Medical Device Sterilization Town Hall: Sterilization Short Topics and Open Q&A
October 30, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello, everyone. Thanks for joining us for our Medical Device Sterilization Town Hall, number 13. 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 within the FDA Center for Devices and Radiological Health. I'll be serving as 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.

For today's Town Hall, we begin with a segment of what we heard from you. Then our panelists will discuss previously submitted questions and comments. Next, activities to support medical device innovators and bundling sterility submissions. And then we'll have our live question and answer segment, where we look forward to hearing from you. If you have a question or comment for our panelists today, please wait to raise your hand in Zoom until we transition to this specific part of today's Town Hall.

I'd now like to share a few administrative items before I introduce and turn it over to our panelists. First, please make sure you've joined us through the Zoom app and not through a web browser, to avoid technical issues. And second, 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.

I now have the pleasure of introducing today's panelists. First is Commander 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 CDRH's Office of Strategic Partnerships and Technology Innovation, or OST. Dr. Lisa Simone, Senior Health Scientist and EtO Incident Lead within the Office of Readiness and Response in OST as well. Dr. Ryan Ortega, Regulatory Advisor on the Regulatory Policy and Combination Products Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ. Ruth Bediakoh, Consumer Safety Officer within the Office of Communication, Information Disclosure, and Training and Education within CDRH's Office of Training and Education.

Also joining us is Kelly Wilkicki, Senior Advisor for Innovation within the Office of Equity and Innovative Development in OST. Dr. Shani Haugen, Assistant Director of the Gastroenterology and Endoscopy Devices team within the Office of Health Technology number 3 in OPEQ. And Dr. Mary Wen, Deputy Division Director in the Office of Regulatory Programs within OPEQ.

Thank you all for participating as panelists in our Town Hall today. I'll now turn it over to Tamara to get us started. Tamara?

CDR Tamara Rosbury: Thanks, Kim. Next slide.

Thank you for joining us for our 13th Sterilization Town Hall. Before we get started with our discussion today, we'd like to take the opportunity to share some questions we received in our mailbox.

Question number one. What is the FDA's current perspective on using UV sterilization as an alternative for medical devices and pharmaceuticals that are not adversely affected by UV exposure? Specifically, I'm interested in understanding A, any recent developments, or changes in the FDA's stance on UV sterilization; B, the key factors the FDA considers when evaluating UV sterilization processes; C, any specific guidelines, or requirements for validation of UV sterilization methods; and D, will there be any challenges issued for developing as a potential sterilization method?

Answer, speaking specifically to medical devices, as that is where CDRH's authorities are, I would say that we are open to any modality as long as you can support its safety and efficacy as well as demonstrate you have adequate control over the process. The difference between the established categories lies in the level of evidence needed to support that process. Since UV would be considered a novel modality, full test reports would be needed for review.

If you would like more information on the established categories, we encourage you to access materials for Town Hall 3, where we discuss 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 3 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.

Currently there are no recognized standards for germicidal UV. At a high level, we'd like to point you to the FDA-recognized standard ANSI/AAMI/ISO 14937, Sterilization of Health Care Products: General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices. This general sterilization validation standard may be a useful starting point as you consider how you might validate a new sterilization method. We are also aware that there are standard methods that can be used to establish that a novel sterilant can achieve certain endpoints, like sporicidal activity.

If you have specific questions about validating a novel sterilant for a medical device or about specific challenges, like material compatibility or shadowing effects, we encourage you to submit a Q-Submission so we can provide input or detailed feedback as appropriate.

Question number two, for a sterile medical device that is presented as a sealed tube, how many sterile barrier packaging integrity tests would the FDA expect to see as part of process validation and stability studies?

Answer, for sterile barrier testing, the agency recommends that you conduct an adequate panel of testing to support your intended container closure system. For example, validation should consider specifics such as material compatibility, biocompatibility, microbial barrier, and other physical and chemical properties of the intended system. The testing panel used to support process validation activities should be based on the specific packaging attributes for which a failure may be anticipated. Testing should demonstrate that your system is able to maintain performance over a stated period of time, which has been supported through appropriate validation testing.

