**Medical Device Sterilization Town Hall: Topics and Formats for the Continuing Sterilization Series**
**April 29, 2024**

**Moderator: CDR Kim Piermatteo**

**CDR Kim Piermatteo:** Hello, everyone and welcome. Thanks for joining us for our sixth Medical Device Sterilization Town Hall. 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.

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 these town hall series.

I would like to share a few administrative items before we get started today. 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 to the subsection titled Sterility. 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 past town halls.

Next, please make sure you've joined us through the Zoom app, and not through a web browser to avoid technical issues. Additionally, 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 the FDA's Office of Media Affairs at fdaoma@fda.hhs.gov. And lastly, we look forward to interacting with you today. If you have a comment or question, please wait to raise your hand in Zoom until after the presentation and we transition to this segment.

I now have the pleasure of introducing our presenters for today's town hall. Dr. Aftin Ross, Deputy Director of the Office of Readiness and Response in CDRH's Office of Strategic Partnerships and Technology Innovation, or OST. Dr. Lisa Simone, Senior Health Scientist and EtO Incident Lead in the Division of All Hazards Preparedness and Response in the Office of Readiness and Response within OST as well. LCDR Scott Steffen, Senior Program Management Officer and EtO Incident Lead in the Division of All Hazards Preparedness and Response in the Office of Readiness and Response within OST also. Dr. Ryan Ortega, Regulatory Advisor on the Regulatory Policy and Combination Products Staff within the Office of Product Evaluation and Quality, or OPEQ. CDR Tamara Rosbury, Health Scientist and EtO Incident Response Team Member in the Division of All Hazards Preparedness and Response in the Office of Readiness and Response within OST also. And Dr. Jon Weeks, Acting Assistant Director of the Division of Biology, Chemistry, and Materials Science in the Office of Science and Engineering Laboratories. Thank you all for joining us.

I'd now like to turn it over to Aftin to start today's presentation. Aftin?

**Aftin Ross:** Thank you for joining us for our sixth Sterilization Town Hall. Before we get started with our discussion today, we'd like to take the opportunity to answer some questions we received in our mailbox.

First question, is there a regulation or guideline that prohibits the practice of including printed instructions for use inside instrument sets subjected to steam sterilization? If it is permissible, are there specific requirements regarding the type of paper used? Or do these papers need to be encased in a sleeve or folded in a particular manner on the exterior of the tray?

In response, we would say that we are not aware of any regulation that prohibits the inclusion of instructions for use in the packaging of the medical device being sterilized or any regulation that specifies the type of paper or its configuration. However, the manufacturer should assess material compatibility of the instructions. For example, cellulose products cannot be sterilized via vaporized hydrogen peroxide. Any instructions or additional paper should be considered as part of the product's validation and as part of worst-case load considerations. Our labeling web page has more information and links related to labeling topics that can be found at www.fda.gov/medical-devices/overview-device - regulation/devicelabeling.

Second question, is there a publicly available list of facilities registered to perform ethylene oxide and gamma radiation in E-beam sterilization in the United States?

In response, we would say that the list of contract sterilizers registered with FDA is available on our Establishment Registration and Device Listing database, or the R&L database. The link is also included on the Resources slide. In the Search Database section of the R&L website under Establishment Type, select Contract Sterilizer from the dropdown list. The results are not listed by sterilization modality. The information from the R&L database can be used to search more broadly to identify additional public information about the facility.

Third question, who at FDA would be able to provide the pathway necessary to introduce our chlorine device for consideration as a liquid sterilant?

In response, we would say, we are always interested in hearing about new and innovative sterilization modalities. If you are interested in marketing a new healthcare sterilizer, a great vehicle to bring this discussion to the agency is through our Q-Submission Program. Under this program, there are several submission types. For this topic, you may consider a Pre-Submission of specific questions for our sterility devices team in OHT4 or an informational meeting if you want to share information with FDA about expectation of feedback. Please be aware that while FDA staff may ask clarifying questions during an informational meeting, they will generally be listening during the meeting and not prepared to provide any feedback. For more information on how to request and prepare for a Pre-Submission or informational meeting, we encourage you to consult our guidance, Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program. A link to this guidance will be included in the Resources slide.

If you are developing a new terminal sterilization modality, then FDA does not clear or prove terminal sterilization methods as these are considered part of manufacturing of a device. We review terminal sterilization as part of our review practices for specific sterile devices, but the sterilization process and validation are assessed within the context of the marketing submission for the specific device. Next slide, please.

We've shared this timeline previously. The updates for this town hall include discussion related to the formation of the EtO Tiger team, the launch of our medical device sterilization series, and the launch of the second part of this medical device sterilization series. Next slide, please.

