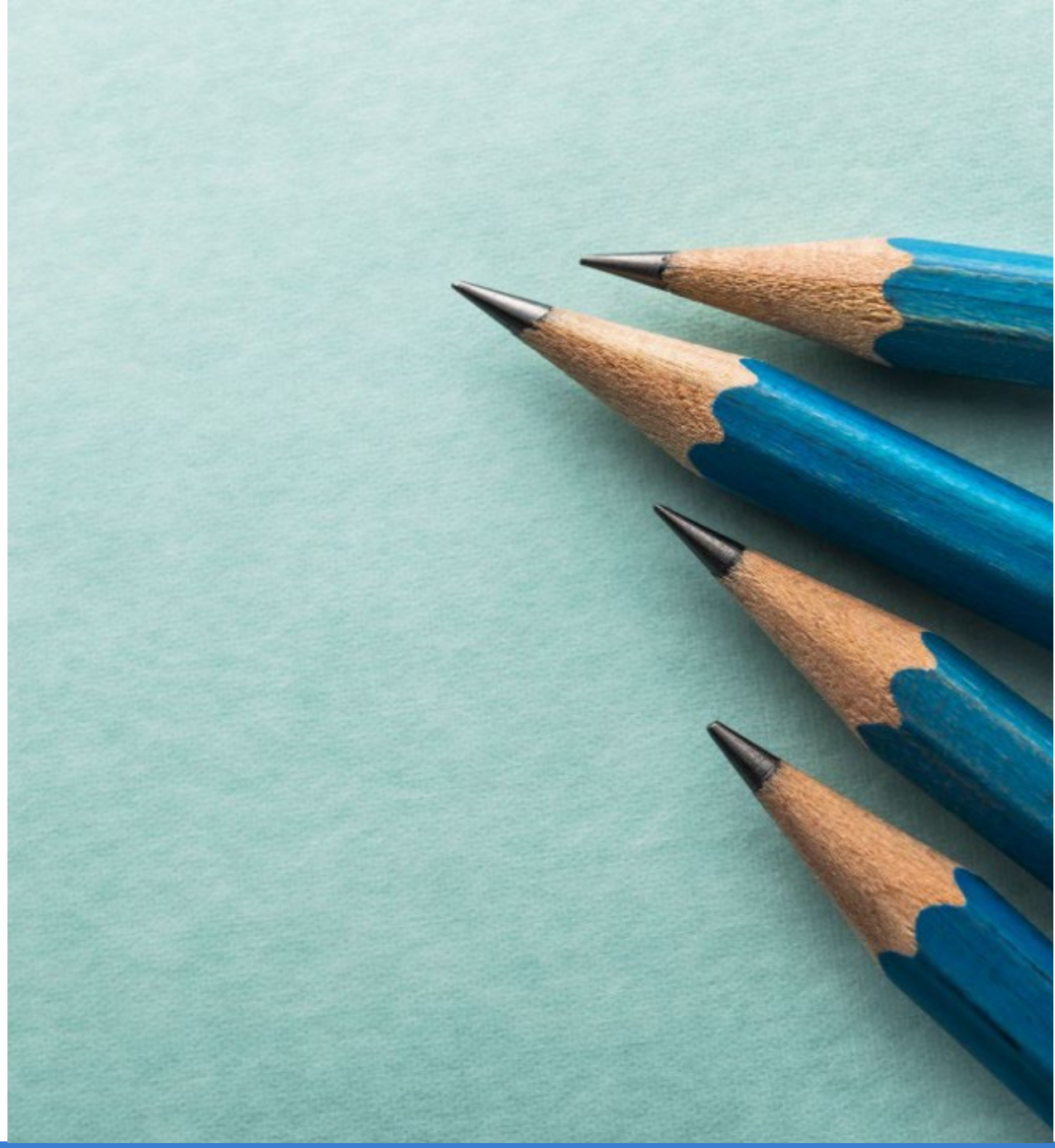
Getting Ready for FDA's QSR to QMSR Transition

Webinar - May 23, 2025

Housekeeping

A few things before we start…

- This Webinar is being recorded and will be available on the MEC website: *www.medicalengineeringconsultants.com*
- The Presentation deck will be sent to registered participants and will also be available on the MEC website.
- During the live Webinar:
  - We'll use Polls to gather input.
  - Please use Teams "Chat" for questions.
    - We will review questions at the end.
    - We will also follow-up directly with participants on any questions not covered, where possible.



