Quality Management System Regulation: Risk & Design and Development
January 14, 2026

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

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CAPT Kim Piermatteo: Welcome to today's CDRH town hall event. 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 town hall, we will discuss how the Quality Management System Regulation, or QMSR, addresses risk management, risk-based approach, risk-based decisions, and design and development. We will also address frequently asked questions regarding these topics through a moderated panel discussion.

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I'd now like to introduce our panelists; 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; 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.

I welcome you all and appreciate you serving as a panelist today.

Before I turn it over to Tonya to get us started, I'd like to provide a few reminders. First, the intended audience for this event 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. And second, for this MS Teams Town Hall event please note mobile web browsers aren't supported. The full Teams mobile app is required. Additionally, when using the Teams mobile app, if you are unable to see the presentation slides, please try selecting the participant icon or attendees button which should appear on the top of your mobile device screen. Once selected, you should be able to see the slides in a minimized mode, but if you click on the actual slides they should enlarge so you can see them better.

We appreciate your patience as we transition to these new platforms for our events, and as always we will try to get the presentation and full transcript posted as soon as possible following the event, so you'll have access to those.

Thank you all again for joining us today. I'll now turn it over to Tonya to start today's presentation.

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Thank you Kim.

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As previously mentioned, today's discussion will focus on Quality Management System Regulation, or QMSR, Risk and Design and Development including answers to several questions received in general and based on two modules currently posted on the FDA CDRH Learn webpage that are titled "Risk Management, Risk-Based Approach, and Risk-Based Decisions" and "Design and Development."

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On December 16, 2025, CDRH hosted a public webinar that focused on QMSR Key Takeaways. The session provided a summary of two modules that are also posted on the FDA CDRH Learn webpage titled, "Overview of Quality Management System Regulation" and Navigating the Quality Management System Regulation." A panel discussion followed the summary providing answers to questions received by CDRH in general and based on the two modules.

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Before we begin the discussion, I will summarize the modules for today's discussion topics, "Risk Management, Risk-Based Approach, and Risk-Based Decisions" and "Design and Development." As a reminder, the Final Rule issued February 2, 2024, amending the Quality System Regulation codified at 21 CFR part 820. Included on this slide is the link to that final rule that is located on the federal register.gov website. You can locate the rule 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 2, 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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Understanding key risk terms is crucial for implementing effective risk concepts in your quality management system. Risk is defined as the combination of the probability of occurrence of harm and the severity of that harm. This term describes what could go wrong, how likely it is to happen, and how serious the consequences would be.

Risk management is defined as the systematic application of management policies, procedures, and practices to the task of analyzing, evaluating, controlling, and monitoring risk. The term systematic used in the definition clarifies that this is a structured and documented approach to addressing risk.

These terms are defined in the American National Standards Institute, or ANSI, the Association for the Advancement of Medical Instrumentation, or AAMI, and the International Organization for Standardization, or ISO, thus the ANSI/AAMI/ISO 13485:2016 Standard titled, "Medical devices- Quality management systems- Requirements for regulatory purposes" and the ISO Standard 14971:2007 version which is referenced in this version of the ISO 13485 standard, titled, "Medical devices-Application of Risk Management to Medical Devices."

As indicated in FDA's response to comment nine of the preamble to the final rule, FDA does not, in this rulemaking, incorporate ISO 14971 or any other standards referenced by, or listed as a source in, ISO 13485, but acknowledges that these other standards may be helpful in understanding application of ISO 13485.

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Two additional key risk terms are risk-based approach and risk-based decision. Risk-based approach is defined as identifying risks and opportunities and focusing on preventing or reducing undesired effects. This is more of a proactive approach. Risk-based decision is defined as making a specific decision based on risk assessment and other criteria. The information obtained is actively used to drive decisions throughout the life of the device and throughout the quality management system.

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Risk management serves several core functions. It helps identify, assess, control, communicate, and review device risks to the quality management system process. It is integral to safe and effective devices and an effective quality management system. Risk management provides reasonable assurance of safety and effectiveness throughout the total product lifecycle, from design and development through postmarket surveillance and eventually discontinuation.

