Navigating the Quality Management System Regulation

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Hello. My name is Tonya Wilbon and I am the Assistant Director of the Division of Industry and Consumer Education in the Center for Devices and Radiological Health, at the U.S. Food and Drug Administration. Welcome to CDRH Learn, FDA's preeminent catalog of mult-media educational modules about regulatory requirements pertaining to medical devices and radiation emitting products!

The title of this presentation is "Navigating the Quality Management System Regulation."

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The Overview of the Quality Management System Regulation or QMSR, is divided into two parts. In Part 1, we provided a general overview of the QMSR. We encourage you to watch Part 1 before continuing with this module, Part 2, "Navigating the Quality Management System Regulation".

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The learning objectives for this presentation are to: discuss the purpose and scope of the Quality Management System Regulation (QMSR) as a review and for clarification; review the key requirements of the QMSR, including reference to ISO 13485:2016 and Clause 3 of ISO 9000:2015 standards; compare the requirements of the 1996 and 2024 regulations, Title 21 Code of Federal Regulations Part 820 (or Part 820); and finally, identify ways to adapt to these regulatory changes.

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Let's begin with reviewing the purpose and clarifying the scope of the QMSR.

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The QMSR ensures the ability to consistently manufacture devices that meet applicable regulatory requirements and device specifications.

It provides a framework for achieving quality throughout the organization, similar to the 1996 QS regulation; in general, it does not specifically tell manufactures how to implement requirements to achieve quality but provides this basic framework. Manufacturers are required to document and establish specific requirements based on the complexity and risk of the device and their establishment.

The QMSR assures that finished devices will be safe and effective and comply with the Federal Food, Drug, and Cosmetic Act, or the FD&C Act.

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The QMSR governs the methods used in and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for humans - so all activities needed and involved with finished devices intended for human use.

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Now let's take a closer look at the actual requirements within the QMSR. The requirements are included in Subpart A and Subpart B. Subparts C through O are reserved.

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Subpart A addresses the General Provisions of the regulation and begins with the scope under section 820.1.

The scope of the QMSR is not different than the scope of the QS regulation. The scope addresses the applicability of the QMSR, specifically, it applies to all finished devices intended for human use. It further clarifies its applicability by providing examples of functions performed by manufacturers that will subject them to the QMSR, including contract sterilization, installation, relabeling, and specification development.

The scope includes requirements for addressing any potential conflicts with other requirements under the FD&C Act or conflicts with clauses in the ISO 13485 standard and the FD&C Act or other FDA regulations. For example, the FD&C Act defines "device" and "labeling", and ISO 13485 also defines those terms. The scope clarifies that the definition in the FD&C Act supersedes the definition in the ISO 13485 standard.

It includes requirements pertaining to the refusal of admission of devices imported or offered for import by foreign manufacturers and includes the criteria for exemptions or variances from requirements within the QMSR.

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Requirements of section 820.3 of the QMSR pertaining to definitions specify that:
the definitions in ISO 13485:2016 and Clause 3 of ISO 9000:2015 apply except as specified in paragraph (b) of this section (820.3) and they do not affect the meaning of similar terms defined in Title 21 Code of Federal Regulations.

In addition, the regulation specifies that the 5 terms defined in section 820.3(a) apply and are either not used or not defined in ISO 13485:2016 and Clause 3 of ISO 9000:2015. Those terms specified are: component; Federal Food, Drug, and Cosmetic Act; Human cell, tissue, or cellular or tissue based product (HCT/P); and Remanufacturer. These definitions are retained from the requirements of the 1996 Part 820.3.

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The regulation specifies that all definitions in section 201 of the FD&C Act apply and they supersede correlating definitions in ISO 13485:2016. It gives the example of the terms "device" and labeling" that are defined in the FD&C Act and correlating terms of medical device and labeling defined in ISO 13485.