WEBINAR OBJECTIVES

In today's session we will:

- Briefly review **what, when and why** 21 CFR 820 is changing from the from Quality System Regulation (QSR) to Quality Management System Regulation (QMSR)
- Discuss **how** the changes are expected to impact the Medical Device Industry.
- Discuss **Readiness Activities** to be prepared for the change.
- Share information through **participant polls and questions.**

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WHAT WE DO

Medical Engineering Consultants (MEC) is dedicated to helping our clients provide safe and effective medical devices, diagnostic devices and pharmaceutical products.

MEC offers contracting & staffing resources, consulting services and training to deliver operational excellence.

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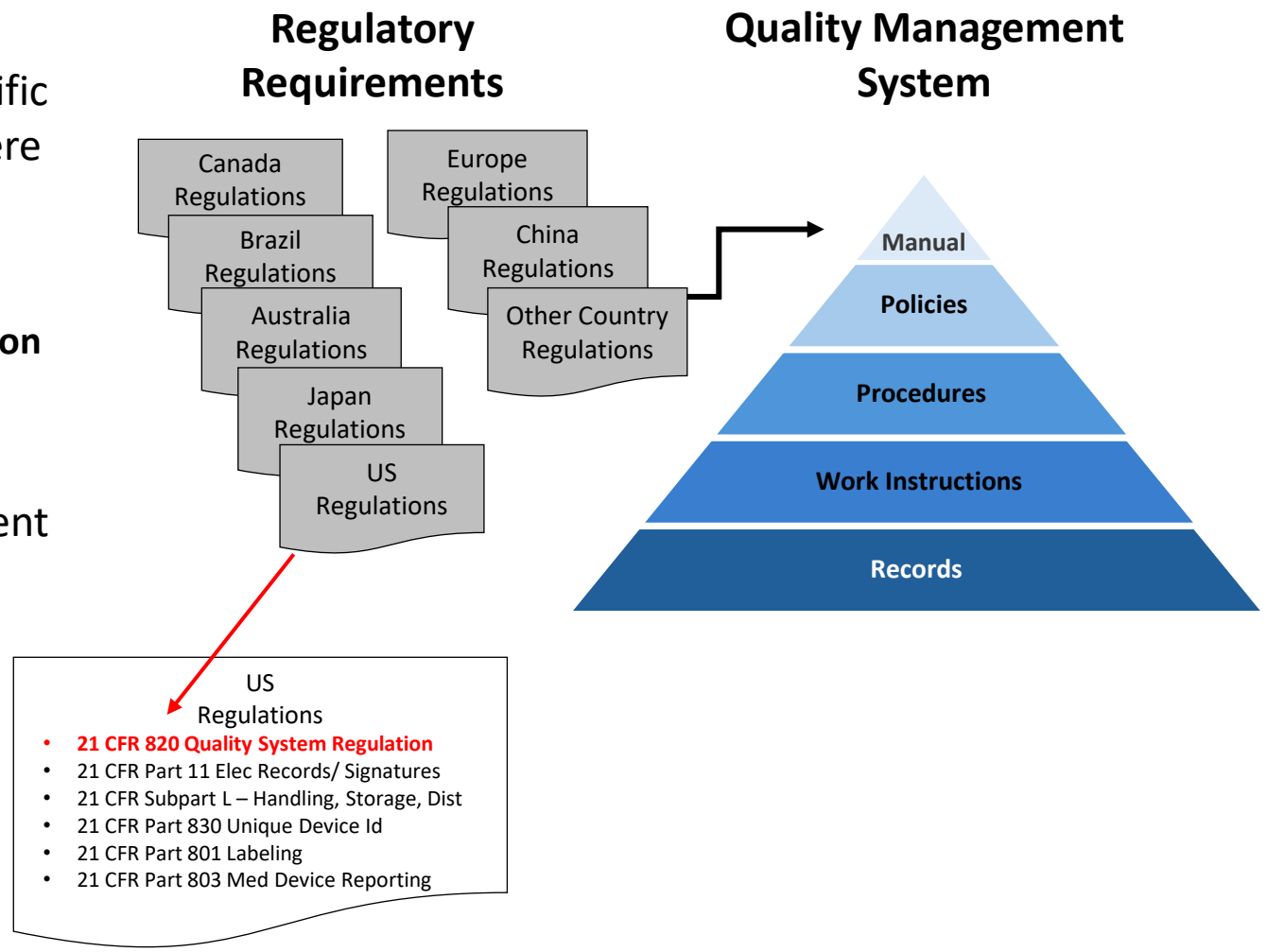
About the Presenter

