Medical Device Sterilization Town Hall:
Mock Pre-Submission on Implementing a Change in Sterilization Method
July 10, 2024

Moderator: Lisa Simone

Lisa Simone: Hello, everyone and welcome. Thanks for joining us for our ninth medical device sterilization town hall. This is Lisa Simone, from the Office of Readiness and Response within the Office of Strategic Partnerships and Technology Innovation, and CDRH's EtO Tiger Team Incident Response Lead. 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 halls.

Before we get started, I'd like to remind you that 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.

As you can already see, the format of today's town hall is different from the previous events. We heard your interest in seeing a mock Pre-Submission meeting focused on medical device sterilization, and we're excited to host such an event today. Because the mock Pre-Submission exercise will involve FDA staff role-playing as both FDA premarket review staff, and also as our fictional firm, we're using a video format to make it easier for you to follow the "who's who" as the mock Pre-Submission meeting progresses.

We've also made another change for this event. We're deferring our regular segment for "What We Heard from You Since Last Time", and our segment for live Q&A, to our next town hall, which is scheduled for August 7th. We recognize you may have questions or comments about the exercise you'll see today, and we'll dedicate a portion of the next town hall for this topic. We'll invite you to share your feedback, at least one week before the next event, at our email address, which you'll see at the end of today's presentation. And as always, we welcome any other related questions or comments.

Now that we have those details out of the way, I have the pleasure of introducing our presenters from across CDRH, who will demonstrate today's mock Pre-Submission exercise.

Our presenters today include: Commander Scott Steffen, a 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 CDRH's Office of Strategic Partnerships and Technology Innovation; Dr. Ryan Ortega, a Regulatory Advisor with the Regulatory Policy, and Combination Products Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ; Christopher Dugard, Assistant Director in the Office of Health Technology number four, within OPEQ; Dr. Nahid Ilyas, a Chemist in the Office of Health Technology number four, within OPEQ; Dr. Johannetsy, or Jojo, Avillan, a Biologist in the Office of Health Technology

number four, within OPEQ; Stephen Anisko, Team Lead for the Sterility Devices Team in the Office of Health Technology number four, within OPEQ; and Dr. Victoria Rodriguez, a Biomedical Engineer in the Office of Health Technology number two, within OPEQ.

Today's exercise will be presented in three parts. First, we'll provide some background information on the fictional device that is the subject of today's mock Pre-Submission meeting. Next, we'll describe the role-playing assignments for our panelists, including who will participate as FDA staff from our review divisions and who will participate as members of our fictional medical device manufacturer. We'll refer to this fictional manufacturer as our "Fictional Firm." We'll also share the list of topics that Fictional Firm has reached out to FDA to discuss. Then our panelists will perform the mock Pre-Submission exercise. And after, we'll provide a high-level debrief of the exercise, in the form of some key take-home messages.

I'd like to mention here, that you may hear the term "Pre-Submission" or "Q-Submission," and for the purposes of this exercise, they are the same. Also, for any guidances or references that you might hear mentioned during the exercise, we'll provide links at the end of today's event.

Now I'd like to pass it to Scott, who will share the background information and get this activity going.

Scott Steffen: Thanks, Lisa. Let's get started with some background information. Before we dive into the mock Pre-Submission exercise, we wanted to give you a sense of the topics you will hear about in our simulation. We have broken our exercise into four topics.

Today, you will hear about testing considerations when moving from ethylene oxide or EtO to a gas chemical sterilant or to radiation. We will also discuss how one can develop their device design early while accounting for how it would be sterilized. Lastly, we will talk about how the information provided to the Agency may differ for a class III device.

In today's town hall, our panel of sterilization experts will present a mock Pre-Submission meeting exercise from a fictional manufacturer discussing their 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 assessment and proposed testing. We hope that this novel and fun way of looking at this information will give you all a glimpse into how we view and approach these issues.

