# FDA's Quality Management System Regulation (QMSR): Medical Device Risk-Based Inspections
# April 1, 2026

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

### Slide 1

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### Slide 2

**CAPT Kim Piermatteo:** [Hello everyone] and 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 this town hall.

Our presenter today is Karen Masley-Joseph, Senior Advisor in the Office of Medical Device and Radiological Health Inspectorate within FDA's Office of Inspections and Investigations.

For this town hall, Karen will discuss the updated Inspection of Medical Device Manufacturers Compliance Program Manual, which went into effect on February 2, 2026. This compliance program includes the new inspection process, which aligns with the requirements of the Quality Management System Regulation or QMSR.

After Karen's presentation we will have a panel discussion of some frequently asked questions about this topic.

Before I turn it over to Karen, I'd like to reminder everyone, 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.

Thank you all again for joining. I'll now turn it over to Karen.

**Karen Masley-Joseph:** Thanks Kim and hi everyone. I'm happy to be with you today to talk about FDA's medical device risk-based inspections which are conducted in alignment with the Quality Management System Regulation or QMSR.

### Slide 3

**Karen Masley-Joseph:** The main areas I will discuss today are the recently updated Compliance Program which contains FDA's medical device risk-based inspection process, and I'll then go over the process as described in the program, and along with that I will discuss the different types of inspections and inspection models and the regulatory or after inspection strategy.

### Slide 4

**Karen Masley-Joseph:** Now on to the Compliance Program updates for QMSR.

## Slide 5

**Karen Masley-Joseph:** I'm happy to say that the QMSR became effective on Monday, February 2, 2026. This slide shows the email FDA sent out to announce the effective date. The message also highlights that as of February 2nd, FDA device inspections will be conducted under an updated process. That means, that starting on February 2nd, FDA no longer uses the Quality System Inspection Technique, which was also known as QSIT, for device inspections. And this is because QSIT was aligned with the former regulation, the Quality System Regulation. With the shift to harmonization and incorporating ISO 13485 by reference we have an updated inspection process aligned with our new regulation the QMSR.

What we have now for the QMSR is a risk-based inspection process for medical devices and it is described in the newly updated Compliance Program titled, Inspection of Medical Device Manufacturers, and that program does have a new number, to distinguish it from the former Compliance Program of the same name.

The new Compliance Program number is 7382.850 and this program includes updates for the QMSR, including the risk-based medical device inspection process, and it addresses all device inspections under the QMSR including PMA premarket and PMA postmarket inspections. This update takes two former compliance programs and puts them into one document that describes our FDA procedures for inspections of medical device manufacturers.

Now let's talk about where you can find the updated program.

## Slide 6

**Karen Masley-Joseph:** You can access FDA's Compliance Programs at fda.gov by searching for the FDA Compliance Program Manual which shows links to the compliance programs for the different commodities FDA regulates. Or if you search more specifically for FDA device compliance programs you will get to the page shown on this slide.

When you've reached this page, select the second program down, the 7382.850 Inspection of Medical Device Manufacturers, and you can download it as a PDF. If you have not done this or you have not read the program, I do recommend taking some time to do so. I will be going through some of the key points in the rest of this presentation so you may want to take a minute to open up your copy and follow along.

While you're doing that, I'd like to point out that FDA's Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws FDA enforces. Device compliance programs reflect FDA's internal procedures, they are not guidance, but we do post the compliance program documents for transparency.

Every compliance program has the same format, and the compliance programs are the places where inspection processes and regulatory considerations are documented, by describing our QMSR inspection process in the Compliance Program, we are aligning our documentation with other centers.

I'd also like to add an important note that Compliance Programs do not create or confer any rights for or on any person and do not bind FDA or the public.

## Slide 7

**Karen Masley-Joseph:** In the next few slides, I will review the medical device risk-based inspection process that is described in the updated Inspection of Medical Device Manufacturers Compliance Program.

## Slide 8

**Karen Masley-Joseph:** The goal of medical device risk-based inspections is documented in Part II of the compliance program.

The goal of FDA inspections of medical device manufacturers has two parts, to evaluate if the manufacturer's quality management system, or QMS, meets FDA requirements and provides reasonable assurance that devices will be safe and effective, and to evaluate if the manufacturer's risk management and risk-based decision making are effectively used in the QMS.

## Slide 9

**Karen Masley-Joseph:** Now let's look at the risk-based inspection process that is described in Part 3 of the compliance program.

The diagram on the screen represents a high-level depiction of the risk-based inspection process, which aligns with the QMSR. The center of the diagram shows patients and users as the central focus of FDA medical device inspections. The risk management circle surrounding patients and users represents FDA's emphasis on using a manufacturer's risk management documentation to help focus the inspection on risk.

To facilitate a focus on risk and to reflect the relationship of QMS processes, the risk-based inspection process organizes the QMSR requirements into six QMS Areas and four Other Applicable FDA requirements. The four Other Applicable FDA Requirements are referred to by the acronym, OAFRs, which we affectionately pronounce 'oa-fer'. Again, this is how FDA has organized the requirements to facilitate a risk-based inspection.