Beth Crandall leads Solution Delivery at MEC with over 25 years of experience in the life sciences industry focused on the regulated medical device market. She has a successful track record of leading large quality management system programs and implementing changes to organizations, policies, procedures, and software systems. She also has direct experience conducting assessments for Quality and Regulatory organizations, including evaluation of processes, best practices, functional responsibilities, structure, and staffing. She earned a BA in Business Administration, Human Resource Management from the College of St. Thomas and has been a certified Project Manager (PMI PMP) since 2012. She has presented at several medical device conferences and published multiple articles throughout her career.

QUALITY MANAGEMENT SYSTEM REGULATION

- Medical Device companies are subject to specific requirements from the multiple countries where their products are sold.
- The United States is updating 21 CFR 820. The regulation is changing from **Quality System Regulation (QSR)** to **Quality Management System Regulation (QMSR)**
- This change will impact the Quality Management Systems of companies that sell products in the United States.



Participant Poll

Who's attending?

Please let us know which of these most closely fit why you're attending today:

Response	Results
I work directly for a company that must comply with 21 CFR 820.	56%
I support clients who must comply with 21 CFR 820.	33%
I work for a regulatory agency, notified body, or competent authority confirming companies comply with specific regulations.	0%
Other: Please describe with a comment. • Continuing education • University faculty	11%

BRIEF HISTORY - US MEDICAL DEVICE REGULATIONS

Era	Actions
1900 - 1970	• 1906: **Pure Food and Drug Act.** • 1938: **Federal Food, Drug and Cosmetic Act (FD&C).** • 1960's: Concerns over unsafe medical devices, such as Dalkon Shield, triggered stricter oversight.
1970 - 1980	• 1976: Congress passed **Medical Device Amendments**; FDA given authority for pre-market review, device labeling and post-market surveillance; Established device classifications: Class I, Class II and Class III.
1980 - 2000	• 1980: **Office of Device Evaluation (ODE)** established. • 1990: **Safe Medical Device Act** strengthened Post-Market Surveillance. • **1996: 21 CFR 820 Quality System Regulation (QSR) established.** • 1997: **Food and Drug Administration Modernization Act (FDAMA)** updated approval process, introduced de novo path for low-to-moderate risk devices.
2000 - 2020	• 2002: The **Medical Device User Fee and Modernization Act (MDUFMA)** introduced user fees to fund faster FDA reviews. • 2012: The **FDA Safety and Innovation Act (FDASIA)** enhanced post-market surveillance and streamlined pathways for innovative devices. • 2016: The **21st Century Cures Act** promoted the development of breakthrough devices and clarified the FDA's role in software regulation. • 2017: The FDA implemented the **Digital Health Innovation Action Plan**, addressing emerging technologies like artificial intelligence and mobile health apps.
2020 - 2026	• 2022: FDA issued proposed rule updating 21 CFR 820 Quality Management System Regulation (QMSR) • 2024: FDA released final rule for 21 CFR 820 QMSR Feb 2, 2024. • **2026: 21 CFR 820 QMSR update in effect as of Feb 2, 2026.**

30 years from 21 CFR 820 QSR to QMSR

WHY IS 21 CFR 820 CHANGING FROM QSR TO QMSR?

