Quality Management System Regulation: Key Takeaways
December 16, 2025

Moderator: CAPT Kim Piermatteo
Panelists: Keisha Thomas, Karen Masley-Joseph, Tonya Wilbon, Joseph Tartal and CAPT Kimberly Lewandowski-Walker

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CAPT Kim Piermatteo: Hello everyone and welcome to today's CDRH Webinar. Thanks for joining us. This is CAPT Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within CDRH. I'll be the moderator for today.

For this webinar, we will be highlighting key takeaways of the Quality Management System Regulation or QMSR, and address frequently asked questions regarding this topic. I'd now like to introduce our panelists.

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Keisha Thomas, Associate Director for Compliance and Quality in CDRH's Office of Product Evaluation and Quality; Karen Masley-Joseph, Senior Advisor in the Office of Medical Devices and Radiological Health within FDA's Office of Inspections and Investigations; Tonya Wilbon, Assistant Director for Postmarket Industry Education and Consumer Education in the Division of Industry and Consumer Education in CDRH; Joseph Tartal, Deputy Division Director of the Division of Industry and Consumer Education in CDRH; and CAPT Kimberly Lewandowski-Walker, Regulatory Officer on the FDA Inspections and Regulatory Audits Team in the Office of Regulatory Programs in the Office of Product Evaluation and Quality in CDRH.

Thank you all for joining today. We'll begin with a presentation from Tonya and then have a moderated panel discussion with frequently asked questions about the QMSR.

Before I turn it over to Tonya, I'd like to provide a few reminders. First, the intended audience for this webinar is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom. Second, we will not be taking questions from our attendees today, therefore, please refrain from raising your hand in Teams. And lastly, for those of you who might want to follow along, you may access printable slides of today's presentation from CDRH Learn at www.fda.gov/Training/CDRHLearn under the section titled "Postmarket Activities," sub-section "Quality Management System Regulation."

Again, thank you all for joining us today. I'll now turn it over to Tonya.

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Thank you Kimberly.

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As previously mentioned, today's discussion will focus on key takeaways of the Quality Management System Regulation or QMSR, including answers to several questions received in general and based on

two modules currently posted on the FDA CDRH Learn webpage that are titled “Overview of the Quality Management System Regulation” and “Navigating the Quality Management System Regulation.”

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Before we begin the discussion, I will review QMSR key takeaways. The Final Rule that issued February 2nd, 2024, amends the Quality System Regulation codified at 21 Code of Federal Regulations Part 820. You can find the complete rule on the federal register.gov website and by typing in the search box medical devices, Quality System Regulation Amendments.

The QMSR aligns our requirements with the international consensus standard for medical devices to continue to promote consistency in the regulation of these devices. This regulation becomes effective on February 2nd, 2026, allowing manufacturers approximately two years to transition their quality systems to meet the requirements of the QMSR. It incorporates by reference two key international standards; ISO 13485:2016, English version, which specifies requirements for a quality management system and Clause 3 of ISO 9000:2015, English version, which provides the fundamental vocabulary for quality management systems.

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Another QMSR key takeaway is that the Final Rule establishes a clear hierarchy for how definitions will be applied under the new QMSR. All definitions in Section 201 of the Federal Food, Drug, and Cosmetic Act, the FD&C Act, apply and these definitions supersede those correlating terms and definitions found in ISO 13485:2016 and Clause 3 of ISO 9000:2015.

When there are conflicts or differences in terminology, definitions in the FD&C Act take precedence, followed by terms defined in the QMSR, then other existing FDA regulations.

To support implementation of the Final Rule, FDA will revise or develop relevant policies, procedures, inspection processes, and other regulatory documents that are impacted by this rulemaking. This includes updates to FDA compliance programs, guidance documents, and internal operating documents such as standard operating procedures, work instructions, and templates. Collectively, these updates are intended to ensure consistency in FDA oversight and to provide clarity for manufacturers as they transition to and maintain compliance with the QMSR.

