Overview of the Quality Management System Regulation

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Hello. I'm Joseph Tartal, Deputy 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 multi-media educational modules about medical devices and radiological products!

In this module, we'll present an Overview of the Quality Management System Regulation. This regulation is part of the Final Rule, "Medical Devices; Quality System Regulation Amendments." I'll use both terms, as well as "2024 Final Rule" throughout this presentation.

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There are many great quotes about quality. This one speaks to me when I think of good quality management systems for medical devices. "*Quality is never an accident; it is always the result of intelligent effort."* And the same can be said for the Quality Management System Regulation. As you'll learn, it is both intentional and intelligent; and its construct makes it easier to have a single, harmonized quality management system in a global landscape.

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We have developed two modules to help you understand the Quality Management System Regulation or QMSR. In this module, Part 1, I'll provide an overview of the Final Rule. In Part 2, we'll walk through and navigate some of the details of the QMSR.

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Let's get into our learning objectives. First, I will discuss the Final Rule, including its Preamble. Then I'll provide an overview of the Quality Management System Regulation. Third, we'll identify some important definitions and their hierarchy of application; and finally, I'll review some FDA activities to implement the rule.

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Let's start with a discussion of the 2024 Final Rule.

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On February 2nd, 2024, FDA published the Final Rule, titled "Medical Devices; Quality System Regulation Amendments" in the Federal Register. A link to the Final Rule is provided at the bottom of this slide. I encourage you to read the rule. You may download a pdf printable version as well.

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Prior to issuing the Final Rule, FDA issued a Proposed Rule, whose purpose was to notify the public of our intent to issue this regulation and to solicit public comment. As part of the issuance of the 2024 Final Rule, it explains the FDA's final regulatory framework, including the background on how the public was engaged in this rule making process and why this regulation was needed.

The preamble of the Final Rule summarizes 83 public comments that FDA received on the Proposed Rule and FDA's responses to those comments. I strongly encourage you to read through the preamble as this

provides some useful insight, context and understanding into FDA's thinking and intent with the issuance of the 2024 Final Rule.

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The 2024 Final Rule revises the Quality System Regulation that was published in October of 1996. This regulation was established in 21 Code of Federal Regulations, or CFR, Part 820. We refer to the 1996 regulation as the QS regulation.

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The 2024 Final Rule revises Part 820, including an update to the regulation title, which is renamed the "Quality Management System Regulation." The Final Rule further harmonizes quality system principles by converging its requirements with international efforts and principles, including current thinking regarding "risk". A harmonized rule makes it easier for global manufacturers to have a single quality management system that efficiently meets global regulatory requirements.

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The transition period from the 1996 Quality System Regulation to the 2024 Quality Management System Regulation is two years. The QMSR effective date is February 2, 2026. This means that all manufacturers that market medical devices in the US must be compliant with the QMSR by February 2, 2026.

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Now, I will provide a brief and high-level overview of the quality management system regulation.

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As you read through the QMSR, you'll find that most of the requirements from the 1996 QS regulation have been revised. However, the 2024 QMSR retains the scope and some of the definitions from the 1996 QS regulation.

From the scope, you'll find that you still decide the needs of your quality management system. You still have the flexibility in using your device, the risk of your device, its complexity, your manufacturing processes, and the risk those processes pose to your device and their complexity, and the size and make up of your company among others as factors when documenting your quality management system.

Also, the regulation includes conforming edits to Part 4 for combination products and the change does not impact the cGMP requirements for combination products.

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Here I outline the new regulation. I recommend getting used to the new format of the QMSR as well as becoming familiar with the structure of the ISO 13485:2016 standard. We have the scope and definitions in 820.1 and 820.3, respectively. This is followed by the incorporation by reference section found in 820.7. Following this, we have the requirements for a quality management system in 820.10, control of records in 820.35, and device labeling and package controls in 820.45. These additional requirements in the regulation will be further explained in the next learning module. Navigating the Quality Management System Regulation. Note that the regulation includes some numbers that are reserved. This means that these regulation sections are identified and have no details at the time of the publication of the 2024 Final Rule. We may provide details in these sections in the future.

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To keep things as simple as we could, we incorporated by reference ISO 13485:2016. This is not a transition or adoption of the standard; it is an incorporation by reference of called out provision to ensure consistency with applicable U.S. FDA requirements, including definitions.