Modernize the regulation

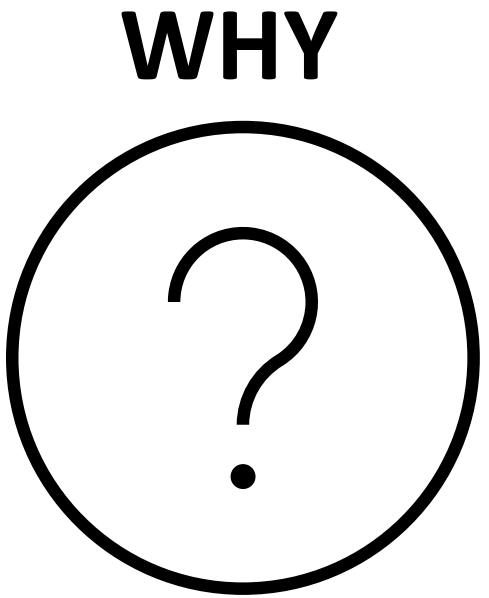
It’s been 30 years! QSR had not been significantly updated since its implementation, and the transition addresses advancements in technology and manufacturing practices.

Harmonize with recognized international standard

Aligning with the internationally recognized ISO 13485:2016 simplifies compliance for manufacturers operating in multiple markets.

Reduce redundancy

Many manufacturers already implement ISO 13485-based systems alongside QSR. Harmonization reduces the burden of maintaining dual systems.



Participant Poll

How Long have you been following 21 CFR 820 QSR

Please indicate the amount of time you've been roles impacted by the original regulation:

a) None – I've never been in a role impacted by the original regulation.

b) Less than 2 years

c) 2 to 5 years

d) 5 to 10 years

e) More than 10 years

f) More than 15 years

Participant Poll

Level of Awareness

How familiar are you with the changes being made to 21 CFR 820?

Response	Results
This is the first I'm learning the details.	29%
I've read articles or heard a little bit about it, but don't know the details.	36%
I've attended other educational sessions (e.g., conferences, events, webinars).	6%
I'm familiar with the details of the pending changes.	26%
Other	2%

WHAT IS CHANGING IN 21 CFR 820 WITH QMSR?

Adopting ISO 13485:2016 “by reference”

Majority of previous numbered sections of 21 CFR 820 removed, replaced with statements that directly reference section of ISO 13485:2016.

Enhanced Risk Based approach

Implements a more risk-based approach than QSR, intended to enhance device safety and effectiveness.

Aligning with Global Markets

By adopting ISO 13485 principles, U.S. manufacturers can streamline their quality management systems, making it easier to enter international markets.

§ 820.7 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration, and at the National Archives and Records Administration (NARA). Contact FDA at: Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240–402–7500; *https://www.regulations.gov/document/FDA-2013-S-0610-0003*. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*. This material may be obtained from the International Organization for Standardization (ISO), BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41–22–749–01–11; *customerservice@iso.org, https://www.iso.org/store.html*.

WHAT IS NOT CHANGING?

Same general scope

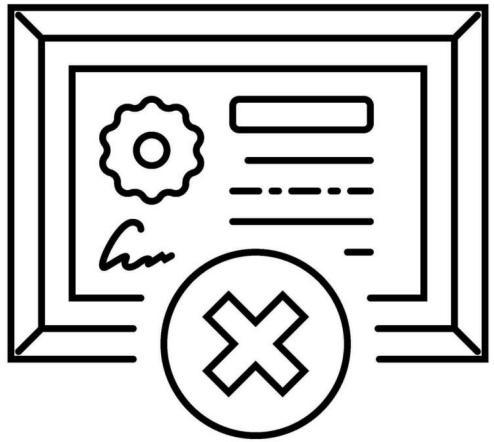
- Scope of ISO 13485:2016 and QSR are aligned.

FDA retains oversight

- The FDA has authority to enforce specific US Centric requirements, such as reporting adverse events and Unique Device Identification (UDI).

FDA will not issue QMS "Certification"

- FDA inspections will not result in the issuance of a certificate of conformity to ISO 13485.
- FDA does not intend to require medical device manufacturers to obtain ISO 13485 certification and will not rely on ISO 13485 certificates to conduct its regulatory oversight of medical device manufacturers.
- ISO 13485 certificate will not be considered or accepted as a substitute for any oversight processes.