The QMS areas are represented as six circles, and there is one hexagon representing the four OAFRs. Roads connecting the various QMS areas and OAFRs reflect their connection to each other, and through patients, users and risk management, as well as the flexibility of the inspection process. The outer circle shows that the inspection process contributes to accomplishing FDA's mission to protect public health.

Each QMS Area and OAFR is described in more detail in Attachment A, and I will review an example of a QMS Area on the next slide.

## Slide 10

**Karen Masley-Joseph:** Attachment A contains tables of the QMS Areas, OAFRs, elements, and requirements, which again, is how FDA has organized the QMSR requirements to facilitate a risk-based inspection approach. Each QMS Area and OAFR is comprised of one or more elements. Each element includes one or more regulatory requirements.

In the tables in Attachment A, the term Clause or Clauses refer to those requirements in ISO 13485:2016, which is incorporated by reference under 21 CFR 820.7.

Manufacturers subject to this part are required under 21 CFR 820.10 to document a quality management system that complies with the applicable requirements of ISO 13485.

Let's take a closer look at the example shown on the slide, which is for the Management Oversight QMS Area. Top management has broad oversight of the quality management system and its processes so an investigation of this QMS Area is based on the requirements from several requirements set forth in ISO 13485 and Part 820. During an inspection, an investigator may review one or more of these elements depending on the inspection type and inspection model which I will discuss in more detail on subsequent slides.

I'd also like to note FDA considers two elements Planning of Product Realization, arising from the requirements set forth in clause 7.1 and Risk-based approach, which is required by clause 4.1.2(b) to be appropriately included under this QMS area of management oversight. Within doing so, FDA considered the discussion of risk in the preamble to the final rule, which says in part that "…the explicit integration of risk management throughout the clauses of ISO 13485 more explicitly establishes a requirement for risk management to occur throughout a QMS and effective risk management systems provide the framework for sound decision making within a QMS and provide assurance that the devices will be safe and effective…"

**Slide 11**

**Karen Masley-Joseph:** Continuing with another example from Attachment A, here is a closer look at one of the OAFRs. This OAFR is for Medical Device Reporting which is required under 21 CFR Part 803 and is referenced in the QMSR under 21 CFR 820.10(b)(3). OAFRs will be evaluated on each inspection, unless they do not apply, for example during PMA preapproval inspections if the subject device is not already on the market.

**Slide 12**

**Karen Masley-Joseph:** Continuing with our discussion this slide describes how FDA investigators conduct a risk-based inspection. Investigators use critical thinking and consider risk throughout the inspection. They become familiar with a manufacturer's roles, products, and processes, and identify product risks that could adversely impact patients or users. To identify product risks, the investigator will become familiar with the manufacturer's roles such as specification developer or finished device manufacturer, they will also become familiar with their products and processes.

Investigators review the manufacturer's risk management documentation throughout the inspection to assist with understanding product risks and associated risk controls. Based on this review, investigators select an element, and evaluate the related requirements, within a QMS Area or OAFR to determine if the manufacturer is meeting requirements.

I'd like to note, again, that the inspection process is flexible, meaning the QMS areas and OAFRs are not required to be evaluated in a specific order.

**Slide 13**

**Karen Masley-Joseph:** So now we'll move on to a few more specifics related to inspections.

**Slide 14**

**Karen Masley-Joseph:** This slide shows Figure 3 from the compliance program, and it is titled Risk-Based Inspection Types and Associated Inspection Models. The table lists the different types of risk-based inspections and describes the situations in which these inspection types may be assigned. It also lists the associated inspection model which should be followed for each.

So going through Figure 3 in more detail, the Inspection Type column identifies seven inspection types. The first two are surveillance inspections, non-baseline surveillance and baseline surveillance. Following these are compliance follow-up inspections, for-cause inspections, Specific Product Risk Assignment or SPRA inspections. And the final two inspection types are PMA preapproval and PMA postmarket inspections.

The middle column, Situation, describes the situations in which FDA will assign a certain inspection type. These situations provide examples and are not all inclusive of the reasons an inspection type may be assigned.

If you look at the last column in the table, Inspection Model, you will see that each of the inspection types will be conducted according to either inspection model 1 or model 2, which are also described in the compliance program. I'll take some time to go over these two inspection models on the next slides.

**Slide 15**

**Karen Masley-Joseph:** Inspection Model 1 is used for most types of inspections, and those include non-baseline surveillance, compliance follow-ups, for cause, specific product risks inspections and PMA postmarket inspection types. During an inspection following Model 1, an investigator will identify product risks that could adversely impact patients and/or users and select at a minimum one element to evaluate requirements in each of the six QMS Areas and OAFRs. So one difference between this inspection process and QSIT is that now, on every inspection, FDA will evaluate, to some extent requirements in each of the main parts of your quality management system and this is done in alignment with the QMSR as ISO 13485 is based on a process approach to quality management.