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Risk management provides a framework for sound decision-making within your quality management system. For example, it helps you identify which design outputs are essential for proper device functioning, guides continuous updates based on postmarket surveillance data, defines the extent of verification activities for purchased products, and determines the appropriate approach to software validation and revalidation activities proportionate to the associated risks with the use of the software.

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FDA makes it clear that quality culture starts at the top. In FDA's response to comment 27 in the preamble to the final rule, FDA clarifies that it is the expectation for medical device manufacturers, led by individuals with executive responsibilities, to embrace a culture of quality as a key component in ensuring safe and effective medical devices. FDA also states that this culture of quality meets regulatory requirements through specific behaviors, attitudes, activities, and processes. In other words, meeting regulatory requirements is not just about what is documented, but how quality is embedded into decision-making, accountability, and operations throughout the entire organization.

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In adopting ISO 13485, QMSR incorporates risk management throughout its requirements and emphasizes risk management activities and making risk-based decisions. These requirements for risk management, use of a risk-based approach, and making risk-based decisions are included throughout ISO 13485 including Clause 4.1 for General Requirements, Clause 6.2 for Human Resources but this is guidance and understanding, Clause 7.1 for Planning of product realization requirements, Clause 7.3 for Design and Development requirements and Clause 7.4 for Purchasing requirements.

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QMSR requirements for risk are also included in Clause 7.5 for Production and service provision requirements, Clause 7.6 for Control of monitoring and measuring requirements, Clause 8.2 for Monitoring and Measurement requirements, Clause 8.3 for Control of nonconforming product, and Clause

8.5 for Improvement. Notice how risk management permeates throughout the quality management system.

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There are several ways in which you can document your risk activities and decisions as depicted on this slide. You can use a Risk Management Plan which outlines the risk management scope, responsibilities, and criteria at the start of product development. You can use a Risk Analysis Report to identify hazards and estimate risks during design and development. Some risk information is captured using a Risk Evaluation Summary to document the justification of the acceptability of individual and overall risk during post analysis and before mitigation of the risk. A more popular example for documenting risk information is by use of a Risk Traceability Matrix which documents that risks are addressed and mitigated throughout the product lifecycle.

There is the Risk Management File which serves as a centralized record of all risk-related documentation maintained throughout the device lifecycle. Yet other examples of documenting risk is use of Design Review Meeting Minutes used during formal design reviews and Benefit-Risk Analysis Reports used when residual risks remain after controls are implemented.

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The QMSR includes requirements for design and development which is defined in ISO 9000: 2015 as a set of processes that transform requirements for an object into more detailed requirements for that object. The ISO definition further states that the terms design and development are sometimes used synonymously.

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Design and Development is important to medical device quality and safety. Manufacturers must maintain a design and development file for each medical device type or medical device family. This file provides documented evidence that design activities were planned, executed, reviewed, and controlled throughout the product lifecycle, and that the final design meets both user needs and regulatory requirements.

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21 CFR 820.10(c) of the QMSR includes requirements for Design and Development. Design and development requirements apply to all Class II and Class III medical devices and to the Class I medical devices specifically listed in the regulation. These include medical devices automated with computer software, tracheobronchial suction catheters, non-powdered surgeon gloves, protective restraints, manual radionuclide applicator systems and sources for radionuclide teletherapy.

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So, when should design and development begin? Manufacturers should document the flow of the design and development process so that it is clear where research ends and design and development begins. Design and development requirements are not intended to apply to feasibility studies or proof of concept. They are required prior to any investigational device exemption. They are required when changes are made to the device and are not intended to be retroactive.

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So there are several key stages to design and development. They include design and development planning, input, output, review, verification, validation, transfer to manufacturing, and changes. Together, these stages provide a structured, traceable approach to developing safe and effective medical devices.

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The next two slides list the clauses of ISO 13485, and the title of those clauses, that include requirements for design and development. They include Clause 7.1, Planning of product realization, Clauses 7.3.1 and 7.3.2, General and Design and development planning; Clause 7.3.3, Design and development inputs; Clause 7.3.4 Design and development outputs; and Clause 7.3.5, Design and development review.

