Medical Device Sterilization Town Hall: Sterilization Open Q&A
June 12, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello and welcome, everyone. Thanks for joining us. This is our eighth town hall in this medical device sterilization series. This is Commander 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 in CDRH's Office of Communication and Education. I'll be the moderator for today's town hall.

The FDA is committed to reducing reliance on ethylene oxide sterilization use, while ensuring the integrity of the supply chain so that patients and providers have continued access to the sterile devices they need. To meet this goal, FDA continues to take a multi-pronged approach, including regulatory flexibilities, supply chain analysis and mitigation, collaboration, innovation, and communication, including this series of town halls.

As always, I'd like to share a few administrative items before we get started. First, printable slides of today's presentation are currently available on CDRH Learn. To obtain these slides, you can go to CDRH Learn at www.fda.gov/training/cdrhlearn and select the section titled Specialty Technical Topics. And then scroll down until you get to the subsection titled, Sterility. And there, you will find the medical device sterilization town halls section, and a link to the printable slides for today's town hall, as well as materials from our past town halls.

Next, please make sure you joined us through the Zoom app and not through a web browser to avoid technical issues. And lastly, trade press reporters are encouraged to consult with the CDRH Trade Press Team at cdrhtradepress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at fdaoma@fda.hhs.gov.

For today's town hall, we will begin with discussing questions the FDA received to the medical device sterilization mailbox in our segment on what we heard from you last time. And then, we will transition to a live question-and-answer segment where we look forward to interacting with you. If you have a comment or question, please wait to raise your hand in Zoom until we transition to the live question-and-answer segment. I now have the pleasure of introducing today's panelists.

First is Dr. Aftin Ross, Deputy Director of the Office of Readiness and Response within the CDRH's Office of Strategic Partnerships and Technology Innovation, or OST; Christopher Dugard, Assistant Director for Sterility Devices in the Office of Health Technology number 4 in the Office of Product Evaluation and Quality, or OPEQ; Dr. Tammy Beckham, Director of the Office of Supply Chain Resilience in OST; Dr. Ryan Ortega, Regulatory Advisor on the Regulatory Policy and Combination Products staff within OPEQ; and Dr. Shani Haugen, Assistant Director for Gastroenterology and Endoscopy Devices in the Office of Health Technology number 3 in OPEQ as well. Thank you all for joining today.

For our audience, if you've attended some or all of our previous town hall events, you'll recognize all of today's panelists who are, again, looking forward to answering your questions in the broad areas of FDA's sterilization activities to date, premarket considerations, and supply chain resilience. So, we look forward to interacting with you during the Q&A segment, and our panel of experts look forward to your questions. I'll now turn it over to Aftin to start us off today. Aftin.

Aftin Ross: Thank you for joining us for our eighth sterilization town hall. As we shared with you in our April town hall, we wanted to ensure at least one town hall event focused wholly on engaging with you in answering your questions. Today is just such an event. We'll start with answering a question we received in our mailbox, then we'll transition directly to the live Q&A portion of the event.

During several of the previous town halls, we've asked for your questions and suggestions for additional sterilization topics of interest. We received an email with questions related to disinfection and sterilization. And we would like to share more about the scope of these concepts, and where you can find additional information.

The questions we received include, where do UV light systems fall in terms of disinfecting and sterilization acceptance? Question two, where does the sanitation wiping fall in terms of disinfecting and sterilization acceptance? And question number three, how long does gas plasma sanitation last in terms of calendar months and still qualify as sterilization?

In response, we like to say that there are many terms in the questions we received that we would like to define. Per ISO standard 14937, sterilization is a validated process used to render product free from viable microorganisms. Disinfection and sanitization have varying levels of microbial reduction, meaning there are some viable organisms still present.

Regarding the UV light systems question, this modality was discussed in town hall 3, where we discussed the three different categories of sterilization modalities described in our 510(k) sterility guidance. We encourage you to access the presentation slides and transcript of town hall three to further understand the agency's thinking on UV systems. These materials can be found at CDRH Learn at www.fda.gov/training/cdrhlearn by selecting the section titled Specialty Technical Topics, and then scrolling down to the subsection titled, Sterility.

For the second question about sanitation wipes, or alcohol wipes, as an example, these are typically viewed as a means of microorganism reduction and not a sterilization method. In part, because devices exposed to sanitization wipes would not achieve the necessary spore reduction, nor are those devices exposed to a controlled sterilization process in a sterile barrier system like sterile packaging.