**Slide 16**

**Karen Masley-Joseph:** During Model 1 risk-based inspections, investigators will also cover the OAFRs that are referenced in the QMSR.

**Slide 17**

**Karen Masley-Joseph:** And also, during risk-based inspections, investigators will cover general items including but not limited to, registration and listing, marketing authorizations, previous 483 and/or compliance issues, and other areas as defined in the assignment. Note that if an inspection reveals objectionable conditions, or if information cannot be adequately assessed through review of minimum requirements, the investigator may consider selecting additional elements for evaluation.

To refresh your memory from our previous slides, Attachment A of the Compliance Program contains tables of the QMS Areas, OAFRs, Elements and Requirements, such as the table we reviewed for the QMS Area of Management Oversight on a previous slide.

**Slide 18**

**Karen Masley-Joseph:** Moving on, now we will review Inspection Model 2 which is documented in Figure 2 of the compliance program. In Inspection Model 2, an investigator will identify product risks that could adversely impact patients and/or users and in this model, they will evaluate, at a minimum, the elements listed under each QMS Area as listed in the model.

Inspection Model 2 is used for baseline surveillance inspections and PMA preapproval inspections and requires the investigator to cover specific elements within the QMS. These are the minimum elements that must be covered, and the investigator may cover additional elements as needed.

**Slide 19**

**Karen Masley-Joseph:** During most Model 2 risk-based inspections, investigators will also cover the OAFRs with the exception if the inspection is for a PMA preapproval and if the subject device is not already on the market. In this case the OAFRs would not be reviewed.

**Slide 20**

**Karen Masley-Joseph:** Similarly to Inspection Model 1, in Inspection Model 2, an investigator covers general items, and this model also includes the statement that if an inspection reveals objectionable

conditions, or information cannot be adequately assessed through review of these minimum requirements, the investigator may consider selecting additional elements for evaluation.

Again, you may refer to Attachment A in the Compliance Program for the tables of QMS Areas, OAFRs, Elements and Requirements.

**Slide 21**

**Karen Masley-Joseph:** So now let's turn to considerations that occur after an inspection.

**Slide 22**

**Karen Masley-Joseph:** As mentioned, Compliance Programs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.

Part Five of each compliance program contains the Regulatory and Administrative or After Inspection strategy. That section has examples for FDA staff to consider when deciding the initial classification of an inspection. In the Inspection of Medical Device Manufacturers Compliance Program, it also describes Situation 1 and 2 which give examples of significant inspectional findings.

Situation 1 provides examples for initially classifying an inspection as Official Action Indicated, or OAI, when evidence supports a significant deficiency, and/or a pattern of deficiencies, within one or more QMS areas and/or OAFRs. And Situation 2 provides examples for initially classifying an inspection Voluntary Action Indicated, or VAI, when overall inspectional findings reveal less significant deviations that may have minimal or no public health impact

Situation 1 and 2 existed in prior versions of this program, and the examples have been updated to reflect the QMSR in this version.

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**Karen Masley-Joseph:** This slide contains two Situation 1 examples that may lead to an initial classification of OAI. The first example is failure to establish, implement, and/or maintain one or more processes for risk management in product realization, which is required under Clause 7.1.

The second example is information gathered through the feedback process and/or postmarket surveillance is not used as potential inputs into risk management for monitoring and maintaining the product realization or improvement processes. This is an example of a reference to Clause 8.2.1.

Situation 1 does contain seven more examples and again these examples can be found under Part 5, Regulatory Administrative Strategy of the Compliance Program.

**Slide 24**

**Karen Masley-Joseph:** Situation 2 provides examples for initially classifying an inspection VAI when overall inspectional findings reveal less significant deviations that may have minimal or no public health impact. Inspection findings fit into the Situation 2 category when the inspection documents QMSR deficiencies that indicate a low probability that nonconforming product and/or defective devices will be produced.

**Slide 25**

**Karen Masley-Joseph:** Inspections are classified using one of the three options shown on this slide. No Action Indicated or NAI means that no objectionable conditions or practices were observed. Voluntary Action Indicated or VAI means that objectionable conditions were observed but do not meet the threshold for regulatory action. Official Action Indicated or OAI means objectionable conditions were observed and regulatory action is recommended.

**Slide 26**

**Karen Masley-Joseph:** If regulatory action is recommended, the compliance program lists options for action and some examples are shown here on the slide. The Compliance Program provides more detail on each of the options.

**Slide 27**

**Karen Masley-Joseph:** This slide shows the resources I mentioned earlier in the presentation, along with the full URL that you can access after the presentation.

**Slide 28**

**Karen Masley-Joseph:** In summary, since we implemented the QMSR on February 2, 2026, the FDA is no longer using the Quality System Inspection Technique, or QSIT, for device inspections, instead, we are following the inspection process outlined in the updated compliance program 7382.850, Inspection of Medical Device Manufacturers. And the prior compliance programs 7382.845 and 7383.001 are no longer in use.

I'll now turn it back over to Kim Piermatteo for our panel discussion.