QSR

Part 820 Quality System Regulation
- **Subpart A** General Provisions
  - **§ 820.1** Scope.
  - **§ 820.3** Definitions.
  - ~~**§ 820.5** Quality system.~~
- **Subpart B** Quality System Requirements
  - ~~**§ 820.20** Management responsibility.~~
  - ~~**§ 820.22** Quality audit.~~
  - ~~**§ 820.25** Personnel.~~
- **Subpart C** Design Controls
  - **§ 820.30** Design controls.
- **Subpart D** Document Controls
  - **§ 820.40** Document controls.
- **Subpart E** Purchasing Controls
  - **§ 820.50** Purchasing controls.
- **Subpart F** Identification and Traceability
  - **§ 820.60** Identification.
  - **§ 820.65** Traceability.
- **Subpart G** Production and Process Controls
  - **§ 820.70** Production and process controls.
  - **§ 820.72** Inspection, measuring, and test equipment.
  - **§ 820.75** Process validation.
- **Subpart H** Acceptance Activities
  - **§ 820.80** Receiving, in-process, and finished device acceptance.
  - **§ 820.86** Acceptance status.
- **Subpart I** Nonconforming Product
  - **§ 820.90** Nonconforming product.
- **Subpart J** Corrective and Preventive Action
  - **§ 820.100** Corrective and preventive action.
- **Subpart K** Labeling and Packaging Control
  - **§ 820.120** Device labeling.
  - **§ 820.130** Device packaging.
- **Subpart L** Handling, Storage, Distribution, and Installation
  - **§ 820.140** Handling.
  - **§ 820.150** Storage.
  - **§ 820.160** Distribution.
  - **§ 820.170** Installation.
- **Subpart M** Records
  - **§ 820.180** General requirements.
  - **§ 820.181** Device master record.
  - **§ 820.184** Device history record.
  - **§ 820.186** Quality system record.
  - **§ 820.198** Complaint files.
- **Subpart N** Servicing
  - **§ 820.200** Servicing.
- **Subpart O** Statistical Techniques
  - **§ 820.250** Statistical techniques.

QMSR

PART 820—QUALITY MANAGEMENT SYSTEM REGULATION

Subpart A—General Provisions

Sec.

820.1 Scope.
820.3 Definitions.
820.5 [Reserved]
820.7 Incorporation by reference.
820.10 Requirements for a quality management system.

Subpart B—Supplemental Provisions

820.20–820.30 [Reserved]
820.35 Control of records.
820.40 [Reserved]
820.45 Device labeling and packaging controls.

Subparts C–O [Reserved]

ISO 13485:2016

Participant Poll

ISO 13485:2016 Awareness

How familiar are you with ISO 13485:2016?

Response	Results
I am not familiar with any of the specific ISO 13485:2016 requirements.	0%
I know some of the requirements, but not all off ISO 13485:2016.	14%
I'm familiar with the ISO 13485:2016 requirements.	46%
I have an expert level understanding of ISO 13485:2016.	38%
Other	2%

KEY CHANGES

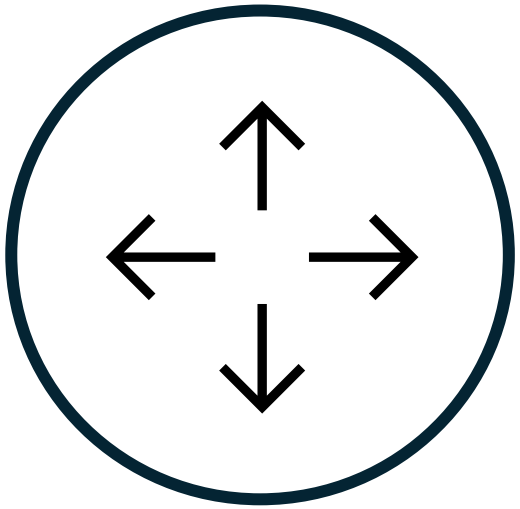
Eliminated Exception regarding QSR FDA access to specific records

- The QMSR does not include exceptions for management review, quality audits, and supplier audit reports, which formerly existed in the QS regulation in 820.180(c).

Definitions

- The Definitions section incorporates by reference **Clause 3 of ISO 9000:2015**
  - This is a change from the proposed rule released in 2022. Several of those proposed definitions were removed from the Final Rule.
- Many previous QSR definitions have been removed and replaced by ISO 13485 or ISO 9000 definitions (refer to next slide.)