We further recommend that in support of your validation approach you develop a sound statistical sampling program, with samples selected over a minimum of three lots. Additional testing may be needed based on the specifics and complexity of your proposed product and packaging system. Ultimately, you may refer to the ANSI/AAMI/ISO 11607 standard series for additional information. Next slide.

We've shared this timeline previously. We have no new items, but our panelists will discuss the highlighted new experiential learning program area of interest published in September. Next slide.

In today's Town Hall on medical device sterilization, we will discuss two short topics with our sterilization experts. These are topic one: activities CDRH has in place to support medical device innovators, including early regulatory assistance, funding opportunities, and knowledge sharing. And topic two: the use of bundling for sterility-related submissions.

Now I'll turn it over to Lisa for the first discussion topic today on activities to support medical device innovators.

Lisa Simone: Thanks, Tamara. Many of you have reached out or shared your feedback on different ways that FDA might be able to help with the current sterilization-related challenges. So today we've invited panelists to discuss resources for medical device innovators. Several of these are listed on our website for medical device innovators, which is included in the Resources slide at the end of today's presentation.

For our first panel, Ruth and Ryan are joining me to talk about early regulatory assistance for medical device innovators. And my first question goes to Ruth. Would you tell us about one common resource, and that CDRH's Division of Industry and Consumer Education, or DICE, and how DICE can help medical device innovators?

Ruth Bediakoh: Sure, Lisa, I'll be glad to. The Division of Industry and Consumer Education, or DICE, or D-I-C-E, educates and provides regulatory information resources to the medical device industry. Staying current on regulatory issues and new scientific advances that educates by developing and updating our educational resources on the Device Advice and the CDRH Learn websites.

One very helpful page on the Device Advice site that we share frequently and refer our stakeholders, our industry stakeholders to, is the How to Study and Market Your Device page. This page outlines the subsequent steps necessary to bring your device to market.

And the other website I mentioned, which is CDRH Learn, is our multimedia educational resource and this page features learning modules that addresses medical device laws, regulations, guidances, and policies. These modules are provided in various formats such as videos, audio recordings, and slide presentations. And these help providers who help the medical device industry with information that is comprehensive, interactive, and easily accessible.

After you have referred to these websites and resources, if you still have questions and would like some direction, or if you are simply just confused about navigating the websites, you may also reach out to us

for assistance. We are available Monday through Friday on the phone or through email. Just be mindful that we do respond to emails within 48 hours.

Lisa Simone: Thanks, Ruth. DICE is a great resource for these individual outreach questions that you've described, but what other resources does DICE have?

Ruth Bediakoh: Yes. So, other educational resources from DICE includes the annual Regulatory Education for Industry Conference. This is a free event that usually takes place between May and June of each year. And last but not least, DICE also educates by conducting the Industry Basics Workshop. Each workshop includes a presentation followed by a live question and answer session and participants or attendees can have their questions answered by the panel of experts for the topic presented.

Lisa Simone: If you've attended any of our previous Town Halls, you've heard our moderator Kim mentioned CDRH events and also CDRH Learn where you can find the slides, recordings, and transcripts for these events that Ruth has mentioned. Thank you, Ruth, for rounding out these other valuable resources from DICE.

And now switching gears, another topic we've mentioned in some previous Town Halls is the value of Pre-Subs for engaging FDA. But we haven't really explored the breadth of the options in our Pre-Submission program. And that's where I'd like to turn to Ryan and ask if you would share more.

Ryan Ortega: Yeah, gladly. You know I'm a big fan of the Q-Sub program. So, if you look at our program guidance, you'll see that it's got several different types of Q-Subs described in that guidance. And you can actually find a link to the guidance in our Resources slide at the end of the presentation. It goes into a lot of detail about type of Q-Sub, how it's best utilized, and any timeframes associated with each type.