Finally, regarding the last question, we believe the questioner was referring to shelf life in the context of sterilization because, as mentioned before, sanitation and sterilization are not synonymous terms. In that case, shelf life is validated based on data using aging studies and considering the ability of the packaging to maintain a sterile barrier over time. Device manufacturer will define shelf life and that manufacturer will perform tests to support that length of time. Now, I'll turn it back over to Kim, our moderator, to get the discussion started on our live Q&A panel.

CDR Kim Piermatteo: Thanks, Aftin. As Aftin mentioned, we will now transition to our interactive question-and-answer segment for today. We had a lot of engagement during last month's town hall, and our previous town halls, so, I do encourage our attendees today to take this opportunity to ask our experts today any questions that you might have, or any follow-up questions you might have from one of the previous town halls.

So, before we get started, I'd like to go over how we'll manage this segment and a few reminders. To ask a question or provide a comment, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll then announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line, please identify yourself and your organization, and then ask your question or provide your comment. If you have a question, please remember to limit yourself to asking one question only. And if you have another question, you're more than welcome to raise your hand again to get back into the queue.

As we wait to receive some of your questions and comments for today, I'd like to start us off with two questions. And the first question, I'll direct that to Chris. So, Chris, the question is, does FDA have any recommendations on what to consider when changing device packaging to accommodate a new modality?

Christopher Dugard: Hi. Thanks, Kim. Great question. It's definitely something we get quite a lot. So medical devices are typically packaged in primary and secondary packaging. Primary packaging means packaging that is, or may be, in direct contact with the device. Secondary packaging means packaging that's not, and will not be, in direct contact with the device, kind of like a second, secondary box.

Regarding sterility, primary packaging serves a critical part of every sterile device by maintaining a sterile barrier, which is what we focus on in the agency. Manufacturers should consider the testing that is needed to support any packaging change, while also considering the implementation of shelf-life testing to show the package will maintain a sterile barrier over the documented expiration date. While the need for new testing can be considered on a case-by-case basis, a new modality typically has the potential to impact the packaging materials. So new testing may be needed. For more information on shelf-life testing, I recommend referring to the guidance titled shelf life of medical devices. Please also be aware that product shelf-life testing can be device specific. Therefore, we also encourage you to consult the OHT that regulates your devices for any relevant guidances, guidance documents, or standards for that particular device. Thank you.

CDR Kim Piermatteo: Thanks, Chris. So, Shani, I'd like to ask you our next question. And that question is, does FDA have any recommendations on how to think about sterilization moving forward through design development and across the total product life cycle?

Shani Haugen: Thank you, Kim. Well, we encourage device manufacturers to consider sterilization requirements for your device well in advance of producing the device, recognizing that changes are much easier to implement early in the development stage. So, thinking about what kind of specific design inputs you would need for your device to be sterilized with different sterilization modalities.

As for the entire total product life cycle of your device, if you decide to switch your sterilization modality, FDA recommends that you have a thorough understanding of benefits, and any caveats about the sterilization modality you are considering. So, things like material compatibility, device geometry, and any challenging features, the lot size for your device, patient contact classification, or even just the general intended use of your device. These are all factors that may play into choosing a sterilization modality.

So, for example, picking up on packaging that Chris just discussed, if you would like to switch to vaporized hydrogen peroxide, this modality has challenges with cellulose-based materials, so, your

packaging may need to be reconsidered. And the secondary packaging process may need to occur after sterilization. So that's just some select examples, and certainly not an exhaustive list of premarket or post market considerations.

CDR Kim Piermatteo: Great. Thanks, Shani. So again, I encourage our audience to raise your hand and ask your questions, but while we wait for you to do that, I'm going to go ahead and ask another panelist a question that we received. And Ryan, I'm going to come to you for this question. And that question is, does a material change warrant biocompatibility testing?

Ryan Ortega: Yeah, thanks, Kim. This is a common question we get actually in a lot of different contexts. In the context of sterility, you know you might think where a manufacturer might want to make a material change if they're trying to support a sterilization change or trying to make something easier to sterilize. And ultimately, just in general, if you're thinking about a material change, and if it could warrant biocompatibility testing, to a certain extent, it really kind of depends on what the actual material change is. But some general things to think about is that a new material typically will warrant additional biocompatibility testing.