CHANGES



KEY CHANGES

Previous QSR Term	Replaced in ISO 13485 and/or ISO 9000 by
Design History File (DHF)	Design and Development File
Device Master Record (DMR)	Medical Device File (MDF)
Device History Record (DHR)	Medical device or batch record
Management with Executive Responsibility	Top Management
Safety and effectiveness	Safety and performance
Record	Separate terms “document” and “record.” Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. FDA adds that the term “specification” is also a distinct term. For example, a record and a specification are types of documents as defined in ISO 9000.

WHAT IS DIFFERENT IN QMSR FROM ISO 13485?

QMSR 820.35 Control of Records

- Includes requirements beyond those in ISO 13485. This was done to ensure consistency and alignment with other requirements in the FD&C Act and implementing regulations.
- Specific requirements related to:
  - Records of Complaints
  - Records of Servicing activities
  - Unique Device Identification
  - Confidentiality

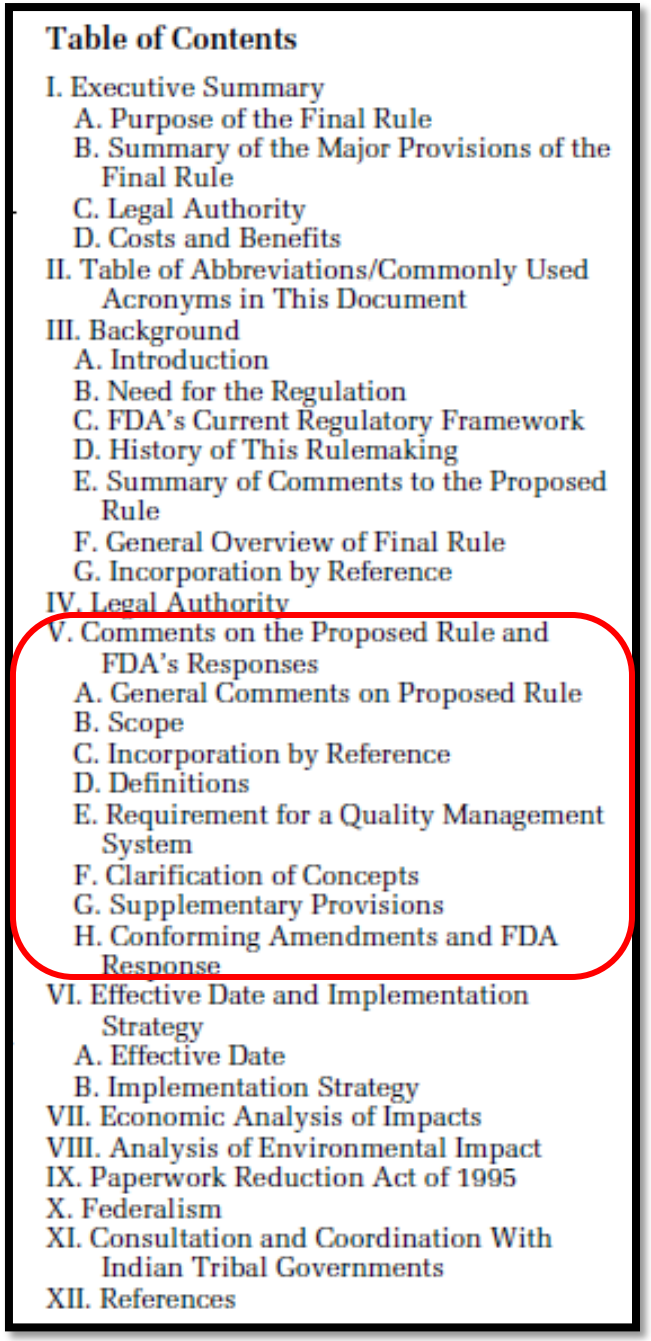
QMSR 820.45 Device Labeling and Packaging Controls

- ISO 13485 does not specifically address the inspection of labeling by the manufacturer.
- FDA is retaining requirements from the QS regulation that strengthen controls for labeling and packaging operations.
- **Note:** The definitions of “Device” and “labeling” in FD&C Act superseded ISO 13485:2016 definitions of “Medical Device” and “labeling.”