The ones that are probably the most pertinent here are the Pre-Submission Q-Sub and informational Q-Subs. And we've mentioned these types of Q-Subs in several of our past Town Halls, just because of how impactful they can be. And if you'll remember, Town Hall 9 even included a mock Pre-Sub that we put together. And that was to really demonstrate what the process looks like and to provide some insight into some best practices and also to some not so best practices for Q-Subs.

Our mock Pre-Sub highlighted what really is kind of the main use case for Pre-Subs. They're generally used when a company has specific questions that they want to ask us about a specific device or situation. For example, a device manufacturer may ask about the information that they want to submit in their device application. Or maybe a manufacturer or a contract sterilizer may ask technical questions about their sterilization plan and validation.

On the other hand, informational meeting Q-Subs are generally used when a company wants to expose us to an idea or a technology. Often, it's something new or novel. And this can happen while they're actually developing it. It doesn't have to be at the end of the process. I think it gives them a chance to teach us about what they're working on. They can familiarize us with a novel technology or a novel approach to something, for example, a novel approach to sterilization or a novel sterilization method. And this can also give the FDA folks who are in the meeting a chance to ask questions. We've seen both type of Q-Subs used in the past in the context of supporting sterilization innovation.

Lisa Simon: So, Ryan, what if a question arises that doesn't seem to fit nicely, or it doesn't focus on a single device or a situation? Are Pre-Subs still an option?

Ryan Ortega: Yeah. So, if you've got a situation or an idea that's maybe a little more cross-cutting, as opposed to something that's for a single, specific device, a Pre-Sub may still be applicable if you've got specific questions about it. I'll give you a for example.

Maybe someone is developing a novel sterilization method, and they have specific questions about cycle design or validating cycles but don't necessarily have a specific device in mind yet for that process. You could still potentially use a Pre-Sub to ask those specific questions and we can work to get the right subject matter experts in the room to respond to your questions or to draft a written response if that's the option you want to pursue. Maybe you might have a specific question about a potential sterilization master file for one of the pilots. And those are generally intended to impact multiple devices. You could come talk to us in a Pre-Sub for your master file submission, for example.

Lisa Simone: Thanks for that clarification and those examples, Ryan. And before we move to our next panel, I did want to mention a few other CDRH programs that have been helpful for developers of innovative medical devices because they offer that opportunity to interact with FDA experts early in the design cycle. This aligns with our goal to encourage medical device manufacturers to consider sterilization at the point they're choosing materials as part of their device design.

One is our Total Product Lifecycle Advisory program, or TAP, which has the goal to expedite patient access to innovative medical devices by providing early, frequent, and strategic communications with the FDA and by facilitating engagement with other key parties for developers of devices of public health importance. This is currently a pilot program available to certain device types with a breakthrough device designation. And our Breakthrough Devices program focuses on more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

I do want to note that at this time, these programs are probably not the most applicable if the goal is only to change the sterilization modality, but I did want to go back and ask Ryan, do you feel that still there might be an opportunity for these programs to be useful?

Ryan Ortega: Yeah, I think so, Lisa. One thing to think about, if someone has a sterile breakthrough device and they are a part of TAP is to consider how you might utilize your TAP advisor to have discussions about sterilization specifically. We've talked before about implementing this idea of an end-to-end approach to sterilization for devices and how it really does make sense to start thinking about sterilization options early in development rather than at the end of product development. And so, breakthrough devices in TAP are, by the very nature of the program, under development. So, your TAP advisor may be able to discuss sterilization with you at an early developmental stage and leverage some of the expertise in the center to help.

Ultimately what I think I really want people to walk away from this discussion with is that if you're developing a new device, whether it's breakthrough, whether it's part of the TAP pilot, or if it's coming to us through one of our regular pathways, consider if using a novel or a different sterilization modality might be a topic to discuss within your existing program or even internally within your organization during product development.