**Slide 29**

**CAPT Kim Piermatteo:** Thank you Karen for your presentation. We will now transition to our panel discussion and address some frequently asked questions about this topic.

**Slide 30**

**CAPT Kim Piermatteo:** Joining Karen for this panel discussion is Keisha Thomas, Associate Director for Compliance & Quality in CDRH's Office of Product Evaluation and Quality; 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. Thank you all for joining our panel discussion.

**Slide 31**

**CAPT Kim Piermatteo:** For today's panel discussion, I'll read a frequently asked question regarding today's topic and then I will ask a panelist to respond. So let's get started.

For our first question I will be directing that to Kim and Kim the question is, we understand that there will be a heightened emphasis on risk throughout the product life cycle. What is FDA's expectation for how companies are to demonstrate how risk management is utilized throughout the total product life cycle?

**CAPT Kimberly Lewandowski-Walker:** Alright Kim, thank you very much for the question. A great one to get us started off. So in essence, manufacturers must document their risk management processes and demonstrate how they apply risk-based approaches throughout their quality management system. So under Clause 7.1, manufacturers must document one or more processes for risk management in product realization. And then under Clause 4.1.2(b), manufacturers must apply a risk-based approach to control the processes needed for the quality management system.

**CAPT Kim Piermatteo:** Thanks Kim. For the next question, I will direct that to Keisha and Keisha the question is, does FDA expect that manufacturers will use the same methodology to assess risk, for example in corrective action and purchasing processes?

**Keisha Thomas:** Yes hi, thanks Kim, I'll take that next question and it's an interesting one that we get asked often. FDA recognizes that different processes within a quality management system carry different levels of risk, depending on the complexity of the device and manufacturing processes associated with that device. Manufacturers can use different risk assessment approaches for different parts of their QMS, as long as these approaches are appropriate for the specific risks involved. The decisions and processes should align with the risk profile of the specific product or process being addressed.

A couple of examples come to mind to me to clarify this a little bit more. Some complaints may pose lower risk than others. A complaint about a cosmetic defect may warrant a different level of investigation and corrective action than a complaint alleging harm to a patient or user. Similarly, a purchasing process for a device with outsourced design and manufacturing may carry higher risk than those associated with in-house machining processes for a device assembled from internally manufactured parts. It's perfectly okay for those risk management processes to be different and those approaches to be different.

What FDA does expect is for manufacturers to document these risk-based decisions within their quality management system documentation and maintain them as required by Clause 4.2.5.

**CAPT Kim Piermatteo:** Thanks Keisha. Our next question I will direct that to Karen and Karen the question is, can FDA provide examples of how inspection expectations will differ under the new Compliance Program compared to the prior QSIT framework?

**Karen Masley-Joseph:** Thanks for the question Kim. That's a good one. I did give one example in the presentation and so I'll go over a little bit more now. In general, the inspection process will stay largely the same. Like for domestic inspections, investigators will give manufacturers an FDA 482 Notice of Inspection when they arrive. And then during the inspections, the investigators will typically, you know, tour the facility; they'll ask to see how products and processes work; they're going to discuss, you know, what the site does, those roles and responsibilities. They are also going to review quality data and documents; talk to and interview staff; and observe or watch processes in action.

Those are some of the same activities investigators have always conducted, and now they'll just be done in a way to assess the requirements of the QMSR using the process outlined in the Compliance Program. And then, while investigators previously have requested risk management documentation, you know, under the QMSR they will emphasize reviewing the risk management documents and evaluating how manufacturers have effectively implemented risk controls throughout their quality management system.

And then, if investigators do find significant problems, they'll still give manufacturers an FDA 483 that lists those observations, and then the manufacturers will still, they still have the ability to choose to annotate the form or respond in writing after the inspection.

**CAPT Kim Piermatteo:** Thanks Karen. Tonya, I'm going to come to you for the next question. And Tonya that question is, what documentation or objective evidence will FDA prioritize during QMSR inspections, especially for risk management activities?

**Tonya Wilbon:** Well good afternoon everyone and thank you, Kim, for that question. I'm sure, as you've heard during Karen's presentation there is some concerns or information we really want to rely regarding risk management activities. So the specific documents and evidence investigators review will depend on the risk, of course, that's associated with the manufacturer's device and the priorities for that inspection. Investigators typically will examine the documentation needed to verify that manufacturers meet the QMSR requirements for the elements being evaluated.

And then as far as risk management activities specifically, investigators may review risk management files and reports for those selected products, including risk analysis that identify your hazards and harms. As well as documentation showing how risk controls were implemented. Investigators may also even look for evidence that risk controls are effective and records demonstrating risk management throughout the product lifecycle. So they are looking at that, those records. Thank you for the question.

**CAPT Kim Piermatteo:** Thanks Tonya. Our next question I will direct that to Kim and Kim the question is, how should manufacturers prepare for the transition period leading up to February 2026 to ensure compliance with the new QMSR requirements?