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The QMSR applies to all finished devices intended for human use that are regulated by the FDA. In addition, QMSR applies not only to traditional device manufacturers, but also to entities that perform certain manufacturing-related functions. Examples of these functions include contract sterilization, device installation, relabeling, and specification development.

As a result, organizations performing any of these activities are considered manufacturers under FDA regulations and are expected to establish and maintain a compliant quality management system appropriate to their role in the device lifecycle.

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An additional QMSR key takeaway is that the key requirements of the QMSR are included in six sections of 21 CFR Part 820: Section 820.1 defines the scope of the regulation; Section 820.3 provides definitions; Section 820.7 addresses incorporation by reference, formally incorporating ISO 13485:2016; and Clause 3 of ISO 9000:2015 into the QMSR; Section 820.10 specifies the requirements for a quality management system; and Sections 820.35 and 820.45 includes additional requirements for control of records and device labeling and packaging controls.

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The scope of the QMSR addresses the applicability of the QMSR, specifically, it applies to all finished devices intended for human use. It includes requirements for addressing any potential conflicts with other requirements under the FD&C Act or conflicts with clauses in the ISO 13485:2016 standard and the FD&C Act or other FDA regulations. The scope 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. A key takeaway is that the scope of the QMSR is not that different than the scope of the current QS regulation.

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Yet another QMSR key takeaway is that 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 basically all activities needed and involved with finished devices intended…

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…for human use.

A few more QMSR key takeaways are that 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 QS regulation; in general, it does not specifically tell manufactures how to implement requirements to achieve quality but provides this basic framework. The QMSR assures that finished devices will be safe and effective and comply with the FD&C Act.

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The next few slides provide a few more QMSR key takeaways about the QMSR requirements for a quality management system. Requirements for a quality management system are included 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 13485:2016.

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Section 820.10 of the QMSR also specifies requirements for complying with Design and Development requirements of Clause 7.3 of ISO 13485:2016 and requirements for devices that support or sustain life according to Traceability for Implantable Devices of Clause 7.5.9.2 of the ISO 13485:2016 standard.

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. Similar to the QS Regulation. Section 820.10 also 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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The QMSR includes additional requirements for Control of records as required by Clause 4.25 of ISO 13485:2016 and Control of production and service provisions required by Clause 7.5.1 of ISO 13485:2016.

These additional requirements are included in Section 820.35, Control of records of the QMSR and Section 820.45 for Device labeling and packaging controls of the QMSR.

A key takeaway for the requirements for Control of records is that they include additional requirements for specific information that must be included in various types of records, such as records of complaints and records of servicing activities, to ensure consistency and compliance with other parts of the FD&C Act.

A key takeaway for the additional requirements for Device labeling and packaging controls, include requirements for documenting and maintaining detailed procedures for both labeling and packaging including requirements for rigorous examination of labeling and packaging for accuracy and completeness before any products are released or stored.

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Now there are two additional modules that are related to todays' QMSR topics for discussion currently posted on CDRH Learn webpage titled, "Risk Management, Risk-Based Approach, and Risk-Based Decisions" and "Design and Development." These modules are located under the Postmarket Activities section of the CDRH Learn webpage.

I now turn it back to Kimberly Piermatteo to begin the discussion.

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CAPT Kim Piermatteo: Thanks Tonya for that presentation. We will now transition to our moderated panel discussion.

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CAPT Kim Piermatteo: As I mentioned earlier, for today's panel discussion, I'll read a frequently asked question regarding our topic and then ask a panelist to respond.

So Keisha, the first question I have, I'm going to direct to you and Keisha that question is, where do I access ISO 13485, year 2016 and ISO 9000, year 2015?

Keisha Thomas: Yes, hi Kim. Thank you for that question. You can access ISO 13485:2016 in the incorporation by reference portal as a read only document that is listed. That website is listed where you can get it in the final rule, but it's ibr.ansi.org/Standards/iso1.aspx. The ISO 9000:2015 standard is available for viewing without cost at the ISO standards website at www.iso.org, and you can look for ISO 9000:2015 there.