SUPPLEMENTARY INFORMATION

The FDA includes 28 pages of supplementary information in the Final Rule

- **Section V** is helpful to understand the rationale of specific FDA decisions.
- Detailed responses are provided to **83 Comments** from the proposed rule.
- The FDA responses help answer many common questions.



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CHANGES FROM PROPOSED RULE

Comment 44: Unique Device Identification

- FDA does not consider the QMSR to require an organization to assign a UDI to devices under development because the provisions in part 830 apply to a device in commercial distribution.
- Similarly, FDA does not take a position on whether an organization should incorporate UDI as part of its documented process for identification of devices that are not in commercial distribution, so long as the requirements of the QMSR are met.

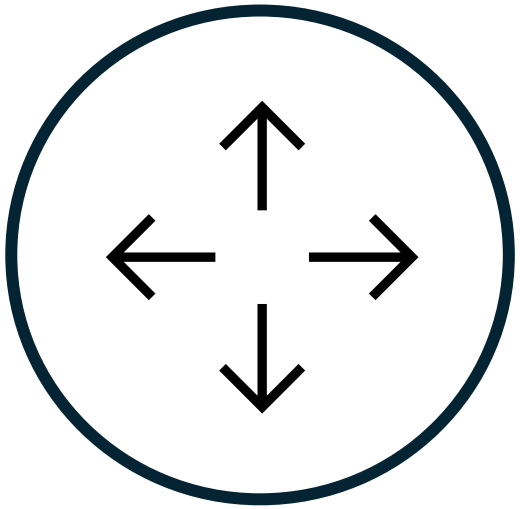
Comment 46: Independent Reviewer

- An Independent reviewer is no longer explicitly required at each stage of design in Design Reviews.

Comment 53: Signatures for approval/reapproval of records

- Removed the requirement that the manufacturer obtain the signature for each individual who approved or reapproved a record, and the date of such approval on the record.

CHANGES



COMMON QUESTIONS

Comment 9: Are any other ISO Standards considered required?

- Aside from ISO 9000 Clause 3, FDA does not incorporate ISO 14971, or any other standards referenced by, or listed as a source in, 13485.
- However, FDA acknowledges the other standards may be helpful in understanding application of ISO 13485.

Comment 21: Do companies still have to pay to get a copy of ISO 13485

- ISO standards have only been available if purchased or accessed through a subscription service.
- A mechanisms has been established to access ISO 13485:2016 through ANSI Standards Incorporated by Reference portal at https://ibr.ansi.org/Standards/iso.aspx

COMMON QUESTIONS

Comment 10: Are the “NOTES” in ISO 13485:2016 considered requirements?

- No, the NOTES in ISO 13485 do not set forth statutory or other legal requirements.
- However, FDA recognizes the NOTES provide explanations for the provisions and those explanations can be helpful in understanding the provisions.

Is Traceability still required?

- Although 820.65 Traceability has been removed, the QMSR incorporates traceability requirements in Clause 7.5.9 of ISO 13485.
- The QMSR 820.10(d) requires that manufacturers of devices that support or sustain life comply with traceability requirements.

COMMON QUESTIONS

Are there any other clarified FDA expectations?

FDA's Response to Comment #54 includes expectations for corporate complaint handling.

> "Consistent with the QS regulation, FDA expects that a firm will make a reasonable and good faith effort to obtain the information required for an investigation. Additionally, we note that if a corporation chooses to operate with different complaint handling units for products and/or establishments, the manufacturer must clearly describe and define its corporate complaint handling procedure to ensure consistency throughout the different complaint handling units. A system that would allow multiple interpretations of handling, evaluating, categorizing, investigating, and following up, would be unacceptable. Each manufacturer should establish in its procedures which one group or unit is ultimately responsible for coordinating all complaint handling functions."

Participant Poll

What is your responsibility?

We asked participants to indicate their role.

Response	Results
I'm a Management Representative or Management with Executive Responsibility, responsible for a company's Quality Management System.	17%
I'm a QMS process owner, responsible for one or more QMS processes or functional areas impacted by QMSR.	29%
I am involved in QMSR Readiness for my company or a client.	25%
I use a QMS impacted by QMSR but am not directly responsible for making updates.	13%
Other: • Regulatory Affairs • Continuing education • Have served multiple roles	16%

Participant Poll

Who's already working on QMSR?