Another scenario to consider is that removing a material while everything else, all the other material, stays the same may actually not result in the need for new testing. You can imagine a case where just that one material is now being removed, but everything else stays the same, and with kind of the same amounts.

Other things to consider, a change in manufacturing could warrant additional testing, even if you've got the same materials. In cases like this, you might think that different contaminants are introduced, or maybe different additives, or different components of the revised manufacturing that could introduce new things in the process and that should be addressed.

Another important consideration, the material, and also the overall devices, type, and duration of patient contact, that's a really important consideration for thinking about what endpoints, what biocompatibility endpoints, you might want to consider. I'll also point folks to our guidance that was, that was really useful to me personally in some of our submission review, but I think generally, is very helpful for biocompatibility. That's the, our guidance Use of International Standard ISO 10993 and that standard is in the biological evaluation of medical device series. It's part one, which is the evaluation and testing within a risk management process.

CDR Kim Piermatteo: Thanks, Ryan. OK, I'm going to go to another question that we received. And Shani, I'm going to actually come to you for this one. So, Shani, the question I have is, can I utilize more than one modality for my product?

Shani Haugen: Yeah, thank you, Kim. Absolutely. If a device manufacturer wanted to offer different versions of their device, their sterile device, using different sterilization modalities, that would make a lot of sense. No one is limited to just offering their device with a single modality. I will note, however, that appropriate testing, meaning that sterilization cycle does need to be validated, device performance with different sterilization modalities needs to be considered, and any biocompatibility concerns would need to be addressed. So, all of that kind of testing should be conducted to support each sterilization modality.

CDR Kim Piermatteo: Thanks, Shani. Alright, so, I do encourage our audience members to raise your hand to take advantage of our panel of experts today, especially about supply chain issues, or any questions you have about premarket considerations. But I'm going to come back to Chris with another question. Chris, that question is, how does one determine which PMA supplement to use for a change?

Christopher Dugard: Thanks, Kim. So, it really depends on the change that's being made. Significant changes to the device itself that may impact the safety and efficacy of the device typically require a 180-day PMA supplement. If the change is minor, a real-time supplement can be considered. For manufacturing changes, a 30-day notice may be appropriate. For more information, please consult our guidance Modifications to Devices Subject to Premarket Approval, which we mentioned in our previous presentation. And a link to the guidance is also in this presentation. And of course, I do always want to encourage folks to reach out to the appropriate OHT for their thoughts on the appropriate submission type as well. Thanks, Kim.

CDR Kim Piermatteo: Thanks, Chris. OK, so I'm going to call on our first audience member. I'm calling on SCD. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

So SCD, that is the name that comes up, I've unmuted your line. Are you able to unmute your line?

OK. SCD, if you have another question, please go ahead, and raise your hand again and I will try to call on you again. Alright. So, the next question is coming from Jocelyne. Jocelyne. Sorry. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Jocelyne Wright: Hello. I would just like to know, given the recent EPA changes that came out regarding the ethylene oxide standards, this was issued around about March 14, 2024, regarding the emissions of EtO, and now manufacturers having to change sterilizers. Is there any guidance or, I guess, best practices that the panel can offer given the timing and the logistics that it normally takes to change from one sterilizer to another?

CDR Kim Piermatteo: Thanks, Jocelyne, for that question. I'm going to turn it over to our panelists. So, Ryan or Aftin, or any of the other panelists, feel free to chime in.

Ryan Ortega: Yeah. I can maybe get us started, and folks can fill in, too, if there's anything additional if I miss anything. We've been, we've had a lot of activities over the past, well, over the past month since F, EPA finalized their rule, but really over the past several years, all kind of leading up to that. I think as far as best practices go; I think we have a handful of options that folks could potentially take advantage of to help make sterilization changes in a least burdensome way. We've got our master file pilots and I think we're always open to outreach for folks to tell us a little bit about if they're facing challenges, that sort of thing. If you anticipate a potential loss of sterilization capacity, especially something that might increase a risk for device shortages, strongly encourage you to reach out to our resilient supply chain team.

You could also potentially have a Q-Submission to our Q-Sub program with your review division for a specific device or device type. If you have some specific ideas or specific questions about what you might want to do with respect to sterilization of your device to help mitigate the potential for shortages, the individual review teams are ready to provide feedback and can also leverage some of the sterility expertise, not just in their office, but across the center.