CAPT Kim Piermatteo: Thanks Keisha. Alright, Karen, I'm going to come to you next. The question is, will FDA start enforcing the QMSR on February 2nd, 2016 or sorry 2026?

Karen Masley-Joseph: Thanks for the question, Kim, and hi everybody. Yes, the Medical Devices Quality System Regulation Amendments final rule was published on February 2nd, 2024, with an effective date two years later, which is coming up quickly on February 2nd, 2026. So in that final rule, it states that the amended regulation will be titled the Quality Management System Regulation or QMSR and the QMSR will be effective February 2nd, 2026. So again, yes, the FDA will begin enforcing the QMSR requirements on February 2nd, 2026. Thanks.

CAPT Kim Piermatteo: Thanks Karen. Okay, Kim, the other Kim, I'm going to come to you for our next question and this question has two parts. So I'll read part one and let you respond and then I'll read part

two and you can respond. So for part one, the question is, does having an ISO 13485 certification mean I'm automatically compliant with the QMSR?

CAPT Kimberly Lewandowski-Walker: Oh thank you. Excellent question. No, ISO 13485 certification by itself does not ensure compliance to the QMSR. Manufacturers must comply with all requirements in the QMSR, any other applicable provisions of the Federal Food, Drug, & Cosmetic Act, and its implementing regulations. FDA will not accept ISO 13485 certifications in lieu of conducting our own assessment of a manufacturer's compliance with quality management system requirements during inspections.

CAPT Kim Piermatteo: Thanks, and now for part two. So part two, the question is, does compliance with the QMSR mean that I am certified to ISO 13485?

CAPT Kimberly Lewandowski-Walker: Oh another great question. So the answer here is no. FDA inspections will not result in the issuance of a certificate of conformity to ISO 13485. Back to you.

CAPT Kim Piermatteo: Great. Thanks Kim. Alright, Joe, I'm going to come to you with the next question, which is, are existing Good Manufacturing Practice or GMP exemptions set forth by individual classification regulations superseded by the QMSR?

Joseph Tartal: Hello all and thank you Kim. DICE has seen this question a few times. And the answer is they are not superseded by the QMSR. Existing good manufacturing practice or GMP exemptions remain under the QMSR. The Code of Federal Regulations will be updated to reflect the Quality Management System Regulation and current exemptions continue to apply.

And this is also noted in the new Medical Devices; Quality Management System Regulation Technical Amendments that were published earlier this month and can be found in the Federal Register. Back to you Kim.

CAPT Kim Piermatteo: Thanks Joe. Alright, our next question, I'm going to direct towards Tonya. Tonya the question is, since FDA is incorporating by reference ISO 13485:2016, does that mean that FDA is also incorporating by reference additional standards referenced in ISO 13485?

Tonya Wilbon: Great question and hello again everyone. As previously indicated, of course the QMSR is incorporating by reference ISO 13485:2016 and Clause 3 of ISO 9000:2015. Other standards referenced are voluntary, as usual, and FDA does not, in this rulemaking, incorporate any other standards referenced by, or even listed as a source in ISO 13485, such as the ISO 14971 that is referenced in the ISO 13485 as a note, so only the ISO 13485 and Clause 3 of ISO 9000. Thank you.

CAPT Kim Piermatteo: Thanks Tonya. Okay Keisha, the next question we have is, where can I access the final rule for the Medical Devices Quality System Regulation Amendments?

Keisha Thomas: Sure thing Kim. Currently, the final rule for QMSR is located in the Federal Register, so you have to go to the Federal Register site. You can do a search for medical devices, quality management system regulation amendments and you will access the final rule inclusive of the preamble and all the comments there. When the Quality Management System Regulation becomes effective on February 2nd, 2026, the actual codify of the regulation will be located in a Code of Federal Regulations, in 21 CFR Part 820 currently, where the Quality System Regulation is and that will be replaced with the Quality Management System Regulation.

CAPT Kim Piermatteo: Great, thanks Keisha. Alright, for our next question, I'm going to go to Karen. Karen, that question is, will there be a new inspection process?