We also want to remind you that in support of this town hall we have a guidance that you may is it find very helpful titled, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" that has a plethora of information relevant to today's event including sample sterilization questions and meeting minutes. The link is included here and also in the resources slide at the end of today's town hall.

In the interest of having the most realistic Pre-Submission meeting experience, we want to set the stage. For today's event, we will be performing a mock Pre-Submission meeting exercise on our device, which is not a real device and is not intended to mimic a real device; however, we've included some common features that should be considered when selecting a sterilization modality. For example, the device discussed today is a single use "device" that is asymmetric, with enclosed spaces, numerous crevices, lumens, tubing, has multiple materials, and a microchip. The considerations discussed today are for class

II devices which have indications and technology equivalent to other devices reviewed through the 510(k) pathway. As well as an indication similar to other class III PMA products. The device is also a member of a large product family. We intentionally did not include a picture to avoid assumptions and to illustrate that these characteristics are not device specific.

The concepts we are sharing regarding how manufacturers approach these questions are generalizable and thus can be leveraged for many device types. For those of you who are not familiar with the Pre-Submission process, manufacturers submit relevant information and questions to the FDA pertaining to their device.

Within their submission they identify the method for how they would like to receive feedback. In this case, the firm requested a meeting with written feedback, for an example a video conference or teleconference with the FDA. However, please note in-person meetings can also be requested.

When manufacturers request a teleconference or in-person meeting, they will get written feedback prior to their meeting either within 70 days of their submission or five days prior to their scheduled meeting, whichever is sooner. Timelines for the various Q-Sub programs are provided in table 1 of our Q-Sub guidance. For this mock Pre-Sub exercise, we'll assume the firm received their written feedback in advance of this meeting.

In addition to the device description, we want to orient you to who will be serving in what roles. Ryan and i will be serving as representatives of the manufacturer today. Ryan will be the CEO, while i will serve as the sterility subject matter expert or SME.

Portraying the FDA review team, we have Chris serving as the Assistant Director, Nahid will be the Lead Reviewer, and we will have JoJo, Victoria, and Stephen serving as other sterility SMEs.

Before we begin the actual Pre-Sub exercise, we wanted to remind you that the exercise is for educational purposes only. The device and manufacturer described are fictional and for illustrative purposes only. The information we are going to present represents realistic generalizations of some of our reviewers' considerations for the sterility topics discussed but is not intended to be a commentary on a specific situation or a specific device or device type.

Now, let's get started with our exercise.

Nahid Ilyas: Good afternoon, everyone, thank you for making the time to attend today's meeting with our fictional firm discussing their device. Before we start discussing our feedback to your questions, we would like to have introductions. Fictional Firm, please introduce yourselves with your titles.

Ryan Ortega: Hi good afternoon, everyone. My name is Ryan Ortega, I am the CEO of Fictional Firm.

Scott Steffen: Good afternoon, everyone, this is Scott Steffen. I am the Head of Sterility and Quality at Fictional Firm. This is everyone we have on the call today, Nahid, so back to you.

Nahid Ilyas: Thank you. We will go ahead and introduce the FDA team. Chris starting with you.

Christopher Dugard: Yes Nahid. My name is Chris Dugard. I am the Assistant Director for the Sterility Devices Team in OHT 4.

Nahid Ilyas: Thank you. Nahid Ilyas. I am the Lead Reviewer for this Pre-Submission, and I am in the Sterility Devices Team. Jojo.

Johannetsy Avillan: Hi my name is Johannetsy Avillan or Jojo. I am the subject matter expert in the Reprocessing and Disinfection Team.

Victoria Rodriguez: Hi there I am Victoria Rodriguez. I am a Bioengineer and subject matter expert in the Occluders and Hemostasis Devices Team in OHT 2. And I also consulted on this submission.

Stephen Anisko: Hello everybody. My name is Stephen Anisko, I am the OHT 4 Sterility Devices Team. I was a SME consultant for your submission.