I would encourage you also for device manufacturers who are concerned about this. And you've got preexisting relationships with sterilization providers, reach out to talk to them. I think it always pays to be proactive about understanding potential impact to your device and understanding what your options are. I think by and large, over the past several years, we've really tried to take an every-tool-in-the-toolbox sort of approach to what FDA can do, and really try to encourage a lot of open communication and collaboration, not just with us, but out there in industry, too, in particular between manufacturers and sterilization providers. So, I'll see if anybody else has any thoughts too.

Tammy Beckham: Hi. Yeah, this is Tammy from the Office of Supply Chain Resilience, and we are very happy to work with you and understand some of the challenges that you might be facing. So definitely reach out to our office. And then if you are anticipating a supply chain disruption, you can always report that to the 506(j) process and you can submit that, and I can put the site in the chat. But and the providers, our health systems, can also submit information to our device shortages mailbox as well. And I'm happy to put that in the chat as well. So, but happy to hear from you and direct outreach so that we might determine how best to help assist with, we'd be happy to do that.

Aftin Ross: And this is Aftin. Since we don't have access, actually, to the chat, we thought that what we would do is we would give you that mailbox. It is deviceshortages@fda.hhs.gov.

CDR Kim Piermatteo: Thanks, Tammy. And thanks, Ryan, and Aftin. And thank you, Jocelyne, for that question. Our next question, or comment, is coming from Steve. Steve, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Steve Davis: OK, can you hear me?

CDR Kim Piermatteo: Yes, we can.

Steve Davis: Excellent. Sorry about that before. So, I have a question about the, if we're using, currently, let's say on bench or our in vivo models, we're using a sterilization method that maybe isn't one of the accepted methods that the, I guess, FDA would use. So, it's not radiation, or EtO, et cetera. We're using UV for just one component of the implant due to heat issues with our implant because we had to use UV. So, is it possible to use something that's not generally accepted? I don't believe that UV is accepted or listed in the guidance for the various methods that the FDA prefers. And if so, how could we, how do we prove that? Let's say we're going to sterilize the whole kit with EtO but this one component we want to use, UV, is that possible? Or do we have to use something like either like a radiation, or a dry heat, or something that is within your current accepted. Can we go off sort of off the list of the usual methods for a component as long as we prove sterility in some way, for the final out final device?

CDR Kim Piermatteo: Thanks, Steve. I think I'm going to turn it over to Chris. Chris, do you have some comments or feedback?

Christopher Dugard: Yes. Thanks, Kim. And thanks for the question, Steve. So that's actually a really great question. So, when we divide our modalities up between the various categories, established A, B, and novel, really, that's to delineate the level of evidence we need to support the validation of that cycle. We, we are not, we are open to any potential modality as long as that you can prove it is a sterilant, meaning you show the adequate log reduction, it's repeatable, you have a monitoring system,

a sterile barrier system. So, for these very new modalities that haven't been proven to be a sterilant yet, you got your work cut out for you, but absolutely, we would not say no to you using that particular modality. And if you're pursuing that, it's another chance for me to highly encourage you to please reach out to the agency and discuss with us before you pursue. But yes, definitely open to it.

Steve Davis: Thank you.

Shani Haugen: And if I can just jump in on that as well, so it might be helpful to look at ISO 14937 to have a general understanding of the type of sterilization validation activities that we might be looking for when discussing your sterilization method.

Steve Davis: OK, thank you.

CDR Kim Piermatteo: Thank you, Shani, and Thank you, Chris, and thanks, Steve, for that question. Our next question is coming from Hannah. Hannah, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Hannah Daniel: Hi. Can you hear me, OK?

CDR Kim Piermatteo: Yes, if you could just speak a little bit louder, that would be great.

Hannah Daniel: Yeah, absolutely. Yeah, since the EPA rule was finalized, I know that there was some concern from FDA about it. So, I was wondering if there is any collaboration going on with FDA and the EPA now that the rule is published.

Aftin Ross: Hi, Hannah. So, we certainly have been for the past bunch of years and continue to collaborate with our partners across the federal government, certainly including EPA. We have regular touch bases with them so that we can remain aware of each other's activities. And we think that that collaboration is certainly going to help us in industry as we go forward. I know the first questioner was asking about, for example, concerns associated with disruptions. And so that certainly is one way that we, getting that stakeholder feedback are certainly things that we can share with our government partners as we work with industry to come into compliance with EPA's rule. So those are certainly some of the things.