Karen Masley-Joseph: Yeah, thanks Kim. This is one of my favorite questions and one that I hear a lot being from the FDA inspectorate office. So the answer is yes, the FDA will have a new inspection process and that process will be aligned with the requirements of the QMSR. On February 2nd, 2026 the current

inspection process which is currently known as the Quality System Inspection Technique or QSIT, QSIT will be withdrawn, and FDA will implement the new QMSR aligned inspection process. So thanks for the question.

CAPT Kim Piermatteo: Thanks Karen. Okay, the next question I'm going to direct to Kim. Kim that question is, now that FDA has incorporated by reference ISO 13485:2016, what happens if the standard is revised?

CAPT Kimberly Lewandowski-Walker: Thank you for that. So the FDA will evaluate any future revisions to the standard to determine the impact of any changes and whether we need to amend the QMSR. If appropriate, amendments to the QMSR will be implemented through the rulemaking process. The good news is, is that ISO officially confirmed the 2016 version of the standard for another five years. So therefore, ISO 13485:2016 will not be revised until at least April of 2030. Excellent question. Thank you for that.

CAPT Kim Piermatteo: Thanks Kim. Next up, Joe, the question I'm going to direct towards you is, are specific labeling requirements set forth in the previous QS regulation maintained in the QMSR?

Joseph Tartal: Thanks Kim. The QMSR retains specific labeling and packaging requirements from the quality system regulation. These include examining the label to ensure it contains accurate unique device identifiers, UDI, or universal product code, UPC, expiration dates, storage instructions, handling instructions, and any additional processing instructions. Manufacturers must document procedures to ensure labeling accuracy and prevent mix-ups during packaging operations. Thanks Kim.

CAPT Kim Piermatteo: Thanks Joe. Okay, for our next question, I'm going to direct that to Tonya. Tonya, the question is, the QMSR specifies requirements for inspection of labeling and packaging prior to release or use. Is manual inspection required or can automated method be used?

Tonya Wilbon: Thank you Kim. Yes, another great question. And as mentioned as a QMSR takeaway, FDA included additional requirements for labeling and packaging devices, in 820.45, that were not specifically addressed in ISO 13485:2016. FDA retained the requirements to inspect labeling and packaging for accuracy before use, document the inspection and release of the labeling to ensure that all devices have correct labeling and packaging and to prevent errors.

So the requirement to inspect labeling and packaging does not preclude automatic readers where the process is followed by human oversight. FDA further clarifies that a designated individual, though, must examine, at a minimum, a representative sampling of all labels that have been checked by automated readers. So that was a great question. Thank you.

CAPT Kim Piermatteo: Thanks Tonya. Okay, the next question I'm going to direct to Keisha. Keisha that question is, what does "reserved" mean in the QMSR regulation?

Keisha Thomas: Thanks Kim. This is a really good question. I'm sure people have read the QMSR so far have noticed that listed within the I think it's the CFR, might be in the actual rule itself. There are sections that are denoted as reserved. Reserved is a placeholder term used in the Code of Federal Regulation to indicate that the FDA may insert regulatory information into that location in the future. What it means is it was intentionally left empty right now so that we did not use it currently. It also indicates that a portion of the Code of Federal Regulations will be intentionally left empty and not accidentally omitted due to printing or computer errors. So we have seen this question a multitude of times regarding what reserve means. That just means we're not using that specific site and that site is being reserved for either use in the future or intentionally left empty.

CAPT Kim Piermatteo: Thanks Keisha. Very important there. Okay, for the next question, I'm going to direct it to Karen. Karen, the question is, where do I find information about the new inspection process for QMSR?

Karen Masley-Joseph: Yeah, thanks Kim. Happy to answer that one and thanks for another great question related to inspections. The QMSR inspection process it will be documented in a revised version of the Compliance Program, which is titled Inspection of Medical Device Manufacturers. This revised compliance program will be effective on February 2nd, 2026, and it will be available on the Center for Devices and Radiological Health Compliance Program FDA webpage. So that's the CDRH compliance program webpage at FDA.gov and that's it. Back to you, Kim.