It specifies that the 5 terms defined in 820.3(b) apply and their definitions supersede the definitions for correlating terms in ISO 13485 or ISO 9000. The 5 terms defined are: Implantable medical device; Manufacturer; Organization; Rework; and Safety and performance.

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Section 820.7 clarifies that certain material is approved to be incorporated into the QMSR by reference, that is incorporation by reference or IBR, is made available for inspection at
the FDA and the National Archives and Records Administration (NARA), and includes the location, both physical and online.

The IBR material may also be obtained from the International Organization for Standardization (ISO).

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The requirements of 820.7 further specify that incorporation by reference to Clause 3 of ISO 9000:2015 is approved for section 820.3, Definitions.

The requirements also specify that incorporation by reference to ISO 13485:2016 is approved for sections 820.1, Scope, 820.3, Definitions, 820.10, Requirements for a quality management system, 820.35, Control of Records, and 820.45, Device Labeling and packaging controls.

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Requirements for a quality management system are codified in section 820.10 of the QMSR. Section 820.10 specifies requirements for documenting a quality management system that complies with applicable requirements of ISO 13485:2016 and for complying with other applicable regulatory requirements to ensure full compliance with the listed ISO 13485 clause. Other applicable requirements listed include, but are not limited to, complying with Part 830 (Unique Device Identification), Part 821 (Medical Device Tracking Requirements), Part 803 (Medical Device Reporting), and Part 806 (Medical Devices: Reports of Corrections and Removals). Again, these may not be the only other regulatory requirements that are applicable to ensure full compliance with ISO 13485.

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Section 820.10 specifies requirements for complying with Design and Development requirements of ISO 13485, Clause 7.3 and requirements for devices that support or sustain life according to Traceability for Implantable Devices of Clause 7.5.9.2 of ISO 13485. It specifically requires that manufacturers of Class II and Class III devices and the specific Class I devices listed in 820.10 (c)(1) and Table 1 of (c)(2), comply with Design and Development requirements.

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Section 820.10 specifies that adulterated devices, as well as the person responsible for the adulteration, is subject to regulatory action. A device is considered adulterated under section 501 (h) of the FD&C Act if it fails to comply with any applicable requirement of Part 820.

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Now let's navigate through Subpart B. Subpart B of the QMSR includes Supplemental Provisions for Control of Records and Device labeling and packaging controls.

Section 820.35, Control of records, specifies additional requirements for specific information that must be included in various types of records to ensure consistency and compliance with other parts of the FD&C Act. This includes documenting information for maintaining detailed records of complaints, documenting all servicing activities, and ensuring comprehensive records for each medical device or batch, which must include Unique Device Identifier (UDI). Additionally, it encompasses the management of records deemed confidential by the manufacturer and marked as such to aid FDA in ensuring sensitive information is securely handled and protected.

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And finally, section 820.45, Device labeling and packaging controls, sets forth the requirements for documenting and maintaining detailed procedures for both labeling and packaging. This includes

requirements for rigorous examination of labeling and packaging for accuracy and completeness before any products are released or stored. These measures ensure that all medical devices are correctly labeled and packaged and increase level of assurance that devices are safe and effective.

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In addition, section 820.45 specifies requirements for documenting the release of labeling for use in accordance with Clause 4.2.5 of ISO 13485. It requires the establishment and maintenance of labeling and packaging operations to prevent any mix-ups, ensuring the integrity and accuracy of product information. It requires that results of labeling inspections be documented as per Clause 4.2.5 of ISO 13485, thus ensuring that the device's label contains accurate information as specified in the medical device file.

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Successfully navigating the QMSR requirements is essential for maintaining regulatory compliance and ensuring product quality and involves several key steps: familiarize yourself with FDA regulations and applicable standards to ensure a comprehensive understanding of compliance expectations; conduct a thorough gap analysis to identify and address any discrepancies between current practices and regulatory requirements; implement robust documentation processes to maintain accurate and complete records; and foster a culture of compliance within the organization to ensure ongoing adherence to quality and regulatory standards.