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Additional requirements for design and development are included in Clauses 7.3.6 to 7.3.10 of ISO 13485 as listed on this slide with their respective titles.

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There are two additional modules that are related to today's QMSR Topic for discussion currently posted on CDRH Learn webpage titled, "Overview of Quality Management System Regulation" and "Navigating the Quality Management System Regulation." These modules are located under the Postmarket Activities Section of the CDRH Learn webpage.

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

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CAPT Kim Piermatteo: Thank you Tonya for your 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 will be reading a frequently asked question regarding today's topics and then ask a panelist to respond.

For our first question, I'll be directing that to Kim. Kim the question I have is, what are FDA's requirements for risk management activities for the class 1 devices exempt from design and development requirements?

CAPT Kimberly Lewandowski-Walker: Oh thank you, that's a great question to get us started off. So Class 1 devices exempt from design and development requirements remain required to maintain records of risk management activities for other aspects of product realization, including, but not limited to, risk management for the production process, purchased products and services, and labeling activities, as appropriate for the device. Additional requirements for risk management activities are included throughout ISO 13485 including in subclauses 4.1, 7.3, and 7.4.

CAPT Kim Piermatteo: Thank you Kim. For our next question I'll be directly that to Keisha. Keisha the question is, will the ISO 14971:2007 standard be available for free as read only similar to ISO 13485 and ISO 9000 clause 3 since it is referenced in the ISO 13485 standard?

Keisha Thomas: Hi Kim, thank you for the question. So no, ISO 14971 is not available for free, it is currently available for purchase. ISO 13485 and ISO 9000 clause 3 specifically, they are incorporated by

reference in the QMSR and those are available for free as read only through either the incorporation by reference website or the ANSI website.

CAPT Kim Piermatteo: Thank you Keisha. Okay, Karen, I'm going to come to you with the next question. Karen the question is, where is the definition of risk that applies to the QMSR?

Karen Masley-Joseph: Yeah, thanks for the question Kim and thanks for having me on the panel today. Yeah to answer that ISO 13485 does defines risk as the combination of the probability of occurrence of harm and the severity of that harm. So FDA does consider that term to be appropriate and we utilize that definition in the QMSR.

CAPT Kim Piermatteo: Thanks Karen. Okay, moving on to our next question. I will direct that to Tonya. Tonya, the question is, what are the requirements in ISO 13485 for who does design reviews? Another follow-up with this question is, is it accurate that there is no requirement for an independent reviewer at each stage in the QMSR?

Tonya Wilbon: Okay, thank you Kim for that question and thank you everyone for tuning in. The QMSR incorporates by reference ISO 13485:2016, as we've said earlier. Clause 7.3.5 of ISO 13485 requires design reviews to include representatives of functions concerned with the design and development stage being reviewed as well as other specialist personnel. But does not explicitly require independent reviewers. ISO 13485 also provides adequate flexibility for organizations to balance personnel resources while ensuring effective independent review. The Agency actually expects manufacturers to include appropriate personnel who can provide meaningful oversight of the design process. So thank you.

CAPT Kim Piermatteo: Thanks Tonya. Kim, I'm going to come back to you. And Kim the question is, what are FDA's requirements for documenting risk-based decisions within the manufacturer's QMS?

CAPT Kimberly Lewandowski-Walker: Oh, that's a great question. So an organization is required to apply a risk-based approach to the control of the appropriate processes needed for the quality management system as described in ISO 13485, subclause 4.1.2. Now FDA recognizes that depending on the complexity of the devices and the process used to manufacture the devices, different levels of risk exist to and within those various processes within the quality management system.

So for example, some types of complaints may be lower risk versus other types of complaints and you know, therefore, different levels of investigation and corrective actions would be appropriate for complaints that, for example, allege a harm to the patient or user. Versus complaints regarding maybe damaged outer carton packaging. Another example might be a device for which the entire design and manufacturing has been outsourced versus another device that is assembled from parts maybe machined in house and where all assembly is performed in house. So for the device where the entire device design and manufacturing is outsourced, the purchasing process in this case may have higher risk associated with it versus maybe for the company that machines the parts in-house. So FDA expects the manufacturer to document these types of risk-based decisions within the quality management system documentation and maintain it as set forth in subclause 4.2.5.