CAPT Kim Piermatteo: Thanks Karen. Okay, so for our next question, I'm going to direct that to Kim. And Kim, the question is, how does the QMSR impact combination products?

CAPT Kimberly Lewandowski-Walker: Oh, thank you for that. So the QMSR does includes conforming edits to Part 4, which is 21 CFR Part 4, for combination products. It should be noted that these changes do not impact the current good manufacturing practice requirements for combination products. Thank you.

CAPT Kim Piermatteo: Thank you for that clarification. Alright Joe, the next question we have is, do manufacturers retain their flexibility under the QMSR regarding their quality management systems?

Joseph Tartal: So thanks Kim for that question. One of the things that I love about the quality system regulation and now is retained in the QMSR is that we retain that scope allowing manufacturers that flexibility in designing their quality management system. They own it and they need to meet the requirements in the regulation, but they have the flexibility in designing that system based on factors such as what type of device it is, what is the risk of that device, what's the complexity of the device, what are the manufacturing processes, what are the risk and complexities of those manufacturing processes, and of course, the size and makeup of the different company. So yes, they get to retain that great flexibility and determine what suits them best as long as they meet all the requirements in the regulation itself. So thank you, Kim.

CAPT Kim Piermatteo: Thanks Joe. Alright, our next question Tonya, I'm going to come to you. And the question is, does specific identifying information need to appear on each batch or lot of a product?

Tonya Wilbon: Yes, hi. Thanks again Kim, for another great question. And again, as I mentioned in the QMSR key takeaways, there were additional requirements for control of records. Section 820.35 requires that for each medical device or batch of medical devices, the Unique Device Identification, or the UDI, must be recorded. This is in addition to complying with the requirements of ISO 13485:2016 standard in Clauses 7.5.1, Clause 7.5.8, and Clause 7.5.9. This ensures, of course, comprehensive traceability and accountability for every device that is produced**.** So yes, there are some additional information that must be included. Thank you for that question.

CAPT Kim Piermatteo: Thanks Tonya. Okay, I have a few more questions for our panel today. The next question I'm going to direct towards Joe. And Joe, the question is, how can industry prepare for the regulation change?

Joseph Tartal: So thanks Kim. If you had a chance to look at the presentation, "Navigating the Quality Management System Regulation," it notes a few helpful steps in there that manufacturers can identify and understand the regulatory changes, so you need to know what the rule and the new reg is. Then conduct a gap analysis to identify the differences and update your quality management system. Revise the processes and procedures to incorporate those changes. Then train staff on those revised processes and procedures; and implement those new processes and procedures; as well as monitor that implementation to make sure that these is the implementation that you wanted.

So hopefully that helps with the different manufacturers out there as they prepare for this change or as they've been preparing for the last two years for this change as it becomes effective February 2nd. Back to you Kim.

CAPT Kim Piermatteo: Thanks Joe. Okay, I'm going to come to Tonya next. And Tonya, the question that I have for you is, are the requirements of 21 CFR 820.180 and 820.198 in the QS regulation still applicable under the new QMSR?

Tonya Wilbon: Thanks again Kim. So for clarification, under the Quality Management System Regulation or QMSR, although general requirements concerning records under 820.180 and complaint files under 820.198 are no longer numbered, the requirements remain, and manufacturers may meet the requirements set forth in those sections by complying with, among other things, 820.35 for control of records and the records and complaint handling portions of ISO 13485. For example, in the QMSR, requirements for records of complaints can be found in 820.35(a) and Clause 8.2.2 of ISO 13485 as incorporated by reference. So while the specific numbering of 820.180 and 820.198 are not included in QMSR, those requirements are. Thank you again.

CAPT Kim Piermatteo: Thanks Tonya. Okay, Keisha, the next question I'm going to direct towards you and that question is, FDA's response to Comment 29 in the preamble to the final rule states that "After consideration, we have included in Section 820.3 one definition for batch" or lot consistent with the definition of these terms in Section 820.3(m) of the QS regulation." Some stakeholders have stated they searched the QMSR for the terms batch and lot but did not find a definition. Will this definition be added to the QMSR prior to its effective date of February 2nd, 2026?