Nahid Ilyas: Thank you for the introductions. Today we are meeting to discuss our feedback to your questions, four questions pertaining to your device. Your device is currently cleared for a class II indication and is sterilized using EtO. You asked four questions based on your desire to switch your modalities from EtO. You also asked a question about your device's design and potentially adding a new indication similar to another class III device.

So, I'd like to go over some key technological characteristics of your device in addition to the two indications. So, your device is asymmetric, it has enclosed spaces, numerous crevices, lumen & tubing, it consists of multiple materials, it has a microchip, it's for single use. And so lastly, your device is a part of a large product family. So, before we start providing our FDA feedback to your questions, I want to ask you, are there any questions that you have about the flow of the meeting or are there any clarifications you want to provide for your device description?

Ryan Ortega: Thank you for that, Nahid. No additional follow-up questions right now. I think you got our device description down pretty well. We may have some follow-up questions as we're going through, but I think we're good to discuss the questions.

Nahid Ilyas: Wonderful. Thank you. So, let's get started with your questions. Over to you.

Scott Steffen: Thank you, Nahid, for that introduction. We at Fictional Firm are excited to get your feedback on how we can move our device away from ethylene oxide.

We provided some proposed testing to be conducted to support the transition from EtO to a different gaseous, chemical sterilant from our previously cleared device and we were also thinking about modifying the device. Does FDA find this testing sufficient, and do you have additional recommendations?

Christopher Dugard: Thanks for that Scott. I can take this one. So unfortunately, we can't provide decisional feedback on the ultimate acceptability of testing before we have a chance to review the data in your formal submission, but this does appear reasonable. We are prepared to provide technical feedback on some of the proposed methods and considerations for testing to complement our written

feedback that we sent earlier, if there are specific parts of the proposed testing that you are still unsure about.

Scott Steffen: Thank you for that feedback, Chris. Recognizing that the move from EtO to another sterilization modality is not trivial, we're not quite sure how to approach the validation for the sterilization change, technically. Can you give us some considerations?

Johannetsy Avillan: Hi this is Jojo. I think I can try to answer that. One thing to consider will be material compatibility and the impact on device performance.

Ryan Ortega: That's helpful feedback. We actually have collected some literature sources information, academic literature, and some trade literature, about material compatibility, in particular with respect to the impact on the material and device performance. Do you think something like that would be enough?

Johannetsy Avillan: So, it may be enough, but the support for your justification needs to be specific to your device and your specific sterilization process. For example, the exposure duration should be reflective of your actual process. So, if you reference any literature, it should specify the same parameters and the materials should be sufficiently representative of the materials in your device. So, if it's not the same specific same materials, then you will need a justification for why the literature information applies to your device. But we can talk also about the potential impact of tweaking parameters in different ways as a part of today's discussion if you would like. And you may also want to review our 510(k) modifications guidance as it is a really good resource for considering changes to your cleared device.

Scott Steffen: Thank you for that feedback, Jojo. We can see how material compatibility could be challenging. If it is ok with you all, we would like touch on the idea of validation. Of the numerous validation approaches discussed within standards, we would like to do an overkill approach using half cycles specifically because of its simplicity, however we are not quite sure how to define it. Could you give us some things to consider and/or any possible recommendations?

Stephen Anisko: Thank you sir. Let me take this question. This is Steve from the Sterility Devices Team. So, when we discuss the overkill method, it is important to understand the proposed cycle and the defined conditions intended to achieve sterilization. We recommend a good understanding of these critical cycle parameters, really important as you look to develop your validation studies and approach. With this knowledge there really are multiple ways you can develop a half cycle method; some are more straightforward where you simply, a time-based approach, where you simply cut the cycle in half. But often times there are more complex cases where the sterilization process requires you to utilize an approach where you look at the total sterilant concentration and reduce based off that.