Today's town hall on medical device sterilization is a transitional event. As we extend our original series of five town halls to include additional topics of interest, we're also interested in pivoting the delivery mechanism of these town halls to be more engaging and interactive and less formal by using fewer PowerPoint slides. That kind of information sharing was important in the beginning when we focused on setting the stage for the current sterilization challenges and exploring current regulatory needs for sterilization related reviews. However, we think a more interactive discussion would be beneficial for upcoming town halls.

We've asked for your feedback on additional topics and today, we'll talk about what you've shared and also relay our thinking for how the format of the town hall series might change to encourage additional interactions with you. Today, we will share our thinking as we move forward and give you the opportunity to respond and potentially course correct our understanding of your needs. We've recast our traditional learning objectives as discussion points and today, our panel will focus on the two topics shown here. These are, discuss the suggestions FDA has received regarding potential topics for the sterilization town hall series, and discuss how FDA will pivot the format of the series to support more engaging discussions on topics of interest. I will now pass it to Lisa Simone to get the discussion started on topic number one. Lisa?

**Lisa Simone:** Thanks, Aftin. Next slide, please.

Since the first town hall in January, you've been providing suggestions about future town hall topics. You've identified a broad range of topics, several of which were offered by multiple stakeholders. And six members of the CDRH EtO Tiger Team, who Kim introduced at the start of the town hall, would like to share thoughts on how we might incorporate your feedback and questions into the town hall series. Next slide, please.

This is the list of topic areas you suggested. It includes feedback from our mailbox, from the live Q&As at the end of each event, and also from discussions that we've had from you over the other past venues. I do want to clarify that the intent of today's discussion is to make sure we understand the scope of the suggested topics and get a better understanding of which topics have the greatest interest or maybe the most meaningful. All while recognizing that we may not be able to discuss every possible scenario. But before I open the panel, Tamara, would you share some of the types of emails that we've been receiving in the mailbox?

**CDR Tamara Rosbury:** Certainly, Lisa. We created our mailbox in December of last year when we launched this town hall series. Since then, we've received emails in several different areas. Most questions pertain to upcoming town hall information, such as links and schedule or dates. Based on your feedback, we've updated our site navigation and are planning to relay town hall details sooner.

The second largest group of questions pertained to sterilization in general or alternative modalities, for example, predetermined change control plans, or PCCPs, steam sterilization, vaporized hydrogen peroxide, or VHP, and novel methods.

The third largest group of questions were regulatory or review-related pertaining to devices and biologic device combo products for 510(k) requirements, electronic labeling, device reprocessing, and international regulatory agency interactions. We've addressed several of these topics at the What We Heard from You Last Time segment at the start of previous town halls. We addressed some individual questions by responding directly to the individual who contacted us, and some represent proposed potential town hall topic ideas, many of which you see here.

**Lisa Simone:** Thanks, Tamara. I'd like to turn to the other panelists to share thoughts on each of these as potential town hall topics and where we might be able to provide some value in exploring each in more detail. Scott, several suggestions focused on technical topics, for example, topics related to sterilization cycle design. Would you share thoughts on these topics?

**LCDR Scott Steffen:** Thanks, Lisa. Cycle design is an area where the expertise is more outside FDA, and we think it may be better initiated by industry through the expertise of their sterilization consultants or contract sterilizers. We might not be the first people you go to for technical insights, but we are here to provide any feedback regarding their impacts to your submissions. This said, please feel free to provide additional thoughts on topics you think FDA may be well positioned to help move the field forward. Cycle design may not be our expertise, but there are other technical topics that we can provide input on, for example, the next bullet on alternative sterilization methods. For this topic, we would defer to industry SMEs for detailed technical information about specific modalities, but we're here to discuss the regulatory aspects of switching modalities, especially those without a modality-specific standard.

In previous town halls, we talked about sterilization methods by category within the context of the updated 510(k) sterility guidance. For example, established A, established B, and novel methods. We also mentioned how one can view modifications in their existing devices in the context of 510(k)s and PMAs. However, this still appears to be a topic of high interest, being we've received several questions about specific modalities and switching to alternate methods, including radiation and chemical sterilants. We could take a deeper dive in this space on things to consider when switching or trying a new modality. Another technical topic that raised great interest is shown in the next bullet pertaining to material compatibility, which is a great topic we plan to discuss. Let me pass it to Jon, who can provide some insight.

**Jon Weeks:** Thanks, Scott. Material compatibility is just one consideration when initially choosing or when switching to an alternative sterilization modality. We do see significant value in a panel discussion that might focus more broadly on considerations, such as materials compatibility, packaging, and logistics. We've also received questions about a risk-based approach for assessing the risks associated with a sterilization change, and we understand that there are questions about the type of documentation that might be necessary during pre-market review.