Lisa Simone: Thanks, Ryan, for those broader thoughts on how other programs might be helpful. And also, to Ruth and Ryan for sharing more about the resources for early medical device innovators.

And for our next topic, Kelly is joining me to discuss another potential opportunity for medical device innovators. Kelly, would you tell us about funding? Does CDRH have any funding opportunities?

Kelly Wilkicki: Thanks, Lisa. Yes, CDRH has a potential funding source, our SBIR program. SBIR, stands for Small Business Innovation Research, and it's a grant program. The main goal of the SBIR program, which is also referred to as America's Seed Fund, is to invest in entrepreneurs, startups, and small businesses to advance their needs, their ideas, sorry, hopefully towards commercialization. Please note that while CDRH provides money through this grant program, we can't fund medical device development. We look for grants that create tools, methods, et cetera.

Lisa Simone: I'm sure that many of today's participants weren't aware of CDRH's SBIR program. Can you give us a little bit more history or background on the program?

Kelly Wilkicki: Sure. Next slide, please.

So, on this slide, we've listed some background on our SBIR program, which started in 1982. The SBIR program is managed by the US Small Business Administration, which is another part of the federal government. The SBIR program currently has 11 different federal agencies participating, including the Department of Health and Human Services, or HHS, which FDA is a part of.

HHS actually has the second largest budget out of all the participating agencies. We are just behind the Department of Defense. Each year, the HHS groups participating in the SBIR program submit updated research priorities. And as you probably guessed, one of CDRH's priorities is sterilization. We've had this priority for a few years, and I don't envision us removing it any time soon.

On this slide, I've pasted the exact wording from the funding announcement regarding sterilization. CDRH can fund phase I or phase II SBIR grants. Phase I is up to $200,000, and phase II is up to $1.5 million. Phase I awards are typically focused on the feasibility of your idea and are one year in duration. Phase II awards build upon the work done in phase I and can span two years.

Lisa Simone: That's great that CDRH has this funding opportunity, Kelly. So, if someone is interested, how can they apply?

Kelly Wilkicki: So, if you're working in this space and want to be considered for a grant, there are a few ways to apply, which I've highlighted on this slide. I've also copied the link to this grant where you can get more information.

The technical name for the funding announcement is PHS2024-2, Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications. You can search for PHS2024-2 or use the link on this slide to get more info. We essentially accept the applications on a rolling basis, and the SBIR program occurs each year. Cutoff dates and the review panel dates are listed in the actual announcement.

The next two cutoff dates are January 5th and April 5th, 2025. The good news is if you are late, your application will just be considered in a few more months. If you do need funding by a specific time, you will need to more closely adhere to the application dates. CDRH typically funds SBIR grants once a year, and that's at the end of summer, early fall time frame, about when the Federal fiscal year switches.

Lisa Simone: Kelly, can you share if CDRH has previously awarded SBIR grants related to sterilization?

Kelly Wilkicki: Yes. So, if you go to USAspending.gov and enter the search criteria of FDA, SBIR, sterilization, and the last two fiscal years, here are some of the past awardees shown on the left here. If you click on the grant number, you can learn more about their proposals, too, which we've shown here on the right.

Some points to note, while FDA's SBIR program is smaller than NIH's I believe they have $1.3 billion set aside, while FDA is about $2 million, we do have some special benefits, such as easier access to our regulatory experts. Also, another point to note, NIH reviews and ranks all of the grants for HHS and assigns them to the participating agencies. So, what this means is that if you apply and want to be matched with the FDA, you might actually be matched with NIH, which could be a good thing since they have a larger budget and can fund many more grants.

Lisa Simone: Thanks, Kelly, for sharing more information about SBIR grants that CDRH funds, also NIH and how someone might submit a grant application for a sterilization-related topic.

And now let's move to our last panel for this discussion point. And let's welcome Shani and bring back Ryan. The previous two panels focused on resources for medical device innovators. Now we'd like to flip that around and talk about one way industry can help FDA staff learn about the challenges that medical device innovators face.