Ultimately, knowledge of your specific sterilization process as well as product definition should be leveraged as you develop your validation approach for an overkill. Some further considerations on this question as you look to develop your validation approach, we also expect that the completed validation study supports an activation of the challenge microorganisms, and that these challenge locations are positioned and predefined worst-case positions within your product load. Part of our review and part of what we will look at is we really want to understand your scientific rationale to support the selected validation method, and this will be something we do look for during our review.

Just a few more notes on the overkill cycle and the overkill approach. Generally, it does a good job demonstrating inactivation under these conditions. However, it's important to understand that the overkill method is considered to be a conservative validation method and oftentimes it will result in determination of a longer cycle durations or ones in which more sterilant is used and is actually needed to achieve your claimed sterility assurance level. For these reasons, you may want to further consider some additional validation methods. These methods if performed properly can provide for reduction in sterilant usage and still support your claimed SAL. These alternate validation approaches may also offer a benefit of reduction in exposure to the sterilant, it could be a reduction in cost, and it could also potentially result in improved device compatibility.

Victoria Rodriguez: Yes, to add to Stephen's comment, there are several options to reduce sterilant usage such as the biological indicator/bioburden approach or the cycle-calculation approach. Of course, these approaches they depend on product bioburden. That is, your product bioburden should be consistent over time and also, its resistance is equal to or less than the biological indicator. Finally, I'd like to point out that when using either approach, we've noticed mistakes in calculating the sterility assurance level, so please be cognizant of this and double-check your math.

Ryan Ortega: We'll definitely keep on eye on that if we go with that approach. You have given us a lot to think about for validation. One thing that I wanted to mention is that we do have similar products that use the new sterilization method that we're thinking about switching to. Do you think it would it be possible to adopt this product into that existing process?

Johannetsy Avillan: This is Jojo. I think I can answer that question. So, we are open to product adoption approaches if it can be justified. So, TIR28 for "Product adoption and process equivalence for EtO sterilization" could be a really good resource for you to consider.

Ryan Ortega: Thanks for that we'll look there. I know we're figuring things out, but we try to provide a little bit of preliminary data in the Q-Sub, just wanted to see if you had any thoughts about that data we sent.

Christopher Dugard: This is Chris. So unfortunately, we generally don't review data during Pre-Submissions. In a Pre-Sub, we can review proposed approaches or strategies to address questions which are intended to be informative for an upcoming submission. So, we're happy to provide additional comments on protocols or plans that you have, but unfortunately, we can't comment on that data in this venue.

Scott Steffen: Thank you for that feedback, Chris. I think we can move to our next question, which is related to question one because we are looking at more than one sterilization modality. We are also considering the option of using radiation as a sterilization modality. Are there additional considerations that differ from the considerations mentioned for question one? Radiation, specifically gamma radiation, may make sense for us, so we're considering it as an option.

Victoria Rodriguez: Hi this is Victoria again. I can provide initial comment to start off our response. So please consider that bioburden control and monitoring is an integral part of radiation sterilization. A manufacturer would typically have an understanding of the seasonal variation of microorganisms, alert/action limits, not just for the final product but for the critical points during manufacturing, as well

as additional considerations of any resistant microorganisms in the native product bioburden. I hope that's helpful.

Scott Steffen: We appreciate that feedback Victoria, that is something we will definitely consider. However, we were also wondering if the change from gas to radiation would impact performance? We have some concerns here and wonder if it would need some degree of performance validation or even verification.

Stephen Anisko: Hi Scott, this is Steve again. Let me provide you with some feedback on this question. So, for a change to the radiation sterilization, if that is something you are looking to adopt, one important consideration is the compatibility of device electronic or software components. We know that there is a potential that due to the radiation involved, that electronic components such as microchips, may be damaged or degraded following exposure to the cycle. If this is something you are seriously considering to implement, we do recommend that you consider these additional questions of compatibility. One thing we would look for is further demonstration and functionality of your device including the electronic components and any software features are maintained following exposure to the intended cycle. In addition to the electronic considerations when we discuss radiation sterilization, please note that gamma may not be the only option available to you. You may also want to consider looking at either X-ray or e-beam?