The other thing I also want to just remind everyone, I think Kim said this at the beginning. But if you are trade press or others, it's also very helpful if you go through our CDRH press officer. Thanks.

CDR Kim Piermatteo: Thank you, Hannah. And thank you, Aftin. I am going to circle back. So, it looks like, Jocelyne, you have another question or comment. I've unmuted your line. Please unmute yourself and ask your question or provide your comment.

Jocelyne Wright: Yes. Just for my question is, is the 510(k) special application process an appropriate application process where there's no changes, just changing the sterilizer? And when I say no changes, meaning it's like for like, the sterilizer is being changed, but there is a parametric release being introduced, which was not in the original traditional 510(k)?

CDR Kim Piermatteo: Thank you, Jocelyne, for that question. I'm going to turn it to our panelists. So, some of our SMEs on the premarket side, Ryan, Chris, Shani, do you want to provide any feedback?

Shani Haugen: Well, I can start and please feel free to jump in. So, for 510(k)s, when you're moving from one established A method to another established A method, I would encourage you to look at the guidance document for modifications to your devices to understand whether, when to submit a 510(k). Most of the time, when switching from one, one established A method to another established A method, we would not actually need to see a lot of sterility information. So that is often a change that can be documented in your internal letters to file. But if there is some kind of very specific device issue associated with concerns regarding parametric release, then that is something that I would encourage you to discuss with your specific review division.

Jocelyne Wright: OK, thank you.

CDR Kim Piermatteo: Thanks, Jocelyne. And thanks, Shani. Does, does any other panelist want to add on? I just want to give an opportunity before I move on.

OK. Hearing none. Our next question or comment is coming from Eddie. Eddie, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Eddie Almeida: Hi. Eddie Almeida. If we're developing a new sterilization modality, such as using nitrogen dioxide, what is the process for appropriate testing to develop chemical indicator strips for the device?

CDR Kim Piermatteo: Thank you, Eddie, for that question. I think, Chris, I'm going to turn it over to you first and then if anyone else has anything they want to add, please feel free to chime in.

Christopher Dugard: Yeah, that's, this is Chris. Thanks for that question. And I'd love to answer it, but unfortunately, it would be a fairly involved answer that we could probably hold a town hall on just on how to develop process monitors. I will point you to our chemical indicator guidance, though. We do have a guidance out there that outlines the testing and requirements needed to develop it and what information we need when you submit that to the agency.

CDR Kim Piermatteo: Thanks, Chris.

Eddie Almeida: Thanks.

CDR Kim Piermatteo: Thanks, Eddie, for that question.

OK, so I don't see any more raised hands. So, I'm going to go back to our panelists for another question that we previously received. And Aftin, I'm going to come to you for this question. The question is, will the new tiger team be able to facilitate challenges a manufacturer might face with a premarket submission related to sterilization?

Aftin Ross: Thank you, Kim, for the question. So, the tiger team, as we've mentioned actually in some of our previous town halls, when we kind of launched the series, it's really focused on a broad set of efforts that are aimed at trying to reduce reliance on EtO for medical device sterilization. While the team is not

directly involved in individual premarket reviews, our team does include review office SME. And this allows us to ensure our activities support effective premarket review, including any potential policy incentives or regulatory activity that might result. So, we would recommend reaching out to the appropriate review, OHT, for specific questions regarding your product.

CDR Kim Piermatteo: Thanks, Aftin. And I think I'm going to jump to Chris. So, Chris, I'm going to come to you for a question related to premarket a little bit. And that is basically, who determines if a change warrants a new, a 510(k), a new 510(k)?

Christopher Dugard: Thanks, Kim. Another great question. Ultimately, it's the responsibility of the sponsor to determine if a change warrants a 510(k). Using the considerations and guiding principles in our 510(k) modifications guidance, which we've referenced a few times. If you would like the agency's input on a proposed change, we recommend you submit a Q-Submission to discuss. And note that regardless of the need for a 510(k) or not, the rationale for this conclusion on whether or not you need to submit a 510(k) should be documented by the manufacturer internally.

CDR Kim Piermatteo: Thanks, Chris. And I think, again, if our audience has any questions, please raise your hand at this time. I would like to circle back to Ryan maybe for one last previously submitted question. And if you have a question, please raise your hand to ask our panel of experts today. But Ryan, I wanted to ask the question, what is FDA planning to do to ease the regulatory burden for testing validation?