And I'd like to start with Shani. Shani is one of our internal senior champions for the reprocessing and sterilization focus area for CDRH's Experiential Learning Program, or ELP. Shani, would you share more about the purpose of the ELP program and how industry can help educate CDRH staff?

Shani Haugen: Yes, absolutely. So CDRH's Experiential Learning Program, or ELP, is intended to help FDA staff close knowledge gaps between emerging and innovative technology. Through ELP, CDRH staff can participate in a training visit which can be hosted by companies, academia, clinical facilities, and other external participants. And during that visit, CDRH staff get an opportunity to better understand the products that we review.

Some ELPs are focused on a specific type of medical device, while others might be on broader categories, such as a new kind of technology or non-clinical testing or manufacturing, et cetera. An ELP would be a great opportunity to help CDRH staff better understand the challenges and innovations associated with medical device sterilization, and specifically with novel sterilization modalities.

I do want to add that these visits are not intended for the FDA to inspect, assess, judge, or perform a regulatory function. I think of them as an interactive learning opportunity where the host can share current industry and clinical practices and discuss challenges and regulatory impacts and needs so that FDA has a greater understanding of the medical device landscape.

Lisa Simone: Shani, can you give some examples of ELPs from the past that have been valuable to CDRH staff education, including any that might be related to sterilization, just so we've got an idea of the types of experiences that CDRH has found valuable?

Shani Haugen: Yeah. I've been fortunate to attend several ELPs over the years. We've visited health care facilities to understand clinical challenges; manufacturing and sterilization sites to understand medical device packaging and industrial sterilization; third-party testing labs, to understand methods to validate sterilization cycles. Some visits have been to a company's headquarters to talk about the device design, device development, the impact of sterilization on the device. So, there's been a wide range of ELP visits, and I personally have gotten so much out of all of them.

Lisa Simone: Well, that is a wide range of topics. ELPs can be offered in a variety of different what we call "areas of interest." And CDRH publishes areas of interest every six months, and these areas do change based on CDRH staff training needs. In September, just a month ago, we published a new area of interest related to sterilization for the 2025 Fall cycle. Ryan, would you share more about this particular area of interest and why we added it?

Ryan Ortega: Yeah, sure. So this area of interest for sterilization is called considerations for different sterilization methods, including alternatives to ethylene oxide. Basically, we have an interest in learning more about different sterilization methods that are used to terminally sterilize medical devices. And this also includes understanding more about considerations for changing modalities, cycle design, cycle validation, and the applicability of different sterilization methods across a broad spectrum of medical devices.

Folks will remember ethylene oxide is used for about 50% of sterile medical devices. And no other modality is really poised to immediately step in and take over that capacity. So another thing to think about is that least burdensome premarket review for alternative methods, I think, would be facilitated by us having a deeper understanding of those alternative sterilization modalities. And training through ELP can help us grow that understanding.

Lisa Simone: But Ryan, if anyone visits the ELP website now, they will see that the proposal period for submissions is currently closed. Does that mean that these opportunities are gone?

Ryan Ortega: Yeah, so that's a good note and a good question. This area of interest, it was added in September, and it closed on October 7th. Since the call was recently closed, we haven't completed review of the submissions. And we may find it necessary to offer the same area of interest again during the next cycle, which will be open for submissions in the spring. So, everybody stay tuned. If you have questions about ELP or suggestions for ELP topics or areas, you can also email the ELP staff at ELP@fda.hhs.gov. Also, you can learn more about the ELP areas of interest on our website, which is included in the Resources slide at the end of this presentation. Or you can also find it pretty easily by searching for ELP areas of interest.

Lisa Simone: Thanks, Ryan. And since you mentioned that call for submissions happens every spring and fall-- so one will be coming up in just a few more months, let's chat for a moment about the application process. Shani, who can apply for an ELP? And how might they go about doing that?