All three of these modalities utilize radiation to support the sterilization process, but one thing that is important to understand is that there are differences between the three. This could have specific impact to your products. For example, the dose rate could be different, the ability of the radiation to penetrate your device packaging or your device product load could be impacted. And again, this really all goes back to an understanding of your product definition, understanding how product is loaded into the sterilizer or how it is presented to that process. You really want to the consider questions such as product load density, material compatibility, we talked about the electronics, but other characteristics that are specific to the device when you select an irradiation method.

I guess the final advice I would give, the final recommendation I would give is independent of the specific radiation source you select, the validation approach will be essentially the same. In that all three really utilize the same recognized consensus standard. For further information regarding validation approaches available we recommend you consider review of the ISO 11137 series.

Christopher Dugard: Hi, this is Chris again. If I can just jump in for a second and add more to that. I also recommend you look at our 510(k) mods guidance for assistance in performing your assessment, that the impact of this change might have on safety and effectiveness. We also encourage you to reach out with an additional Pre-Submission supplement if you have specific questions regarding verification or validation of a radiation-based cycle.

Ryan Ortega: Thank you all. We'll take a look at those resources. I think we're good on this question. We can move on to the next one.

For our next question, we had mentioned we're in the pretty early design stages for the modification, but we are pretty sure that it could result in a change to the device's geometry. We might have to change some materials, so we wanted to ask if you had any input on things like challenge features or material compatibility concerns with respect to device performance? And really are there any other

things we should be considering as we are developing our device with respect to how we sterilize it? Just to clarify, real quick, whenever we're asking about material compatibility we're thinking about performance at this stage. We know that biocompatibility is a whole other thing, and we'll probably give you a future Pre-Sub to just specifically talk about biocompatibility in the future.

Christopher Dugard: Thanks for that question. This is Chris. I'll jump in. So, certainly we look forward to your supplement on biocompatibility regarding your question on design of the device. Really ultimately, it's up to you as the manufacturer how you're going to design it, the materials you select, and what the geometry and challenge features are going to look like with regards to sterilization. We're happy to comment on your proposals, however we don't get involved in things like design of the device.

Nahid Ilyas: This is Nahid. I want to add that we can certainly provide you with some considerations for your device design stage. This is not all inclusive but some things we recommend you consider is please make sure that if you change your materials, they are compatible with the sterilization modality and the device can still perform as intended.

The FDA fully recognizes the AAMI TIR17:2017, also fully recognized the most recent revision in 2023. This technical information report discusses the compatibility of materials subject to sterilization. So, some examples I want to share please make sure the adhesives/sealants are still compatible through any changes and maintain integrity. Any materials and components that provide mechanical strength or stability, they should still serve that function post exposure to your sterilization.

Ryan Ortega: Thanks. That's helpful feedback. I do want to say that we recently decided that we're going to conduct some ASTM standard mechanical testing things like, we will probably do some impact testing and some of that dog-bone coupon strain testing. I know we just confirmed that and did not put it in our Pre-Sub, but wanted to ask if you could provide any thoughts on would this be sufficient to show that the mechanical performance of the new material of the device is maintained? Do you have any thoughts about that approach or the methods?

Christopher Dugard: Hi, this is Chris again. Thanks for the question, but unfortunately, I do have to acknowledge that this is new information on a subject we hadn't originally considered as a part of our initial Pre-Sub feedback. So, we can't comment now in this meeting, but these are definitely very good questions to submit in a future Q-Sub so we can get the right SMEs to speak with you on the topic. And I do want to say if you go that route, i wanted to note the more specific that you can get with your questions, the more specific our feedback can be. If you'd like some other examples of good specific questions, then please do have a look at our guidance and that has good examples in there.