**CAPT Kimberly Lewandowski-Walker:** Alright, thank you for the question. So the transition period has ended, and this was addressed in prior webinars. So we are, we are past the transition period and companies need to be compliant with the QMSR now.

**CAPT Kim Piermatteo:** Great, thanks for that clarification, Kim. Keisha, I'm going to come to you for the next question or with the next question. And that question is, does FDA have any guidance, training or educational material available to address or that addresses QMSR requirements and inspections, or ISO 13485 requirements?

**Keisha Thomas:** Yes Kim, thank you for this question. So the short answer is yes, CDRH has on its Device Advice webpage several CDRH Learn modules that focus on the requirements of QMSR. On that same webpage, we have the updated Inspection of Medical Device Manufacturers Compliance Program that is the subject of this webinar which describes the QMSR inspection process as well as compliance considerations and regulatory strategy associated with QMSR inspections. There is also a list of FAQs listed on the same webpage that has a list of questions and answers that are frequently asked questions that we've gotten over the implementation period as well as now in the effective period that provides insight as well.

**CAPT Kim Piermatteo:** Thanks Keisha. Very helpful information. For the next question, I'll come to Karen and Karen the question is, will investigators follow the MDSAP audit approach for QMSR inspections instead of the QSIT under QSR?

**Karen Masley-Joseph:** Thanks Kim, that's a good question and it's always good to clarify that no, FDA investigators will not follow the MDSAP audit approach for QMSR inspections. The investigators are going to follow the risk-based inspection approach that I went over in the presentation and which is the same approach that's outlined in the Inspection of Medical Device Manufacturers Compliance Program. The number of that is 7382.850. Thanks.

**CAPT Kim Piermatteo:** Thanks Karen. Okay, we're going to continue to move on with more questions. And the next question I will direct towards Tonya. Tonya, the question is, will investigators still apply a statistical sampling plan during the inspection?

**Tonya Wilbon:** Thanks Kim. Another great question and again you know lends itself to being clarified. The simple answer is actually no and this is stated in Part 3.B.(3) of the Inspection of Medical Device Manufacturers Compliance Program that the investigators will conduct records review, and not just not sampling of records. So they will review records as they deem appropriate during the inspections.

In addition, it clarifies that investigators may review records in order to evaluate whether or not a manufacturer is meeting FDA requirements and then whether or not any controls for the product risk that could adversely impact patients and/or users have been adequately implemented.

So sometimes depending on the outcome of information that they're gathering it may lead them to review additional records, but records should be selected based on the identified product risk and the investigator's experience, of course, as well as any professional knowledge and not just sample sampling a number of records. Thank you for that question.

**CAPT Kim Piermatteo:** Thanks Tonya. Okay, I'm going to come back to Kim with another question and Kim the question is, how will the new approach for device inspections be utilized for Drug Device Combination Product pre-approval inspections that use the drug GMP streamlined approach?

**CAPT Kimberly Lewandowski-Walker:** Oh that's a great one. So inspections of drug device combination products that use the drug streamlined approach by showing compliance with drug GMPs at 21 CFR Parts 210 and 211 will also need to comply with applicable provisions of the QMSR which are set forth at 21 CFR Part 4.4.(b)(1).

In particular, implementing risk management in product realization is part of 4.4.(b)(1)(ii) as it reads, "Design and development. Clause 7.3 and its subclauses of ISO 13485. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained…" But that's an excellent question.

**CAPT Kim Piermatteo:** Thanks Kim. Alright, our next question I will direct that to Keisha and Keisha that question is, will manufacturers who are being monitored after an enforcement action, such as a warning letter or consent decree, be inspected under the new rule?

**Keisha Thomas:** Thanks Kim. Buring question I'm sure that people are wondering out there, not at all unexpected. The answer is yes. All medical device inspections conducted post February 2nd or starting February 2nd, 2026, and after will be inspected to the QMSR, using the process that's listed within the Ins Inspection of Medical Device Manufacturers Compliance Program and that would be for any and all types of inspections done after that time including compliance follow-ups.

**CAPT Kim Piermatteo:** Thanks Keisha. Karen, I'm going to come to you for the next question. And Karen, that question is, are records created prior to February 2nd, 2026, expected to meet the requirements of the QMSR?

**Karen Masley-Joseph:** Thanks Kim. That's a good one. It's come up in a lot of places so I'm happy we can clarify. In essence the answer is no. No, manufacturers, they do not need to revise or recreate records that were created before February 2, 2026, to comply with QMSR requirements. FDA doesn't expect manufacturers to like go back in those older documents to add references to ISO 13485 or its language. You know, again in those records that were prior to February 2nd, you know, you don't need to remove 1996 QS regulation terms such as design history file or device master record or anything like that.

But there is a however, you know, FDA does expect manufacturers to identify where processes might need to change to comply with the QMSR and then develop a plan that addresses any necessary changes. So if manufacturers review their pre-QMSR records and they discover gaps in their quality management system, those gaps should be addressed.