If you are involved in QMSR readiness, let us know what applies to you. *(More than one may apply)*

a) Our company has already done a **Gap Assessment**.

b) Our company has a **Quality Plan** established.

c) Our company has **begun making updates** to our QMS to prepare for QMSR.

d) Our company **has not yet done anything formal** to prepare for QMSR.

e) N/A: **I'm not directly involved** in QMSR readiness.

EXPECTED INDUSTRY IMPACT

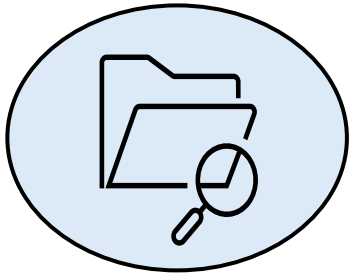
Simplified Compliance

- Aligns with recognized international standard, reduces challenges faced due to lack of harmonization.

Changes to FDA Inspections

- The FDA intends to replace its current inspection approach for medical devices, Quality System Inspection Technique (QSIT), with an inspection approach that will be consistent with the requirements of the QMSR.
- The successor to QSIT will "involve the collection of information to support observations noted during the inspection" in a manner similar to the QSIT manual.
- Details have not been announced.

EXPECTED INDUSTRY IMPACT



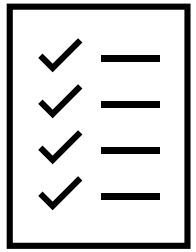
Updates to QMS Procedures and Training

- Updates to add 13485:2016 requirements, if not already incorporated.
- Updates to remove or update previous QSR language and requirements.
  - E.g., changes to procedures and software systems that use DHF, DMR, DHR terminology and requirements.
  - Increased use of risk-based approach.
- Changes to QMS procedures will trigger training updates for impacted personnel.

FDA allowed to access certain records

- FDA may request records management review, quality audits, and supplier audit reports
  - Notified Bodies are already allowed access to these records, but this will be new for US focused clients who had only been subject to FDA inspections.
  - Clients may want to review these specific records and record keeping processes.

READINESS ACTIVITIES



- ❑ If not currently in your QMS scope, conduct a **QMS gap assessment to ISO 13485:2016** requirements.
- ❑ Conduct a **QMS gap assessment to the new QMSR requirements**, specifically 820.10, 820.35 and 820.45.
- ❑ If you have **suppliers registered as contract manufactures** with the FDA, check their QMSR readiness.
- ❑ Review procedures for **original QSR language** that will no longer have a basis in regulation.
- ❑ Determine and **address any needed software system updates** related to procedure updates, such as those based on original QSR language (e.g., DHF, DMR or DHR).
- ❑ Review **training procedures** to ensure appropriate **focus on competency**, as required in ISO 13485.
- ❑ Confirm **records are inspection ready** for management review, quality audits, and supplier audit reports.
- ❑ If applicable, **update detailed QMS trace matrix**, to remove references to QSR sections and add the new QMSR regulations and ISO 13485:2016 clauses.
- ❑ If there are **different complaint handling units for products and/or establishments**, ensure there is a corporate complaint handling procedure to ensure consistency throughout the different complaint handling units.

Participant Poll

Are you ready for QMSR?

After learning more about the changes and impact, is your company ready for QMSR?

a) **Yes.** Our company is ready for the change.

b) **Not yet.** we expect to be ready, but work is still in progress.

c) **No.** Our company still has a lot to do before being ready.

d) **N/A**: QMSR does not directly impact me or my company.

QUESTIONS

Submitted Questions

We asked participants for specific questions they'd like addressed during the webinar:

- Looking for AS-IS to TO-BE state and what's the impact on the organization to compliance to new changes.
- If a company complies with 820 and maintains a 13485:2016 certificate, how much additional work are companies doing to harmonize to QMSR?
- Include slides from a Software as Medical Device (SaMD) point of view.
- If it is possible to know the direct relation between ISO requirements and 21 CFR 820.

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THANK YOU!

For further information or support contact:

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