Victoria Rodriguez: This is Victoria again. To go back to sterilization aspects of a planned design change, if you are re-designing the device, consider the end-to-end microbial control. So essentially a total product life cycle approach to mitigating bioburden, in some cases, bacterial endotoxins. So, from device design to standing up routine manufacturing, conducting routine monitoring, and even investigating and adjudicating excursions in alert or action limits. For example, design something that can be sterilized without too much difficulty when you consider the design process. Also, if purchasing new materials, consider how your purchasing controls ensure manageable bioburden. I definitely recommend you consider the quality of materials from your suppliers.

Stephen Anisko: Thank you Victoria, just to quickly add to this, as you redesign your device, we do recommend that you consider how modifications, such as smaller lumens or enclosed spaces could increase the challenge to sterilization process. In addition to the lumen characteristics the smaller you get, the more difficult, changes to materials, packaging, and we spoke earlier but product loading density, may introduce additional challenges to the sterilization process itself. The impact of these changes should be considered as part of your activities.

Johannetsy Avillan: This is Jojo, I would like to add to Steve's comments about re-design. I would suggest for you to consider what changes might mean for sterilant residuals. Also, please note that devices that are used for pediatric populations may have lower residual limits.

Also, another aspect to consider will be if you would need any change of packaging and if so the impact of that packaging change. And we can talk about some of the validation work to consider if there is any packaging change, so for example, shelf-life considerations, maintenance of sterility, et cetera. And also, depending on the modality that you change to, be intentional with your packaging selection and design because it could help to reduce the amount of sterilant that you use and also make is easier, or make it easier to sterilize.

Ryan Ortega: Okay. Thank you. All good advice, things to consider. I think we are good for that question and if you're ready, we can probably move on to our final question.

As we talked about a little bit earlier, we are considering adding an additional indication to this device and it is similar to what we have seen in some existing class III devices. So, we just wanted to ask, does FDA agree with the proposed scope of testing and information that we proposed to submit to the Agency? Also, is there any additional information we need to provide with respect to sterility if we go after that class III indication? Because the current indication of the device is putting it in a class II classification regulation, but we know some of these devices are similar devices have a class III indication, so we are considering adding it for use with our device. We know in general the sort of performance testing that would be needed for that class III indication, but we do still have some questions about the differences in the sterility information that would be needed to support our eventual marketing application for class III.

Nahid Ilyas: This is Nahid. So, for class III indications, this would be PMA, generally, and the PMAs we expect full test reports for sterilization versus class II indication.

Scott Steffen: Thank you for that Nahid. When you're saying full test reports what does that mean exactly in this case? We want some clarity, so we don't send too much in or not enough in for our next submission.

Stephen Anisko: Thank you, Scott. This is actually a very good question because we do see situations where insufficient documentation has been provided. When we say full reports, this will generally include all the documentation related to validation of your subject device and process validation. This could include protocols and methodology for all reports provided. For example, this could include reports supporting shelf life, packaging, if you guys intend on including barometric release, how you intend to monitor and control that, we would be interested to see that validation as well. As applicable, this could also include full validation reports for the characterization of any biological indicators and/or chemical indicators.

And I guess finally, I should mention, any residual assessments conducted, any microbial testing, endotoxin, pyrogen testing, we would look to see full test reports for that. Let me just close, this isn't an exhaustive list but just highlights what we mean when we say full report. Thank you.

Scott Steffen: Yeah, thank you for that clarification, Stephen. That makes me wonder actually, we did some batch release testing for our IDE, would that be enough for the PMA?

Victoria Rodriguez: That is a good question, this is Victoria again. We do recognize that some devices have very small and possibly infrequent lot sizes where single-lot testing may be reasonable; however, this may not be a sustainable approach upon market release. We typically review full validation of terminal sterilization at a production scale, not just on per batch basis.

Scott Steffen: Thank you Victoria, that is good to know. In our original 510(k) submission we provided a summary of the endotoxin batch testing. Can we leverage that information in future submissions?