For example, you know, if they do a gap analysis and a manufacturer realizes that they did not previously incorporate feedback into their risk management process. You know, upon incorporating this feedback, due to the QMSR requirement, they might recognize that risk controls are absent or ineffective and in those cases manufacturers really should develop and implement a plan to address that gap. So I hope this helped clarifies that question.

**CAPT Kim Piermatteo:** Thanks Karen. Okay for our next question I will direct that to Tonya. Tonya the question is, the final rule explicitly states that ISO certification from a Notified Body does not equate to compliance to the QMSR. Can Notified Body audits be used to complement a manufacturer's internal audit requirements under the QMSR?

**Tonya Wilbon:** Yes, great question Kim. We receive this often in DICE. So the answer, plain and simple, is that a Notified Body audit that focuses on ISO 13485 conformity assessment may not replace an internal audit of the QMSR requirements as the QMSR requirements include all the requirements for 21 CFR 820. And as you may be aware, there are some supplemental provisions with that regulation as well. So the Notified Body audit may complement now the internal audit, and the information from the Notified Body audit can be valuable.

Additionally, under ISO Clause 8.2.4 regarding Internal audits, the manufacturer must also conduct internal audits according to their own documented procedures. So if you have stated in your procedure that you're going to conduct additional audits or audit certain areas, then you have to comply with that and then this procedure must describe the responsibilities and requirements for planning and conducting those requirements, as well as recording and reporting the audit results. Notified Body audits are of course third-party audits that serve different purposes and typically do not follow a manufacturer's internal audit procedure. So they would not satisfy QMS internal audit requirements.

However, this information from the Notified Body audits can play an important role in assessing the manufacturer's quality management system compliance for the FDA. Manufacturers can leverage findings and observations from these third-party audits and use them to supplement and strengthen their internal audit process. For example, a manufacturer might use the Notified Body audit results to identify areas for deeper internal review, and then validate those internal audit findings, or inform their audit planning and risk assessment activities. So I hope that clarifies, cause we do get that question often.

**CAPT Kim Piermatteo:** Thanks Tonya. Okay I think we are good on time, we're going to keep going through some more questions today. So the next question I will direct towards Kim and Kim that question is, we understand that with the shift to QMSR, FDA will be looking for a culture of quality and leadership accountability across the company, not just within the quality organization. How will this be assessed and/or how can companies be prepared to demonstrate that they do in fact have a culture of quality?

**CAPT Kimberly Lewandowski-Walker:** Well thank you for that question. So FDA will assess quality culture by examining the decisions that manufacturers make and the actions that they take throughout their quality management system. The regulation emphasizes that leadership must embrace a culture of quality as essential to manufacturing safe and effective medical devices.

So FDA expects manufacturers led by individuals with executive responsibility, to embrace a culture of quality as a key component in ensuring the manufacture of safe and effective medical devices that otherwise comply with the FD&C Act. So a culture of quality meets regulatory requirements through really a set of behaviors, and attitudes, and activities, and processes. And then top management ensures that applicable regulatory requirements are met through the integration of the QMS processes.

So during inspections, FDA investigators will look for evidence of a culture of quality in how the manufacturers operate. So using information from relevant quality management system processes, including risk management, to make appropriate risk-based decisions demonstrates behaviors and attitudes consistent with that culture of quality.

So in effect manufacturers don't need to take special steps to document quality culture for an FDA inspection; rather quality culture will be reflected in the decisions made and the actions taken as part of the quality management system operations.

**CAPT Kim Piermatteo:** Thanks Kim. Keisha, I'm going to come to you with the next question. And Keisha, that question is, what guidance is FDA giving investigators as to how they are to review and

utilize records that were previously excluded in 820.180c, which was management review, internal audit, and supplier audit? How far back will FDA look?

**Keisha Thomas:** Thank you Kim, this is an excellent question. When we were developing and promulgating the QMSR, harmonization was central to our decision making and the rationale for moving in this direction. Within the preamble to the QMSR specifically in comment 55, the exemption that previously existed for these records is not a part of QMSR. FDA investigators will follow the Compliance Program 7382.850, which addresses the review of management review, internal audit, and supplier audit related processes. For baseline surveillance inspections and premarket pre-approval inspections, these processes are expected to be reviewed. For other types of inspections, these records may be reviewed depending on the inspection's focus and which quality management system elements the investigator selects for evaluation. Our investigators use critical thinking to select the appropriate elements necessary to evaluate whether manufacturers are appropriately identifying and controlling risks that could adversely impact patients and users.

For example, if an inspection reveals that their design deficiencies that result in a significant device recall, it may be appropriate for investigators to assess how the manufacturer is auditing or has audited its design and development process.

FDA investigators may review records that are part of a manufacturer's quality management system, including those that were created prior to February 2nd, 2026. I think Karen actually eluded to that in a question that she had a little bit earlier. We also have one of the FDA frequently asked questions that's listed on the DICE webpage that addresses that, I believe it's question 7. But as noted, FDA does not expect manufacturers to revise or recreate records made before February 2nd, 2026 to comply with QMSR requirements. But they are still fair game for us to look at if the inspection direction leads us there.