CAPT Kim Piermatteo: Thanks Kim. Keisha, I'm going to come to you with our next question. And the question is, the term Risk Management is used in ISO 13485, where the QS regulation used Risk Analysis, does this mean we are required to also conform to ISO 14971?

Keisha Thomas: Yeah Kim, this is a really good question. So there is no QMSR requirement that calls out conformity to ISO 14971. QMSR allows the flexibility for manufacturers to use any appropriately validated risk management process in order to carry out their risk management activities.

CAPT Kim Piermatteo: Thanks Keisha. Karen, I'm going to come back to you. So Karen, the question is, does a contract manufacturer who (a) meets the definition of a manufacturer and (b) is also not

responsible for medical device design and development, need to maintain risk management documentation under the QMSR?

Karen Masley-Joseph: Okay, Kim, thanks. Yeah, that's a good one. This one does come up since we do conduct inspections of these firms. So yeah, I'll get started on an answer. Let's see. So yes, a contract manufacturer, who meets the definition of a manufacturer, yes, they are required to maintain risk management documentation as set forth in ISO 13485 Clause 7.1, planning of product realization. Clause 7.1 requires manufacturers that of course, include contract manufacturers who meet the definition of a manufacturer, to document one or more processes for risk management and product realization and to maintain records of risk management activities, regardless of whether they are responsible or not for design and development.

So I have a little more to add on this one. While the contract manufacturers not explicitly required to maintain complete copies of the finished device manufacturer's management files, they must have sufficient information to fulfill their own risk management obligations under the QMSR. That kind of documentation, documentation between you know the finished device manufacturer and the contract manufacturer, that documentation should really establish each entity's risk management responsibilities.

And so I have a couple of examples of that, that I can think of. The finish device manufacturer should provide, should provide the product characteristics that are essential for safe and proper use of the device to help the contract manufacturer prioritize the risk management activities. And then the contract manufacturer should analyze their processes and perform risk management activities and provide related risk management documentation to the finished device manufacturer so that that can be integrated into that finished device manufacturer's risk management process. So it's kind of a back and forth and making sure everybody has agreements and understands their clear, you know, kind of roles and responsibility.

And then another thing I can think of which has a little bit more background is something that's FDA stated in the preamble to the rule. And actually I have a quote about that. So the quote from the rule is that "ISO prioritizes an effective quality system systematically identify, analyze, evaluate, control, and monitor risk throughout the product life cycle to ensure that the devices they manufacture are safe and effective." So that's again from the preamble, and since production is a critical component of the product lifecycle you know that's definitely included in that thought. So I hope that helps. Thanks Kim.

CAPT Kim Piermatteo: Thanks Karen. Very helpful, very informative. Moving on to our next question, I will be directing that one to Tonya. Tonya, the question is, does FDA require or expect quantitative information for describing risk?

Tonya Wilbon: Thank you Kim for that question as well. And this, of course is a relatively simple one that the simple answer is that there is no requirement in the QMSR or in ISO 13485 for a quantitative description of risk. However, if data is available, it may be very, very useful in you defining and quantifying your actual risk of that device. So it's helpful. It's just not required. Thank you.

CAPT Kim Piermatteo: Thanks Tonya. Okay, Kim, I'm going to come to you for the next question. And the question is, does FDA require specific risk management tools to be used by manufacturers?

CAPT Kimberly Lewandowski-Walker: Thank you. So no, manufacturers may utilize whatever risk management tools are appropriate for the complexity of their devices and their QMS process. We don't require any specific risk management tools, nor do we require the use of ISO 14971 for risk management activities.

CAPT Kim Piermatteo: Thanks Kim. Okay, our next question I'm going to direct to Keisha. And Keisha the question is, is an unclassified preamendment device exempt from design and development requirements in the QMSR?

Keisha Thomas: Yeah. So no, an unclassified preamendment device is not automatically exempt from design and development requirements. Unclassified devices are generally subject to design and development requirements if it meets the device descriptions listed in 820.10(c) and the changes have been made to the devices marketed before October 1997. Manufacturers should be very careful in making sure that they evaluate whether design and development requirements apply to their specific situation and their specific device.