One possibility is based on OSEL's work in considerations for evaluating performance and safety risks with the sterilization change. We recognize all these topics might raise review-related questions, which have been the focus of many topic requests from you. Ryan, would you share some thoughts on review topics in various mechanisms for interacting with the agency?

**Ryan Ortega:** Yeah, sure. Thanks, Jon. You know, like you said, there's a lot of different things we could potentially talk about from a review perspective. Those in the audience may have heard us say in the past that ultimately, a manufacturer is the most knowledgeable about their device, or maybe a sterilizer

is the most knowledgeable about their process. But we do see a lot of technical information over the course of our review. So, I think we have a wide perspective that we could share, and we've been able to develop our own technical expertise. And we could conceivably talk about technical topics like validation methods, microbiological methods, and quality. We could talk about assessing device function after sterilization or after sterilization changes, that sort of thing.

We could also talk about some of our perspective with respect to the sort of information to put in a submission. I will say, for a topic like that, it's really important to keep in mind that there is some overlap between the technical and the regulatory topics, but not everything that goes into sterilization and microbiological control ends up in every submission. It depends on the device type, the submission type, and if it's part of a change to sterilization, the type of change also. And we've talked a little bit about this in previous town halls, but I think we could cover more aspects of sterility information in regulatory submissions in upcoming town halls, maybe with some different formats.

One thing that we're thinking about with respect to format is a mock Pre-Submission or maybe a case study for a sterilization change from one modality to another. We've used that mock Pre-Sub format in the past in different venues, and they can be really effective for sharing technical and generalized regulatory information and some examples. We've actually received some interest already in this format. So, we are discussing internally how we could make that happen in this venue.

Some other feedback we've received is to specifically feature changes to hydrogen peroxide or radiation. So, we're also thinking about how we could structure a mock Pre-Sub to make it as generalizable as possible with respect to the questions and the discussion points.

**Lisa Simone:** Ryan, we continue to receive positive feedback about our engagement and great ideas like that mock Pre-Submission. And we've also received requests around our current incentive structures or potentially different ones. Could you share a little bit more about the [INAUDIBLE].

**Ryan Ortega:** Yes, so in the past, suggestions we've gotten from industry have driven the development of some approaches to reduce ethylene oxide use, like the sterility master file pilots. Also, our revision to the 510(k) sterility guidance. And we definitely welcome additional thoughts on where you anticipate challenges and how we could help. Really, anything that you could tell us about these existing initiatives, how it's worked for you or where you'd like to see changes to make them work for you, we'd be interested in that sort of feedback.

Also, if you have thoughts on new approaches or creative solutions that you think we should be exploring or testing, we welcome that input too. We could work on our own to develop solutions that we think are going to be useful and effective, but I really think that the best version of creative regulatory flexibilities or incentive structures should be informed by the needs of our stakeholders. Ultimately, it's this collaboration that will help ensure that we're maintaining access to sterile devices for patients and for care providers. And as we hear more ideas or develop any new approaches, we could use the town halls as a venue for discussing them.

Let's see. For the master files, we've received several questions about the master file pilot programs, and that's why they've been a subject of several of our previous town halls. We have come to understand that there are some broad questions about how to approach both developing and using the master files and the value that they can provide.

We'd really like to know if you'd like to see a town hall that discussed some sample situations to help you get started in seeing how one of the pilot programs might help you. For example, maybe we could talk about some common best practices or challenges we've seen during security master file review during the pilots. We could walk through the actual process of submitting one and responding to FDA feedback. And depending on interest, we could maybe even bring in some more of our sterility SMEs who have worked on the sterility master file pilots and have a discussion or maybe a Q&A about their experiences. So let us know if something like that would be valuable to you.

**Lisa Simone:** Thanks, Ryan. That's a great overview of the different incentive structures and also some of our internal thoughts about pursuing the master file as a town hall going forward. One comment that we've received pretty frequently is that FDA flexibilities won't be helpful to those who have an international presence, which does lead to the next suggested topic that of engagement with other regulatory jurisdictions. Aftin, is this a potential area for a future town hall?

**Aftin Ross:** This has been another common suggestion. We recognize challenges exist for those of you with an international presence, and we welcome conversations and engagement. During our last town hall, town hall five, we fielded some insightful questions about some of the challenges you face, and we asked about your experience or suggestions in the area of international alignment or harmonization or alliance. While we haven't received any specific thoughts since the last town hall, we continue to welcome those additional suggestions, whether that be today during our town hall or in our mailbox in follow up.

**Lisa Simone:** Thanks, Aftin. And thank you to everyone on the panel for sharing thoughts on how we might incorporate the suggested topics into future events and the additional information that we'd like to hear from you and now we'd like to use a poll to hear from you directly. Next slide, please.