Ryan Ortega: Yeah, thanks, Kim. And I think this has some similarities to the question I believe it was that Jocelyne asked earlier. I think we're always trying to strike the right balance about the information that we need for review. And that matters kind of it's based on the type of submission, and for sterility, the type of sterilization method that's used. And we really want to try to be as least burdensome as possible. So, one of the things that we're doing, we're leveraging what we've learned so far from the master file pilots and the innovation challenges. We're exploring different opportunities for regulatory flexibilities, trying to think, what might help lessen the regulatory burden while still providing that reasonable assurance of device safety and effectiveness? So, I think, we're trying to cast a wide net. We are trying to be creative ourselves, and also facilitate our external stakeholders being creative as well.

So one thing I want to note here is that if you have questions about trying something novel, or exploring a unique way to address sterilization challenges that you might be facing, or even if you just want our feedback on what might be the least burdensome set of information to include in a submission with respect to device sterility, again, I know we sound like a broken record, but our, I want to point you to our Q-Submission process because it can be such an effective way to get some feedback from FDA and connect with the review team for your specific device to ask your specific questions. So, I definitely encourage folks to leverage that program.

CDR Kim Piermatteo: Thank you so much, Ryan. OK, so next, I'm going to call on, I believe, Daniela. Daniela, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Daniela Bocioaga: Hi. Thank you. We wanted to know how to approach validating a rapid readout biological indicator. Can you offer some guidance? Thank you.

CDR Kim Piermatteo: Danielle, I apologize. Could you restate that question. I had a hard time hearing you.

Daniela Bocioaga: Oh, OK. Yes, we are working towards submitting appropriate submission for validating our sterilizer, and are considering utilizing a rapid readout BI, and would like to know how to approach using a rapid readout, including a rapid readout.

CDR Kim Piermatteo: Oh, thank you. Thank you for, yeah, thank you for clarifying. Chris, I'm going to turn it over to you.

Christopher Dugard: Thank you, Kim. So again, great question, but also, another question that could potentially be a very long answer. So instead of getting into the nitty gritty details about it, I will refer you to both our biological indicator guidance, but also the standard ISO 11138 part eight, which discusses the method to validate a reduced incubation time. That should walk you straight through it and that, combined with our guidance, should give you everything you need to validate whichever incubation time you're going for. And of course, the theme of my responses has been, please communicate and reach out to the agency when you have questions. This is another great example of a situation where when you're developing a BI, reaching out to us early in the process would be a great benefit to you. Thank you.

Daniela Bocioaga: Thank you.

CDR Kim Piermatteo: Thanks, Chris. And thanks, Daniela.

OK, so I'm going to make one last call out. If anyone has a question for our expert panel today, please raise your hand in Zoom.

OK, Steve. I'm going to go ahead. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Steve: OK, can you hear me, OK?

CDR Kim Piermatteo: Yes, we can.

Steve: OK, excellent. So, I believe someone had mentioned using the Q-Sub process in order to get feedback on maybe using a sterilization method that's outside the norm. So, I was curious, what, is there a typical lead time for getting a response to those types of questions? Like, should we sort of a Pre-Sub where it takes 70 to 75 days to get either written, or a meeting response? Is there, right now in your division, is there a certain amount of time, just so we can plan ahead if it's a long period of time, or if it's a pretty quick turnaround? I was just curious.

CDR Kim Piermatteo: Thanks, Steve. Ryan.

Ryan Ortega: Yeah,

CDR Kim Piermatteo: OK. Sorry. Go ahead.

Ryan Ortega: No worries. Steve, that's a good question. I think one thing that I know, my answer, I probably could have made more clear, at least whenever I was talking about referring to the Q-Submission process as a way to talk to us, I think by and large, most of the types of interactions that we've described today would be within that Pre-Submission process, which is one type of Q-Submission. So, the, it sounded like you're familiar with the timelines for a Pre-Sub. Those would be the ones that would generally apply to the types of interactions that we've talked about here. And for folks who haven't seen our Q-Sub guidance, that guidance does go into some of the different types of Q-Submissions, Pre-Submission is one of those, and talks about the timeline for those sort of reviews.

CDR Kim Piermatteo: Thanks, Ryan. And thanks, Steve. OK, I'm going to come back to Eddie. Eddie, do you have another question, or would like to provide a comment?