**CAPT Kim Piermatteo:** Thanks Keisha. Great. Alright next question, I will direct that to Karen and Karen the question is, ISO 13485 year 2016, and thus QMSR, requires a risk-based approach to QMS processes such as Clause 4.1.2(b). Will the FDA expect to see risk assessments for administrative processes like document control or training, or will they focus strictly on product-related risk?

**Karen Masley-Joseph:** Yeah, thanks for the question Kim. This one will be really important to clarify. It's come up several times and so I'll just start by saying that you know the risk-based approach that's required under Clause 4.1.2(b) that does apply to all processes in the quality management system, including those so called administrative processes. However, this risk-based approach it's different from the formal risk management processes and documentation that's required under Clause 7 for product realization.

Manufacturers do not need to create separate risk assessments or risk management documents for these, like administrative processes, like document control or training. And instead, when they're making decisions about these processes, the manufacturer should use a risk-based approach that references existing risk management documentation for the related product or process, and then they should really document those decisions.

So for example, if a manufacturer is deciding how often to retrain staff on a manufacturing procedure, a manufacturer would not need to create a formal risk assessment for, you know, like training frequency, but instead, they may reference the existing risk management documentation for the manufacturing process that they are thinking about training people on and if that process is high risk, then that information should inform their decision to either train more frequently or implement more rigorous training programs.

So the FDA's focus during inspections is really going to be on whether manufacturers are using the product-related risk information to make those appropriate decisions about their quality management system processes. You know, we're not really going to be considering or looking at whether

manufacturers have created separate risk assessments for every administrative function. So I hope that helps that one.

**CAPT Kim Piermatteo:** Thanks Karen. Tonya, I'm going to come to you with the next question, which is, how will the FDA assess effectiveness of training during inspections? Will investigators look for documented evidence such as supervisor evaluations or skill assessments, that goes beyond a simple quiz?

**Tonya Wilbon:** Yes, thanks Kim. This is always a great question and we do find it that industry typically does have this question. So now under ISO Clause 6.6 of the 13485 standard, personnel shall be competent, you know, on the basis of appropriate education, training, skills, and experience, and the manufacturers must evaluate the effectiveness of any actions taken to achieve or maintain that competence. So you get to decide how best to evaluate that. The method used to check the effectiveness of these actions should be appropriate again or proportionate to the risk associated with that work.

The risk of the processes and product should be a factor in determining both the competence required of personnel performing the work that could affect product quality, as well as the method used to evaluate the effectiveness of actions taken to achieve or maintain that competence. So the type of evidence needed to demonstrate effectiveness will thus depend on the risk level. You know, evaluating training effectiveness goes far beyond just evaluating whether or not training was completed. You know you can't just do a check box.

So for those higher-risk processes, manufacturers may need more robust evidence beyond simple quizzes, such as supervisor evaluations, you know, skill assessments, or even practical demonstrations may be necessary. Or ongoing performance monitoring. You may need to monitor their performance afterwards.

And whereas for those lower-risk types of processes, simpler verification methods may be appropriate. So FDA will assess whether the manufacturer's approach to evaluating the effectiveness of training or other actions thus is appropriate for that level of risk that is involved. And I hope that helps.

**CAPT Kim Piermatteo:** Thanks Tonya. Alright, I'd like to get through a few more questions for today. So the next question I'll direct to Kim and Kim the question is, has the threshold for taking compliance actions on a medical device manufacturer changed with the implementation of QMSR?

**CAPT Kimberly Lewandowski-Walker:** Great question. So essentially no, the threshold for taking compliance actions has not changed with QMSR implementation. However, the compliance program manual has been updated as described in Inspection of Medical Device Manufacturers compliance program document, 7382.850.

The compliance program provides specific examples of what constitutes serious deficiencies, particularly in areas such as risk management, design and development controls, and process monitoring and measurement. These updates reflect QMSR's risk-based approach and harmonization with ISO 13485.

So while the framework for evaluating compliance has been updated to align with QMSR, the regulatory requirements that determine when compliance action is warranted remain the same. And FDA will continue to take compliance action as appropriate to protect the public health.

**CAPT Kim Piermatteo:** Thanks Kim. Keisha, I'm going to come to you with the next question, which is, will FDA be releasing an additional document that replaces QSIT and supplements the compliance program Inspection of Medical Device Manufacturers,7382.850?

**Keisha Thomas:** Thanks for that question Kim. So no, FDA does not intend to release an additional document that supplements the compliance program, that includes the Inspection of Medical Device Manufacturers for QMSR inspections. The Compliance Programs provide instructions to FDA personnel

for conducting activities to evaluate industry compliance with the Food, Drug, and Cosmetic Act and other laws and implementing regulations. But there will be no additional document that will come out in place of, in lieu of, or in addition to, compliance program 7382.850 as it relates to the inspection process for QMSR.