Many of your suggestions came earlier this year as the series began, and we'd like to give you the opportunity to provide some real-time feedback with a live poll. And if you're following along separately, we are on slide 11 and I'll ask Kim now to launch our first poll question.

The poll should now appear on your screen separately from the PowerPoint slide. This poll includes specific feedback from you that the panel discussed on the last slide and also some other topics that have been popular during our past Q&A sessions. For each, please rate your level of interest for including the topic in a future town hall. The options are very interested, interested, slightly interested, and not interested. And please consider each of these topics individually as this is not a ranked scoring poll.

Also, be sure to expand the poll window or scroll down to see all eight options and the Submit button. You'll be asked to score each option in order to submit. And we'll keep the poll open for about 30 seconds. A note, if you do minimize or you lose the poll, you can restore the poll by navigating to your Zoom window and at the bottom, clicking on the Polls icon.

**CDR Kim Piermatteo:** Thanks, Lisa. This is Kim, and I'll let everyone know how much time is left and when the poll will be closing. We'll give you about another 15 to 20 seconds to provide your responses.

And don't forget, you may need to scroll down to see all the options in the Zoom poll and be sure to hit that Submit button on the bottom right of your poll box. And I'd also at this time just like to remind everyone, if you're unable to participate in the poll, or if you would prefer, you may submit suggestions to the medical device sterilization mailbox, which that email is provided on the bottom of the slide.

Alright, I will give it about another 10 seconds before I close the poll.

Alright, for those of you, wrap up your responses.

OK, Lisa, I'm now going to close the poll, and I will share the results.

**Lisa Simone:** Thanks, Kim. It looks like we're waiting for them to pop up. OK, I can see the response here. It looks like all of the topics have generated some level of interest with some higher interest options, including the alternate sterilization modalities, risk-based approach to sterilization validation, and also the international additional regulatory considerations. Thanks for sharing your live feedback, and we do plan to take a closer look at the results after today's event. So, at this time, you can go ahead and close the survey window.

**CDR Kim Piermatteo:** Thanks, Lisa. Closing now. Sorry.

**Lisa Simone:** Oh, no worries. And I do see that it has gone on my screen. So, a final thought on this topic, if we've missed something here or you'd like to add additional detail to any of these topics, or if you've got other topics, there's still time to make some suggestions either today during the Q&A or via our email address that is shown on this slide, and it'll be at the end of the event. So now I'd like to turn it over to Scott Steffen for our second discussion topic.

**LCDR Scott Steffen:** Thank you, Lisa. Next slide, please. And next slide, please.

Now we want to go over some general thoughts on how we could pivot our town hall series to more interactive formats. One of our goals during the first five town halls was to share as much information as we could about the current sterilization landscape and challenges while also providing a broad base of understanding related to expectations for sterility pre-market review.

To do so, those town halls were heavily focused on providing information in a more didactic format while saving half of the event to answer your questions. Those Q&A sessions, along with any feedback we received from our medical device sterilization mailbox, help to inform our topics and approach to future town halls. As part of our current town hall format, we include what we've heard from our attendees, like we did today. However, we also recap the topics, sorry, we also want to recap the topics from our previous town hall Q&A sessions. Tamara, could you please share the overview of our live Q&A sessions over the first five town halls?

**CDR Tamara Rosbury:** I would be happy to share, Scott. The vast majority of questions asked during the live Q&A session pertain to sterilization in general or to alternative modalities and mentioned PCCPs, material changes, VHP, shelf-life validation, novel methods, and changes in sterility assurance level.

Our second largest group of questions were regulatory or review related involving master files, 510(k)s, and whether FDA was working with international agencies.

The third largest group of questions involved general topics such as pyrogenicity testing, labeling, and electronic labeling.

Last, but certainly not least, some stakeholders expressed comments of gratitude for FDA's proactive engagement with industry during the town hall series.

**LCDR Scott Steffen:** Thank you for that overview, Tamara. The live Q&A have certainly generated a lot of good discussion. The Tiger Team has looked for other opportunities to increase our engagement with you and one way is through alternative delivery mechanisms for topics of interest, and we'd like to share that on the next slide.

Thank you. This slide shares the proposed formats for the series going forward. Lisa, would you share what aspects of the series will remain the same?

**Lisa Simone:** Sure, Scott. We are proposing to continue the series with the same basic structure for all town halls, opening with the welcome and the What We Heard from You Last Time, like we did today, and these might also be pre-submitted questions through our mailbox or follow-ups to questions like Tamara described from previous events. We understand that segment generated a lot of interest, so we feel it's important to continue that segment going forward. Another aspect we're planning to retain is the Q&A at the end of the town hall to ensure we continue to have that great engagement with you as the series continues.