CAPT Kim Piermatteo: Thanks Keisha. Okay, I'm going to, I'm going to come back to Karen. Karen, the question that I have is, if the finished device includes software, does the QMSR require the manufacturer to validate that software?

Karen Masley-Joseph: Great question Kim. Yes, there's a lot of mentions of software and validation in the QMSR. So yeah, let's be clear. We're talking about the software that's in the device, and yes, the QMSR requires that the finished device and its software be validated for its intended use. And those requirements are set forth in ISO 13485, including in Clause 7.3. And I just wanted to kind of reiterate that device software validation, it does require a comprehensive approach and that does include planning, verification, testing, traceability, configuration management, and other good software engineering practices. Thanks.

CAPT Kim Piermatteo: Thanks Karen. Okay, we have a few more questions that I'd like to go through today. And the next question, Tonya, I'll be directing this one to you. And Tonya, the question is, are U.S. Initial Importers or Initial Distributors of finished medical devices from a foreign manufacturer that do not perform design or manufacturing required to comply with quality management system elements such as design and development?

Tonya Wilbon: Wow. Thank you Kim for that question. We do hear that quite often. So in general, [the QMSR] applies to manufacturers of finished devices. These manufacturers are subject to those requirements that are applicable to the operations and the activities being performed at their establishment. This means that organizations must implement only those quality management system elements that correspond to the activities that are being performed at their facility.

So Initial Importers and Distributors who do not perform design and development activities are thus not required to comply with design and development requirements. However, you will be required to comply with other regulatory obligations, such as, complaint handling, Medical Device Reporting, MDR reporting, maintenance of distribution records, device traceability requirements where applicable, and coordination with the foreign manufacturers for device corrections and corrective actions as required. So yes, thank you. Great question.

CAPT Kim Piermatteo: Thanks Tonya. Alright, our next question, I'm going to direct towards Kim. And Kim that question is, how will designs that are developed under the previous 820 regulation be evaluated by FDA?

CAPT Kimberly Lewandowski-Walker: That's a great question. Yeah, so we recognize at FDA that there's many, many devices that have been designed under the 1996 Quality System Regulation requirements but those design files will be reviewed during FDA inspections conducted after February 2, 2026.

Now we know the requirements of ISO 13485: 2016, the current Quality Management System Regulation, and the 1996 Quality System Regulation are substantively similar. So FDA does not expect organizations to retroactively reference the ISO 13485 standard in pre-February 2, 2026 design and development files. Nor do we expect organizations to scrub those files, for lack of a better term, for specific 1996 QS Reg terms, such as design history file. So we do at FDA encourage manufacturers to conduct a gap analysis of their pre-February 2, 2026 designs that are marketed after February 2, 2026 to ensure that the requirements of the ISO 13485 standard are met.

CAPT Kim Piermatteo: Thank you Kim. Very, very informative. For our next question, I'm going to direct that to Keisha. Keisha the question is, are there any free resources we could use to assist with implementing risk management activities?

Keisha Thomas: Yes, Kim, thanks for that question. There are several free resources available on our FDA webpage such as the CDRH Learn presentations on risk management, which I believe the formal title is "Risk Basics for Medical Devices" and presentation entitled "Application of Risk Management Principles for Medical Devices." There are also free resources that are searchable on the web that I'm sure you can utilize. So find some additional free resources.

CAPT Kim Piermatteo: Thanks Keisha.

Keisha Thomas: Thank you.

CAPT Kim Piermatteo: Yep, thanks. Okay, the next question I'm going to direct towards Karen. And Karen, the question is, could you provide some clarity to ISO 13485 Clauses 8.2.1, 8.4, and 8.5.1, as they relate to postmarket surveillance and feedback into the risk management process?

Karen Masley-Joseph: Okay, Kim, yeah that's, that's a good one. Let's see, you mention a few of the requirements there. So first I think I'll review the requirements of the ISO 13485 clauses that you mentioned. So I first hear Clause 8.2.1, and that clause requires that information gathered in the feedback process must serve as potential input into risk management for monitoring and maintaining product requirements as well as for product realization or improvement processes. So that's the requirement part I think that connects to risk management for that one.