**CAPT Kim Piermatteo:** Thanks Keisha. Karen I'm going to come to you next, and the question is, what's the difference between a non-baseline surveillance inspection and a PMA postmarket inspection?

**Karen Masley-Joseph:** Thanks Kim. Yeah, I could see since both a non-baseline surveillance inspection and the PMA postmarket inspection, they do both follow Model 1 according to the Compliance Program. So the difference would be that the PMA postmarket inspection is going to typically focus on the specific product that recently received the PMA approval as well as any specific actions that were required in the PMA approval letter along with of course Model 1 and any all the inspections have to follow anything specific in their assignment. And then the non-baseline surveillance inspection, it might focus on one or more devices that are selected by the investigator and any of the risks that may be posed to the patients or users from those devices and you know, they may decide that based on their review of the firm's operations, the product risk, and other considerations.

**CAPT Kim Piermatteo:** Thanks Karen. Okay let's try to get to a couple more questions today. Tonya, the next question is, do you have any suggestions for how manufacturers can prepare for a QMSR risk-based inspection?

**Tonya Wilbon:** Wow, thanks Kim. Another great question. The bottom line is the best way really to prepare for an FDA inspection is simply to meet the FDA requirements that apply to your FDA regulated product. That's plain and simple. FDA really recommends that firms be prepared really to discuss and provide records that demonstrate compliance with all the applicable QMSR requirements.

So as the QMSR has an explicit emphasis on integrating risk management throughout the product lifecycle, one helpful action may be to just ensure your internal audit program evaluates how risk management is actually integrated throughout your product realization as well as whether or not you're applying a risk-based approach to control your QMS processes. You know, this may involve evaluating whether risk controls are effective by tracing them through your processes, starting with identified patient risk, then following the associated risk controls through each impacted process. And then finally, I would recommend that you just simply be prepared, you know, to demonstrate that risk-based decisions were well-justified and documented, and that you took appropriate actions when needed. So thank you Kim for that question.

**CAPT Kim Piermatteo:** Thanks Tonya. Okay, Kim I'm going to come to you with another question, and that question is, when may an inspection expand beyond review of the minimum required elements?

**CAPT Kimberly Lewandowski-Walker:** Sure, I think this is a very timely question here and I'm going to stress two words, one of them being minimum and one of them being flexible.

So both inspection models in the compliance program define the minimum requirements investigators must evaluate, and the approach is intentionally designed to be flexible. So it's completely normal and expected for investigators to examine additional elements beyond minimum requirements as part of the standard evaluation. This should not really be thought of as expanding the scope of the inspection but really rather how the risk-based inspection approach is intended to work.

So for Model 1, the requirement of one element per QMS area ensures broad coverage across the quality management system rather than concentration in one area. Investigators routinely cover more elements based on what's necessary to verify that manufacturers have established effective processes to identify and control risks. The approach encourages investigators to examine whatever elements are needed to understand how well the manufacturer meets the QMSR requirement and to manage device-related risks.

And then the investigators will continue to communicate with the manufacturer as the inspection progresses.

**CAPT Kim Piermatteo:** Thanks Kim. I am going to sneak in one last question, Keisha, before we close out and I'm going to come to you with that question, which is, where in the compliance program is the complaint handling system coverage under Model 1?

**Keisha Thomas:** Sure thing Kim and I will try to be comprehensive but also quick. During an inspection conducted using Model 1, an investigator may request to review information in your complaint databases and other quality data sources early in the inspection. As the investigator continues the inspection, and they begin to evaluate requirements in each QMS Area they may request to interview personnel, review records, or observe complaint handling processes if they choose to evaluate the Complaint Handling element in the Measurement, Analysis and Improvement QMS Area. Complaints are also one type of feedback under Clause 8.2.1 so an investigator may also evaluate how complaints, as part of the feedback process, are used as an input to risk management. I hope that helps Kim, and we're at time.

**CAPT Kim Piermatteo:** Right, great, thanks Keisha. And thank you. That will wrap up the panel discussion. So thank you to all of our panelists for providing responses to those questions. I am going to now…

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**CAPT Kim Piermatteo:** …turn it back over to Karen to provide a call to action. Karen…

**Karen Masley-Joseph:** Thanks Kim. Yeah, so as we conclude this presentation, I'd like to leave you with a few takeaways, so first and most importantly, implement the QMSR and ensure you are meeting the requirements. They are now effective. Second, if you'd like more information on medical device risk-based inspections, you can review the updated Inspection of Medical Device Manufacturers Compliance Program, the 7382.850 document, and this is the document that now contains the FDA inspection process for medical device manufacturers. We at the FDA are no longer using QSIT. And then lastly, for even more information about QMSR, you can review the QMSR frequently asked questions that are here on the screen.

So now I'm going to turn it back to Kim Piermatteo to close us out.

**CAPT Kim Piermatteo:** Thanks again Karen.

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**CAPT Kim Piermatteo:** Before we conclude today's town hall, I want to remind everyone a recording of today's event, the slides 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 at www.fda.gov/CDRHevents.

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

## Slide 34

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