**LCDR Scott Steffen:** Thanks, Lisa. Going forward, we propose to use three main approaches. Some topics may be best suited for the information-sharing approach we used in our first five town halls where we share our activities as that information becomes available. We're also proposing to add additional formats listed here. Ryan, you talked about Pre-Submissions earlier. Would you share how we might use this approach in the town hall event coming forward?

**Ryan Ortega:** Yeah, sure, Scott. As I mentioned, we've used this format before, and it can help us talk about both technical and regulatory review-related questions. Some of the unique value is that this format can also be used to show some examples of best practices for Pre-Submission interactions and potentially also some not-so-best practices. It really lets us explore some review-related questions and also show how a Pre-Submission can be interactive and collaborative.

We could do something like get a group of our SMEs together. Some could pretend to be a company and ask some sterility questions similar to what we've seen in real actual Pre-Subs. And other SMEs could play the FDA review team and demonstrate what these reactions can look like, complete with some back and forth and maybe some collaborative conversation.

If we do utilize this format, again, it's really important that we make it clear that what is being presented in something like this is generalized information, and it's not meant to be specific to any given device or device type. So, we're also thinking about how we might ensure that this aspect of this format comes across very clearly. I think we definitely have to let people know up front that the mock Pre-Sub is using imitation content, and it's not an actual device or an actual situation. We would absolutely want to ground the general information we're sharing in reality. It needs to be authentic. But there would have

to be that caveat that the information from the mock sponsor and the feedback from the mock review team are generalized examples and not intended to provide information about a specific scenario.

I'll also say that we've used this format before with, I think, a lot of success. So, I really do think we could make work here. Jon, do you have any thoughts about some of the things that we could try with formatting?

**Jon Weeks:** Yeah. Now, you make a really good point about mock Pre-Submissions that could be a really good mechanism to speak about review-related questions, but these may not be ideal for all mechanisms or all topics. And specifically, those that are more technical in nature or that would benefit from a more organic discussion. Several of the topics that you all have suggested could benefit from a panel discussion. We plan to broaden the pool of panelists going forward. So, in future events, you'll hear from more of our sterilization and review SMEs from across OPEQ, OSEL, and OST.

Additionally, case studies might be an interesting format for us to share information. As we've hinted in the previous topic discussion, you'll see an upcoming slide that we're announcing Town Hall Seven, which is an interactive panel discussing considerations for choosing alternative sterilization modalities. Scott?

**LCDR Scott Steffen:** There may be other formats you might suggest or additional considerations for the formats we've already identified here. As we did for topic one, we'd like to open up to another poll to gain your feedback. Next slide, please.

Like we did for the last discussion topic, we'd like to use a poll to get your feedback on the current and proposed town hall formats. Kim, would you launch the poll, please?

This poll is similar to the last, and the same scoring applies. So, select your interest in these formats from very interested, interested, slightly interested, or not interested. The first three options are formats we've used since January, where the first is questions we've received from last time. The second is the traditional information sharing type of presentation. And the third is the live Q&A at the end. The last three options are the new proposed formats for mock Pre-Subs, case studies, and interactive panel discussions.

Please rank each of these independently. Again, this is not a ranked order poll. You may need to scroll down to see all six options. The poll is open for 30 seconds, and please click Submit when you are finished.

**CDR Kim Piermatteo:** Thanks, Scott. Again, this is Kim, and I'll let everyone know how much time is left and when I'll close the poll. So, we appreciate your feedback. I already see quite a few responses, so thank you.

We'll take about another 15 or so seconds. Don't forget to scroll down to see all the options and be sure to hit that Submit button.

And as another friendly reminder, again, if you were unable to participate in our poll today, or if you would prefer, you may submit your suggestions to the medical device sterilization mailbox, and that email is provided on the bottom of the slide again.

OK, I'll give it about another 10 seconds before I close the poll.

Alright, Scott, I'm now going to close the poll, and I will share the results.

**LCDR Scott Steffen:** Yeah. Thank you, Kim. Appreciate that. It looks as though everything has really had a lot of interest in providing feedback from you all. It looks as though a lot of people really are favoring the interactive panel discussions, case studies, and the mock Pre-Subs. But I have to say that what we've been doing in the past has been really receptive as well. So really, thank you very much for that interaction. This is really helpful for us on how we package and move forward with this. And as always, if you have additional feedback, please let us know today or via email. Now I'll turn it back to Lisa to share some additional details about the future event scheduling. Lisa?