Johannetsy Avillan: Yes, this is Jojo. So, it may be possible to leverage previous information, but keep in mind that for a PMA we will expect full reports rather than the summary information provided in your past 510(k)s. If you'd like to review some guidances with detailed information, you can look through our guidance: the 510(k) Sterility Guidance, the 510(k) Mods Guidance, the PMA Supplement Guidance, the PMA Mods Guidance are really good resources. The titles and links to these guidances will be provided in the written feedback as Chris mentioned earlier.

Nahid Ilyas: Thank you Jojo. I think we addressed all your questions for this Pre-Submission. Do you have any further questions?

Ryan Ortega: Thanks for checking Nahid. I think we are good. I think this covers all of the questions that we had for today. Really appreciate your feedback, and I think on our end we are good to wrap up.

Christopher Dugard: Thanks again for attending this meeting today. As a gentle reminder, please submit draft meeting minutes as an amendment to this Q-Sub and submit them to the FDA within 15 calendar days per our guidance.

Ryan Ortega: Understood. Before we go, I just want to thank the FDA team for a very robust discussion. We definitely appreciate your time and your feedback and talking through some of our questions with us. Chris, to your point, we will provide the meeting minutes in the form of an amendment to our file, and we will do this within 15 days. Thank you all and we hope you have a good afternoon.

Nahid Ilyas: Thank you so much.

Scott Steffen: Thank you, everyone.

You just observed an exercise of a Pre-Submission meeting that discussed four questions from a fictional medical device manufacturer.

This slide includes some of the key takeaways from this exercise. First, we'd like to emphasize while Pre-Subs are not a vehicle for prereview they can be a useful collaborative mechanism for manufacturers to

discuss specific questions with FDA to facilitate device testing or to help prepare a complete well organized regulatory submission. Separate Pre-Subs or Pre-Sub supplements are recommended for discussing any new topics about the same device presented during a meeting or for in depth subject matter review.

Second, when changing your sterilization method, you should consider any impacts from the design and the manufacturing processes. Such as compatibility of materials, packaging, and the potential need for any additional testing.

Next, as you saw during the exercise many Pre-Sub discussions focus on testing documentation needs. It's important to consider the device class when thinking about what information is needed in your eventual regulatory submission. For example, PMA submissions generally require complete test reports for sterility information, while 510(k) submissions may only need summary information in many cases.

Finally, providing clear information about your proposed testing and regulatory approach will facilitate effective and robust Pre-Submission discussions during your meetings with us. In addition, thoughtful and specific questions, like those exemplified in our Q-Submission Program guidance will help you get the most out of your interactions with us. Now let me send it back to Lisa to close us out.

Lisa Simone: Thank you, Scott. To summarize today's event, we performed a mock Pre-Submission meeting exercise by FDA and a fictional medical device manufacturer. Before the exercise, we shared background information about the fictional device and firm, the role-playing cast of characters, and the Pre-Submission meeting discussion questions. Then we performed the exercise, demonstrating interactive discussions with FDA, and we debriefed the exercise to convey the scope and key takeaways of a sample Pre-Submission meeting.

This slide includes the resources mentioned during today's exercise, along with the full URLs that you can access after the presentation.

I'd like to provide a few administrative closing remarks. As I mentioned earlier, printable slides of today's presentation 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. 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 exercise or presentation, as well as, if you have a comment or question for a future town hall, please email medicaldevicesterilization@fda.hhs.gov. You can find a listing of our upcoming town halls and other CDRH events, via the link provided on the bottom of this slide at www.FDA.gov/CDRHevents.

Before we move on to close today's event, I am excited to announce our next Medical Device Sterilization Town Hall on August 7th, where we'll start with your questions and comments from today's mock Pre-Submission event. We plan to host three short topic discussions on bioburden, bacterial endotoxins, and packaging integrity testing for sterile medical devices. Our panel will also engage in interactive discussion and live Q&A on other topics identified by the audience, and topics provided prior to the event via our medicaldevicesterilization@fda.hhs.gov mailbox.

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

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