Shani Haugen: Yeah, well, as I mentioned, we've been hosted by a variety of participants. So participants can range from companies to academia to clinical facilities. Although for this topic, the most relevant participants might be those focused on using or providing sterilization modalities, including alternative modalities.

ELP proposals are selected based on applicability to the areas of interest, CDRH resource availability, and logistical considerations. If someone is interested in hosting FDA for an ELP visit, whether that's in person or a virtual visit, they can visit our ELP website. And that link to that website is later on in this slide deck.

So, in terms of applying, someone would want to take a look at our current training area of interests. For this audience, again, the reprocessing and sterilization area of interest will probably be of most interest. They'd want to look to see when that submission period is open. Although our submission period is currently closed, as you mentioned, Lisa, we're expecting another submission period to open sometime in the first half of next year. We ask that interested parties prepare a site visit request which identifies just one training area of interest. We also ask that we be provided with a site visit agenda, which will outline the topics for discussion and the duration of the visit. Most ELP visits are one or two days or half days, and we've been doing many virtual ELP visits. There are examples of a site visit request and a site visit agenda on the ELP website, so folks can take a look at that to understand what all is involved with those.

Once the site visit request and the site visit agenda have been prepared for the specific training area of interest, you would then submit that information via email by the closing date and time. And as we've noted, submission periods are open for about a month, so we want folks to be on the lookout for the next submission period and the ELP training areas of interest when those are released next year.

Lisa Simone: Thanks, Shani, for sharing more about that process for submission. Before we end this panel, do either of you have any final thoughts about the ELP program and its potential value for new or changes in sterilization methods?

Shani Haugen: Yeah, I'll just add that the logistics for having FDA travel out to visit a site, they can be daunting. So I'll put out a plug for virtual ELPs. We've been doing more of these virtual ELPs alongside the traditional on-site options. But virtual visits allow for greater flexibility in selecting staff for these visits, selecting proposals, and helping to increase exposure to the program. It also helps us to right-size the duration of the visit. So instead of one very long day to minimize travel time, we could break the agenda up into two half-days. And that facilitates the same kind of learning but lets us approach the information fresh each day.

So, if folks would like to talk to FDA about one of the current areas of interest, and if your organization can accommodate a virtual site visit, please do indicate that when completing the site visit request.

Ryan Ortega: I'd also like to share some of my personal perspectives on the ELP program. I'm a frequent flyer for ELP training and site visits, and I think my experience really parallels Shani's, like she talked about earlier. I get a lot out of it. For me, they give a unique opportunity to learn more about sterilization science, in particular the technologies and the practices, and learning this from the experts, the people who are conducting these activities and those who are developing the novel approaches to industrial sterilization.

I've had the opportunity to learn about different types of gas and vapor phase sterilization and radiation sterilization, both virtually and on-site, as well as learning about maintenance of sterility and some of the realities of sterilization as just a part of the manufacturing process. The value that I see is that I and the others who participated in the ELP can take that knowledge back with us to CDRH. And we can use it in our regulatory review or use it to inform our policy work. It helps us to understand what sort of challenges and successes manufacturers and sterilizers are facing and hear how everyone is working to ensure that patients have access to safe and effective sterile devices. I strongly feel that the knowledge that we get from ELP experiences, excuse me, it makes us better regulators and better public servants. So, I appreciate the chance to share my perspective, Lisa.

Lisa Simone: Absolutely. Thanks to both of you for sharing your experiences and your perspective to the Experiential Learning Program and especially to Ryan for bringing that back around to the patients as well.

And now I'm going to turn the whole thing over to Ryan for our second discussion topic for today.

Ryan Ortega: Yeah, thanks, Lisa. Our final topic today has to do with bundling for sterility-related submissions. And joining me for this topic are Mary and Shani. So first, Mary, I think I'll start with you. Can you please give us a bit of an overview of what bundling is and how it might be used to reduce regulatory burden?