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Additionally, ISO 13485 has a normative reference which we incorporated by reference into the regulation. This reference is ISO 9000:2015, Quality management systems--Fundamentals and vocabulary clause 3, and it contains terms and definitions necessary for the application of ISO 13485.

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Where can you find these standards? Read-only versions can be found at the link noted here on the slide. The link is also in the Final Rule. You can also purchase copies of the standards from the American National Standards Institute, or ANSI.

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You may ask, what happens when the ISO 13485:2016 standard is updated? Any future changes to the standards will need to be evaluated and if needed those changes will need to be addressed through further rule making.

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Next, let's discuss definitions.

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One of the things I found important to understand is how the different definitions are laid out and their hierarchy. In the next few slides, I'm going to talk through a flow chart on how these definitions are linked to one another and their hierarchy. At the top of the hierarchy, and in this slide, we have the Food, Drug and Cosmetic Act, or the FD&C Act, the law. Section 201 of the FD&C Act has definitions that impact the QMSR, such as 201(h), which is the definition of a medical device.

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Next, below the FD&C Act on the slide, and next in hierarchy from the law, is the regulation and the definitions within it, which are under section .3 of the QMSR. As you see in the regulation, it also explains which definitions supersede those in the standard and which ones are terms not defined in the standard but defined by FDA.

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Then last, and completing our flow chart in this slide, we have the definitions in the standards themselves. We have the terms and definitions found in clause 3 of ISO 13485:2016 and then those of clause 3 of ISO 9000:2015. These definitions, like the standards themselves, are incorporated by reference.

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The QMSR identifies which definitions supersede, the definitions found in the various standards. These superseding definitions include all of those found in Section 201 of FD&C Act, such as the definitions for a medical device and labeling.

In addition, we have terms defined in the Code of Federal Regulations, such as "implantable medical device," and various terms defined in the QMSR itself, such as "manufacturer," "organization" and "rework."

And notably, the QMSR uses the phrase "safety and performance" instead of "safety and effectiveness."

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Finally, we have terms that are not in the standards and are included in the QMSR. These terms are specific to FDA and include the "Federal Food, Drug and Cosmetic Act," "component," "finished device," "human cells," "tissues based/products regulated as a device" and "remanufacturer."

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Let's wrap up this overview by going over some of the FDA activities to implement the 2024 Final Rule.

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Let's start with FDA inspections. It's important to explain that FDA retains its inspectional authority. As a result of an inspection, FDA will not issue certificates of conformance to ISO 13485:2016; and manufacturers who hold a certificate of conformance to ISO 13485:2016 are not exempt from being subject to FDA inspections. Keep in mind that FDA will not require ISO 13485 certificates.

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As a result of this rule, FDA will update various technological systems. FDA will also revise and develop relevant policies, procedures, inspection process and other documents impacted by this rulemaking. These include the compliance program guide, guidance documents, standard operating procedures, and work instructions.

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FDA will train internal FDA personnel about the 2024 Final Rule, and will issue public communications, and conduct external education, like this CDRH Learn module that you're viewing now.

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On this slide, I list a few of the resources that I referenced during this presentation and the slide where I noted the topic.

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Now I will summarize what we covered in this module.

FDA has issued the 2024 Final Rule, which is titled the "Medical Devices; Quality System Regulation Amendments." The rule includes the preamble that provides some background on FDA's review of public comments and thinking that led to the rule. The Final Rule also includes the QMSR. The QMSR incorporates by reference two standards: ISO 13485:2016 and ISO 9000:2015 clause 3.

The 2024 Final Rule and QMSR include a hierarchy of definitions. And finally, FDA will conduct various activities while implementing the rule and retains its inspection authority.

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This is your call to action. Read the 2024 Final Rule, including the preamble. Review the QMSR and use all the available educational resources to help you implement it. And finally, watch Part 2 of this CDRH Learn module series, titled "Navigating the Quality Management System Regulation".

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I started with a quote on quality, and I will conclude with one on success, "Success is the sum of small efforts, repeated day-in and day-out."

Every day, work is done in your quality management system. We know quality matters and it impacts the devices developed and manufactured. This requires a daily effort and includes understanding regulatory requirements for quality.

Thank you for your attention during this module: Overview of the Quality Management System Regulation.

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