**Lisa Simone:** Thanks, Scott. We do intend to continue the town hall series through the rest of 2024, and we're aiming to announce each event at least one week ahead of time. However, to help with your planning, we're also working on an update to the Town Hall section of our Sterilization for Medical Devices web page, which will list the date, the time, and the tentative topic for each event through the rest of 2024 and we're aiming to have that information available soon after today's town hall.

It's also our intent for the more information-dense events, like those interactive panels and the mock Pre-Subs, to be alternated with shorter events that focus on engaging you with those live Q&As. Those events might feature smaller topic areas as those needs arise. And as always, questions and comments are welcome at any time. Next slide, please.

The next two slides include resources mentioned earlier in the presentation, along with the full URLs that you can access after the presentation. Next slide.

To summarize, today we shared feedback we received for potential town hall topics, and the panel discussed the suggestions in light of how each might be incorporated into a town hall event. We also shared how we plan to pivot the delivery format to be more interactive and engaging. And for each topic, we used a poll to gather real-time feedback from you. Next slide, please.

Before we open up the discussion, I'm excited to announce our next town hall on May 23, where our interactive panel will discuss what to consider when choosing a sterilization modality or changing sterilization modalities. Information about the town hall series can be found at the link here. During today's Q&A, it would be helpful to hear your reactions to the topics we heard during the initial town halls and our pivot in the format that we propose today. And now I'll turn it back over to Kim.

**CDR Kim Piermatteo:** Thanks, Lisa. And thank you to all of our presenters and again, I'd like to thank all of our attendees for your participation in the polls today. We will now transition to our interactive segment of today. And I'd like to go over how we will manage this segment and a few reminders before we begin.

First, to ask a question or to provide a comment, please select the Raised Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line, 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 try to keep it as short as possible. And after you ask your question or provide your comment, please lower your hand again in Zoom. If you do have another question or comment, please raise your hand again in Zoom to get back into the queue, and I will call on you as time permits.

As we wait to receive some of your questions or comments today, I'd like to ask a few of our presenters a few questions. Scott, the first question, I'd like to direct to you. That question is, did you receive any suggestions for future town halls that you won't pursue?

**LCDR Scott Steffen:** Yeah. Thank you, Kim. Yes, there were a few great suggestions that we believe that an FDA-led event would not be the best venue. For some, we are simply not the best subject matter experts. For instance, a discussion about sterilization cycle optimization or about the detailed science and technology behind a particular sterilization modality is just not suited for us. Other topics would benefit from a broad set of panelists that should also include industry stakeholders. And for those, we're actively engaging in external conferences and workshops to deepen discussions.

Some topics likely don't warrant an entire town hall, for example, discussing package testing and these instances where we're looking for ways, we might include them as possibly mini topics for the mostly live Q&A town halls for future events. Overall, the events that are shaping up for the rest of 2024 are events where we feel FDA might be best suited to lead the discussion-- for example, a mock Pre-Sub that focuses on aspects of a sterilization modality change. Back to you, Kim.

**CDR Kim Piermatteo:** Thanks, Scott. Ryan, I'd like to come to you next and ask you the next question. That question is, will you have industry participants in future town halls, for example, to represent a manufacturer coming with one of the mock Pre-Submissions?

**Ryan Ortega:** Yeah, that's a good question. I think generally, no, all of the town hall panelists will be FDA staff. And that would include any of those who would play the role of a medical device manufacturer in a mock Pre-Sub type exercise. Otherwise, I think we really couldn't be as nimble as we would want to be in preparing and hosting these events largely because of additional vetting and coordination with non-FDA participants. However, I do think we will strive to ensure that the exercises that we're working through, and designing are as representative of the industry challenges as we can make them, which, again, is another reason why we request your input to our mailbox. It could be really helpful for us on that front. If you do have specific questions for mock Pre-Sub topics or questions that a medical device manufacturer might raise, please share those details with us either during the Q&A here or potentially through our mailbox that we've talked about as the work on those town halls is currently in progress.

**CDR Kim Piermatteo:** Thanks, Ryan. I'd now like to take one more question to Aftin. And, Aftin, that question is, can we still suggest town hall topics?

**Aftin Ross:** Absolutely. We are always looking for beneficial content. As you can imagine, it takes some time for us to develop content and to prepare it for presentation. So, it is most helpful if you are able to provide your suggestions as soon as you can. We understand that topics may change as the EtO landscape evolves. And we will continue to be as responsive to those changing needs as we can be. Very much appreciate any thoughts you have on future town hall topics. Back to you, Kim.

**CDR Kim Piermatteo:** Thanks, Aftin. OK. At this time, we would now like to open it up for any live questions or comments. Again, please raise your hand in Zoom, and I will call on you, or I will give you permission to talk. So please raise your hand in Zoom.