Keisha Thomas: Yes, so the preamble accurately states the Agency's intention. However, we have now corrected the missing information in the technical correction for the Medical Devices; Quality System Regulation Amendments, that was published in October 2024. So there was an admission administrative error and that error has been corrected. It has now been updated and that technical correction actually has the appropriate information that was omitted previously.

CAPT Kim Piermatteo: Great, thanks Keisha. Very helpful. For our next question, I'm going to come to Kim. And Kim, that question is, is there anywhere to obtain a comparison between the Quality System Requirements and the QMSR?

CAPT Kimberly Lewandowski-Walker: Oh, thank you for that question. So FDA, at FDA we do not have a formal side by side comparison between the requirements in the Quality System regulation and the QMSR. So as manufacturers you would need to perform an appropriate gap analysis for your system and identify those gaps and comparative sections.

CAPT Kim Piermatteo: Thanks Kim. And Joe, we have one last question and I'm going to direct that to you. And Joe, the question is, will an Investigational Device Exemption or IDE, which has been approved under 21 CFR 812, still require compliance with Design Controls when the QMSR becomes effective?

Joseph Tartal: So thanks Kim. I've seen this question come up and I've seen it come up a couple different times. The short answer is yes. IDEs approved under 21 CFR 812 will be required to comply with Design and Development requirements in the QMSR. So if you look through the quality system regulation talks about design controls now in the QMSR we're talking about design and development. But both will be required when you're doing your investigational device exemption because when you're doing any type of design work, it's not retrospective, you're doing it prospectively. So the short answer is yes, you're going to have those eight, underneath of 812, you'll do design and development requirements in the QMSR. Under 21 CFR 820.10(c), which directs manufacturers to the requirements set forth in ISO 13485, Clause 7.3. And I hope that that helps it clear up that question, that that comes up. So with that, turning it back to you Kim.

CAPT Kim Piermatteo: Thank you Joe, and thank you Tonya, Keisha, Karen, and Kim. That will wrap up our panel discussion for today.

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CAPT Kim Piermatteo: At this time, I am going to turn it back over to Tonya to provide some final thoughts regarding today's topic. Tonya.

Tonya Wilbon: Okay, thank you again Kim and thank you to everyone for joining today's QMSR key takeaways webinar. I hope you found the information very helpful and useful as you begin to transition to the QMSR.

I would like to leave you with a call to action. I would encourage you to embrace a culture of quality and continuous efforts of global harmonization; read the 2024 Final Rule including the preamble and read and familiarize yourself with the QMSR, ISO 13485:2016 version, and Clause 3 of ISO 9000:2015. I'd encourage you to conduct a gap analysis of your current quality management system procedures to identify any gaps in meeting regulatory requirements. And then as another call to action, I would encourage you to review additional resources available for implementing the requirements of the QMSR, as we've mentioned earlier today.

Thank you again for joining this webinar and I will now turn it back to Kimberly Piermatteo.

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CAPT Kim Piermatteo: Thanks Tonya. Before we conclude today's webinar, I would like to remind everyone a recording of today's webinar and a transcript will be posted in the next week or so to the webinar event page, as well as to CDRH Learn under the section titled "Postmarket Activities," and the sub-section "Quality Management System Regulation." A screen shot of where you will be able to find these materials on CDRH Learn is provided on this slide.

If you have specific questions about the QMSR final rule, feel free to email QMSR-Rule@fda.hhs.gov. If you have additional general regulatory questions regarding today's webinar, feel free to reach out to DICE at DICE@fda.hhs.gov.

And lastly, I encourage you to monitor our CDRH Events webpage for a list of upcoming CDRH Events, including future webinars and town halls at www.fda.gov/CDRHevents.

Thank you all again for joining us. This concludes today's CDRH Webinar.

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