By employing these general steps, your organization will have a path to begin to effectively implement the QMSR requirements, ensuring both compliance and the manufacture of safe and effective devices.

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Now let's briefly compare the requirements of the 1996 and the 2024 21 CFR Part 820 regulations.

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Here are a few key points when comparing the 1996 and 2024 Part 820 regulations:

- The title of the 2024 regulation was updated;
- The regulations were issued approximately 28 years apart; and
- Comparing the effective dates, the 2024 Part 820 will become effective 2 years after the 2024 Final Rule issued, whereas the 1996 Part 820 became effective 1 year after the 1996 Final Rule was issued.

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Overall, the 2024 Final Rule amends many of the provisions of the 1996 Part 820 and incorporates by reference requirements of ISO 13485:2016 and Clause 3 of ISO 9000:2015 for the 2024 Part 820. The 2024 Final Rule establishes additional requirements that clarify certain concepts in ISO 13485:2016 and ensures that inconsistencies with other applicable FDA requirements are not created for the 2024 Part 820.

Here you see that requirements for General Provisions and Design Controls are substantively similar with requirements for the 2024 Part 820 and have requirements that are incorporated by reference to ISO 13485:2016. Requirements for Document Controls are incorporated by reference for the 2024 Part 820 and include additional requirements in section 820.35 for controlling records.

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Requirements of the 1996 Part 820, Subparts F through J, were revised to be incorporated by reference to ISO 13485:2016 for these requirements: Identification and Traceability, Production and Process controls, Acceptance Activities, Nonconforming Products, and Corrective and Preventive action. This includes requirements that are linked to other regulations for the 2024 Part 820.

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Here again, requirements of the 1996 Part 820, Subpart K through O were also revised to be incorporated by reference to ISO 13485:2016. Requirements for Labeling and Packaging Control are incorporated by reference and include additional requirements in 2024 section 820.45, Device labeling and packaging controls. Requirements for Records and Servicing are also incorporated by reference to ISO 13485 and include additional requirements in the 2024 section 820.35 as well as links to other regulations.

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Adapting to regulatory changes is crucial for maintaining compliance and moving towards greater global harmonization.

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Here are a few ways to adapt to regulatory changes to promote consistency in the regulation of devices as well as maintaining compliance:

- Identify and thoroughly understand the new regulatory changes to ensure you are aware of all new requirements. This will include ensuring you obtain access to the regulation, standards and other supporting documents.
- Conduct a comprehensive gap analysis to compare current practices with the new regulation and standards.
- Identify any differences and areas that need adjustments.
- Revise existing processes and procedures to incorporate these changes, ensuring your operations remain compliant.

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Additionally, to adapt to regulatory changes, make sure you:

- Train employees on the revised processes and procedures to ensure they understand and can effectively implement the updates.
- Formally implement the new processes and procedures within your organization.
- And then monitor the implementation to ensure compliance, address any issues that arise, and make further adjustments as necessary to maintain regulatory compliance.

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There are several resources available to assist in navigating the QMSR and that were referenced during this module. The actual 2024 Final Rule that contains the QMSR is linked on this slide as well as the ISO standards along with other supporting documents.

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In Summary: the Quality Management System Regulation (QMSR) specifies requirements that provide assurance that devices are safe and effective; it incorporates by reference ISO 13485:2016 and Clause 3

of ISO 9000:2015 standards; and all definitions in section 201 of the FD&C Act and in the QMSR supersede correlating definitions in ISO 13485 and Clause 3 of the ISO 9000 standards.

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Let's conclude with your call to action. Embrace these continuous efforts of harmonization. Familiarize yourself with the following documents: 2024 Final Rule, QMSR, ISO 13485:2016, and Clause 3 of ISO 9000:2015. Conduct a gap analysis of your current procedures to identify any gaps in meeting the regulatory requirements. And finally, engage in continuous training on implementing the QMSR.

Thank you for your attention to this module, "Navigating through the Quality Management System Regulation."

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