For Clause 8.4 that requires the firm to collect and analyze data generated as a result of monitoring and measurement to demonstrate the suitability, adequately, adequacy, sorry, and effectiveness of the QMS. So I think that's a key part of that one to think about for this question.

And then for Clause 8.5.1 that one requires the firm to identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the QMS, as well as medical device safety and performance. And it does then say through the use of postmarket surveillance, among other QMS processes. So thinking about all those requirements that we just went over, those requirements, they can be implemented through a robust postmarket surveillance process.

And then within that process, the data to be reviewed in going to really depend on the nature of your operations and it really should include both production information, which you know could be product monitoring and measurement data, nonconformities process performance and also this process should include post production information. We don't want to forget about that. And those would be some examples, like complaints, adverse events and like other customer feedback. Of course, as all those are applicable to your process. So that's kind of thinking about it as a, as a robust postmarket surveillance process. And then the key connecting it back to the risk management, you're really going to be looking at that and ensuring that emerging risk information is captured and evaluated in a timely manner so that you can maintain the effectiveness of your risk management process to then make those improvements as you need to throughout your device life cycle. So I hope that connects how all those requirements relate to postmarket surveillance and feedback and risk management.

CAPT Kim Piermatteo: Thank you Karen. I very much appreciate your in-depth response. That was great. Okay, next question I have, I will direct that to Tonya. And Tonya, the question is, what is an example of making a risk-based decision?

Tonya Wilbon: Okay, thank you again Kim for that question as well. So as I reviewed earlier during the summary of the modules today, risk-based decision is making a specific decision based on risk assessment and other criteria. So just a few examples, and again these are just examples of when you're making risk-based decisions, it would include: defining the type and extent of control to be exercised over

your products, services, suppliers, contractors, and consultants; you will be making risk-based decisions when you're describe necessary process controls, documenting major equipment that is used for validated processes, again, where appropriate; you'll be making risk-based decisions when determining the need for an investigation of a nonconforming product; as well, determining the supplier that you will use. So again, these are just some of the examples of when you, when you're actually making risk-based decisions. Thank you for the question.

CAPT Kim Piermatteo: Yes, thank you Tonya. Okay, I have one last question for our town hall today and I'm going to direct that question to Kim. Kim the question is, does FDA expect or require the Design and Development file to be continually updated for the life of the device?

CAPT Kimberly Lewandowski-Walker: Okay great. So yes, when changes are made throughout the life of the device, records are required to be maintained in accordance with ISO 13485 subclause 7.3.9 which is control of design and development changes. And these records can either be included in the design and development file or maintained elsewhere. For example, as part of the change control records.

CAPT Kim Piermatteo: Thanks Kim. And thank you to all of our panelists. That will wrap up our panel discussion for our town hall today.

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CAPT Kim Piermatteo: I'll now turn it back over to Tonya to provide some final thoughts regarding today's topics. Tonya…

Tonya Wilbon: Thank you again Kim. And again thank you to everyone who stayed on during this town hall meeting today, we hope that the information provided will be helpful in you transitioning from the QS regulation requirements to now the QMSR regulation requirements. So again, thank you for joining the seminar.

So I would leave you with a call to action. And what I would say is to make sure you review the QMSR requirements for risk management, risk-based approach, risk-based decisions and design and development. Document risk management activities thoroughly and revisit those frequently. I would encourage you to use risk management as a framework again for sound decision making within your complete quality management system to provide that assurance that your device will be safe and effective.

Also, I would say your call to action would be, make sure you ensure that your design and development addresses the intended uses and defines and meets all appropriate requirements. And then finally, use design and development to build quality, safety and effectiveness into your medical devices. Again, thank you. And Kim, I turn it back to you.

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CAPT Kim Piermatteo: Thanks again Tonya. Before we conclude today's town hall, I do want to remind you that a recording of today's event and a transcript will be posted in the next week or so to the 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 has been provided on this slide.

If you have specific questions about the QMSR final rule, feel free to email QMSR-Rule@fda.hhs.gov. And if you have additional general regulatory questions regarding today's town hall, 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 listing 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 town hall.

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