Eddie Almeida: Yes, I have a new question.

CDR Kim Piermatteo: Sure.

Eddie Almeida: So, for a new sterilization modality such as nitrogen dioxide, how many rounds of tests would be required to validate the device while being the least burdensome for us?

CDR Kim Piermatteo: Thanks, Eddie. So, I'm going to turn it to our panel. I know this is a very specific question. I'm, I'll turn it to our panel. OK.

Christopher Dugard: I can take this. This is Chris. I can take this one. Unfortunately, I'm not sure I have a specific answer for you because, again, it depends on your specific situation. But I'll refer back to an answer that Dr. Haugen provided earlier, referring you to ISO 14937, which if you've got a new modality, and you're unsure of where to go, that's the first document you need to look at. And then if you've got a specific device that you're thinking of, and a specific cycle, please do reach out to us. And we can provide you feedback on your proposed methods and get you on the right track.

CDR Kim Piermatteo: Thanks, Chris. And thanks again, Eddie. Alright. I'm going to make one last call out. If anyone has a question or comment, please raise your hand in Zoom at this time.

OK. Seeing none. That will wrap up our comment and question-and-answer segment for today. I'd like to turn it back over to Tammy from our supply chain team to provide an update from a previous comment made earlier. So, Tammy.

Tammy Beckham: Yeah, thank you. And just a closing comment. Certainly, if there are, if you guys are experiencing any issues around supply chain disruptions, please do reach out to us. We are happy to engage with you and realize that in the process of implementation of some of the new regulations, that there could be periods of time, temporary shutdowns, and so, we're happy to engage and understand what that looks like. For manufacturers, you can email us at cdrhmanufacturershortage@fda.hhs.gov. For medical device healthcare systems, et cetera, you can email us at deviceshortages@fda.hhs.gov. So, we're happy to hear from you and happy to engage if needed. So please reach out to us. Thank you.

CDR Kim Piermatteo: Thanks, Tammy. And thanks again, everyone, for your participation today. I will turn it back over to Aftin to provide her final remarks for today. Aftin.

Aftin Ross: Thank you very much, Kim. And thank you, everyone, for joining us today. We recognize what hectic schedules you have and with summer upon us, that becomes even more hectic. We had a lot of good dialogue and discussion today, including about ways manufacturers can share challenges that they are facing from a supply chain perspective, as well as questions that they might have as they think about using novel sterilization methods as well [AUDIO OUT] validating indicators.

We also learned more about some of the considerations for those novel sterilization methods, and some of the resources that are available to help manufacturers as they work through this in addition to being able to reach out to FDA. And I think that's the primary theme that we have from the discussion that we've had today, is that we want to engage with you. We would like to engage with you early and often on these critical sterilization modality, questions, comments, and concerns. So please reach out in the various ways that we've talked about today, be it the Q-Sub, be it some of our different mailboxes, we want to hear from and engage with you. Thank you, Kim.

CDR Kim Piermatteo: Thanks again, Aftin. So, a few closing remarks from my end. As I mentioned earlier, printable slides of today's presentation are currently available on CDRH Learn at the link provided on this slide under the section titled Specialty Technical Topics, and the subsection titled, Sterility. A recording of today's town hall and a transcript with all those links and those emails that we mentioned in that transcript, and that will be posted to CDRH Learn under the same section and subsection in the next few weeks.

A screenshot of where you can find these materials on CDRH Learn is provided on this slide. Also mentioned earlier, if you have any additional questions or comments about today's topic, or presentation, or as Aftin mentioned, just to provide feedback to the agency, please submit those to the medical device sterilization mailbox. That email is provided on the slide as well. You can find a listing of all of our upcoming town halls and other CDRH events via the link provided on the bottom of this slide at www.fda.gov/cdrhevents.

And lastly, I am excited to announce our next sterilization town hall on July 10 from 1:00 to 2:30 PM. We had several questions today about using our Pre-Submission program, or sorry, Pre-Submission or Q-Submission process. So, for our next town hall, our panel of sterilization experts will present a mock Pre-Submission from a fictional manufacturer discussing a fictional device. The panel will discuss the manufacturer's Pre-Submission questions, including the manufacturer's proposed approach to a sterilization modality change, focusing on the manufacturer's risk assessment and proposed testing. So, we hope you're able to join us for this future town hall.

This concludes our town hall for today. Thank you, again, for joining us. And have a nice day.

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