While we wait for some of our attendees to come up with their questions, I'd like to circle back to Scott. Scott, the question I have for you is, what has been the most popular town hall so far?

**LCDR Scott Steffen:** Yeah. Thank you for that question, Kim. Our first town hall garnered the greatest attendance. Likely, it was because it was the first of a series. We didn't really clarify the scope of the series in detail prior to the event. But really, suffice it to say, the remainder of the initial series town halls two through five really also had a robust attendance as well that appears to reflect those who were specifically interested in pre-market review topics related to sterility review. Back to you, Kim.

**CDR Kim Piermatteo:** Thanks, Scott. OK. At this time, I'm going to make a last call out for anyone who wishes to ask a comment, or ask a question or provide a comment today, to please raise your hand in Zoom.

Alright. Our first caller is K Calleja, I have unmuted your line. Please unmute yourself and ask your question.

**Khaterah Calleja:** Oh, I think if you're referring to me, Khaterah Calleja. Is that right?

**CDR Kim Piermatteo:** Yes, yes. Thank you.

**Khaterah Calleja:** Thank you very much. I just wanted to offer a comment more than a question that's based on the list that you provided of future town halls from an industry perspective. We are very supportive of a mock Pre-Submission or case study type format and would absolutely welcome that looking at transition of sterilization modality as a good practical way to get, like you said, the technical and regulatory. So, I just wanted to chime in terms of that being a high value and of great interest to us. So, thank you so much for including that for the future town halls. That was my comment. Thank you so much.

**CDR Kim Piermatteo:** Thank you very much. We appreciate that.

OK. Does anyone else have a question or comment for our presenters?

Alright. Our next, I'm going to call on Fabian. Fabian, I have unmuted your line. Please unmute yourself and ask your question.

**Fabian Kuhn:** Hello. This is Fabian Kuhn from Baxter International. My question is, would you be able to share any [INAUDIBLE].

**CDR Kim Piermatteo:** Fabian, I apologize. You cut out a little bit. Can you restate your question or comment?

**Fabian Kuhn:** OK. Can you hear me clearly now?

**CDR Kim Piermatteo:** Yes, I can. Thank you.

**Fabian Kuhn:** OK, very well. I was talking about the FDA innovation challenges. I remember there were two challenges, one on novel technologies and one on reduction of EtO emissions. Could you share some insights on your experiences from the past few years regarding these challenges?

**CDR Kim Piermatteo:** Thank you, Fabian. Ryan, I'm going to come to you first. Did you want to provide a response?

**Ryan Ortega:** Sure, yeah. I think we can provide some high-level information there. From my perspective, seeing how the innovation challenges started back in 2019 and seeing where we are now, I think it's safe to say that a lot of what we learned in the innovation challenge has rolled into some of our other efforts, right? For example, the innovation challenge on better or more efficient or effective ethylene oxide use or abatement of gas, I think that informs some of our work on particularly that first ethylene oxide master file pilot program for PMA devices.

I think we've certainly learned more than we knew initially about things like efficient cycle design, what can be done in different cycle design strategies, and how to facilitate some of the validation methods that aren't necessarily used as often, like the BI/bioburden or even calculated overkill. So those are some of the lessons learned from the challenge about better use of ethylene oxide.

And then for the other challenge, the alternative methods and some of the lessons we learned there, I think that fed directly into our 510(k) sterility master file pilot, which, as everyone may know, really targeted those modalities that we consider established category B or novel according to our 510(k) sterility guidance. I think some of our lessons learned there fed into our recognition of the hydrogen peroxide validation standard and the update to our 510(k) sterility guidance. But we also gained insights about really what it practically takes to make some of these newer methods scalable, how the validation might look like, some validation methods were used to for some of these gaseous alternative methods and, in some cases, how they might be a little bit different from the validation we're used to seeing.

So, a lot of take-homes there, and I know that's fairly high level, but we're also thinking about how we could continue to wrap in some of these lessons learned from the innovation challenges into our outreach and our initiatives moving forward.

**CDR Kim Piermatteo:** Thanks, Ryan. And thanks, Fabian, for your question. Our next question is coming from Vamsi. Vamsi, I've unmuted your line. Please unmute yourself and ask your question.

**Vamsi Karicharla:** Thank you. First of all, I would like to thank the panel for taking the time to schedule this town hall series. My question is, if we were to change a modality to a newer technology, what kind of information do we need to provide for a Pre-Sub to understand whether we are on the right track because some of these novel technologies don't have a standard to follow. In those cases, what does typically FDA look in a Pre-Sub to understand whether this modality is appropriate for the device or not?

**CDR Kim Piermatteo:** Thank you, Vamsi, for your question. I'm going to look to Ryan or Jon. Ryan, did you want to start?

**Ryan Ortega:** Yeah, maybe I'll start. And, Jon, I know you've worked on Pre-Submissions too, so you might have some thoughts there as well. You know, first and foremost, the information that is most helpful in a Pre-Sub depends a little bit on the specific type of questions that you ask. But maybe to frame that up, I will say that some of the things that we've provided feedback on in sterility-related Pre-Submissions in the past, if you do have specific questions about validating that alternative method, we can certainly talk about that, maybe even getting into deeper specificity if you have questions about how to potentially use the general sterilization validation for medical device standard for a alternative modality that doesn't have a modality-specific standard. That is a potential area for specific questions. You could also ask specific questions about the regulatory submission itself, understanding the expectations for the content in those submissions.

I will say, that will depend a little bit on if it's a 510(k) or PMA, so information about the actual device. What type of device is it? What's the classification? What type of submission? If you know that up front, definitely be sure to put that sort of information in the Pre-Sub so that the review team has a good understanding of the device itself and not just the sterilization mechanism that you're thinking about. So, there's a couple of different things like that, both technical and regulatory where we could provide feedback.

And so, again, it goes to what specific questions that you have. And then I guess my recommendation would be to provide enough background information so that the review team can consider that information in the context of your question and provide some specific feedback. Jon, do you do you have any additional thoughts or anything that I might have missed?

**Jon Weeks:** Yeah. So, a couple other things, so Ryan touched a little bit on questions related to the sterilization validation portion. You may want to, or you may consider questions to us regarding how you're assessing compatibility of materials with the sterilization modality that you're considering and any questions that you may have regarding performance or other safety considerations.

I want to reiterate, as part of the Q-Submission process, we typically do not review data. So, we will typically review protocols to help to understand whether or not that will address a regulatory concern or consideration. I'll pass it to Scott. Do you have any other things that you wanted to add in?

**LCDR Scott Steffen:** Yeah. Thanks, Jon. So, Vamsi, thank you for the question. This is something we hear about a lot of times. But I think what I wanted to do is dovetail on what Ryan and Jon were saying. As you can hear from them, it's really important about how you stage, and you write your questions. So, making them as clear as possible and as focused as possible really helps for the review teams to really pinpoint that feedback to really answer the question that is at the root of either your issue, your concern, or what you're getting feedback for.

With that, I just wanted to encourage you to go and look at our Q-Sub program guidance, it's actually going to be in the resources slide of this presentation, and really point you to Appendix Two. Appendix Two actually has some examples of Pre-Sub questions that may help you package your information in a certain way and also ask the questions in a certain way that would really make that meeting or that feedback from FDA be the most beneficial and fruitful for you when you reach out to the agency. And that concludes my comment. Unless anybody else wants to speak, back to you, Kim.

**CDR Kim Piermatteo:** Thank you, everyone. Thank you for a good discussion. Thank you, Vamsi, for that question. At this time, I would like to go ahead and wrap up our comment and question and answer segment for today. Thank you all for your participation. Again, thank you so much for your participation in our polls earlier. I'm going to turn it back over to Aftin to provide her final thoughts for today. Aftin?

**Aftin Ross:** Thank you, Kim. And thank you, everyone, for attending today's town hall. We appreciated you sharing feedback on the potential town hall topics and formats via our new interactive element, the Zoom poll. We heard from you that there is certainly interest in having some of the more innovative methods, such as the mock Pre-Sub and case studies.

We also had questions today in our Q&A related to the innovation challenge as well as having a good Pre-Submission. These are all topics that we will continue to revisit as we go forward in our town hall series, trying to make sure that we are delivering content that is greatest value for you. We look forward to continuing to engage with you and hope that you have a great rest of the day.

**CDR Kim Piermatteo:** Thanks, Aftin. I'd like to also provide a few administrative closing remarks. So, as I mentioned earlier, printable slides of today's presentations are currently available on CDRH Learn at the link provided on the slide under the section titled Specialty Technical Topics and the subsection titled Sterility. A recording of today's town hall and a transcript will be posted to CDRH Learn under the same section and subsection in the next few weeks. And a screenshot of where you can find those materials on CDRH Learn is provided on the slide.

Also mentioned earlier, if you have additional questions or comments about today's topic or presentation, as well as if you have a comment or question for a future town hall, please email medicaldevicesterilization@fda.hhs.gov. If you have additional general questions about today's town hall, feel free to reach out to DICE at dice@fda.hhs.gov.

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, as Aftin, I think Lisa mentioned earlier, we hope you're able to join us for our next medical device sterilization town hall, which is scheduled on Thursday, May 23rd from 1:00 to 2:00 PM Eastern Time.

This concludes our town hall for today. Thanks again and have a great day.

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