Mary Wen: Sure, I'm happy to. So bundling refers to the inclusion of multiple devices or multiple indications for use for a device in a pre-market submission for the purposes of review and user fee payment. When appropriate, bundling can be used to reduce regulatory burden by allowing similar scientific and regulatory issues that impact multiple devices or indications to be efficiently addressed during one review of one submission. Because there is only one user fee per submission, appropriate bundling can also prevent applicants from having to pay multiple user fees for review of similar scientific and regulatory issues impacting multiple devices or indications.

Ryan Ortega: Yeah, thank you, Mary. Are there any resources that we have regarding bundling? Where can somebody go to learn more about it?

Mary Wen: Yes, we do. So FDA has a guidance titled "Bundling Multiple Devices or Multiple Indications in a Single Submission," which is shown here on the slide. This guidance goes over what bundling is, the general bundling principles applicants should follow, as well as several frequently asked questions regarding bundling. Some FAQs addressed in the guidance include but are not limited to things like, when is it appropriate to bundle multiple devices? Either within a generic device type or across differing generic device types? In a single 510(k) or PMA submission? When is it appropriate to bundle multiple indications for use in a single 510(k) or PMA submission? When is it appropriate to bundle 510(k) and PMA devices together? And when is it appropriate to bundle changes affecting multiple devices in a single submission?

Ryan Ortega: Thanks, Mary. You mentioned that our guidance goes over some of the general principles of bundling, those that we recommend applicants follow. Can you give us a little summary of what those general principles are?

Mary Wen: Sure, absolutely. As described in FDA's bundling guidance, the general principles are, first, bundling is appropriate for devices that present scientific and regulatory issues that can most efficiently be addressed during one review. In determining whether FDA can review a bundled submission during the course of one review, FDA may consider whether the supporting data are similar, whether primarily one review division or group will be involved, and whether the devices or indications for use are similar. Second, FDA should not call out a device or indication for use from a premarket submission for the purpose of collecting additional user fees. And third, applicants should not inappropriately combine devices in a premarket submission for the purpose of avoiding user fees.

So those are the general overarching principles of bundling. The guidance then goes into further detail on situations where it generally may or may not be appropriate to bundle different device types or indications for use.

Ryan Ortega: Yeah, thanks, Mary. Important stuff for people to keep in mind if they're considering bundling. Can you give us some examples of those situations you mentioned?

Mary Wen: Yes. So for example, the bundling guidance states, you generally may bundle multiple devices within the same generic device type in a single 510(k) or PMA. In some cases, you may bundle differing generic device types in a 510(k). For example, if they are used together during a single procedure, the guidance does say you generally should not bundle differing generic device types in a PMA. The guidance also says you may bundle multiple related indications for use in a 510(k) but generally should not bundle multiple indications in a PMA unless much of the data needed to support approval of the indications would be the same, for example, the same clinical data. And then the guidance also says you generally shouldn't bundle PMA and 510(k) devices together, but there are some exceptions for devices used together in a single procedure or that are part of a system.

Finally, I wanted to note that the guidance says that you may bundle a change affecting multiple devices if the impact of the change on each of the devices can be efficiently assessed during one review.

Ryan Ortega: Yeah, thanks, Mary. That's a lot of helpful information about bundling. And to everybody listening, I would strongly encourage you to check out the FDA bundling guidance for more information if you're interested.

Mary Wen: Yes, it definitely is a lot of info, and I recognize also that the information I provided was general, as it relates to all types of devices and submissions. So perhaps we can turn now to Shani to talk about bundling as it relates to submissions containing sterility information.

Ryan Ortega: Yeah, that sounds good. Thanks, Mary. Shani, I'll turn to you. Can you give us some sterilization related examples of bundling?

Shani Haugen: Sure. First, I want to note that the FDA bundling guidance does include a sterilization-related example of bundling, specifically bundling in a single PMA submission, changes in sterilization. So, for example, a change from EO to radiation or a change in sterilization release method, where the scientific evidence provided is valid for all devices referenced.

So, a potential hypothetical example of appropriate bundling for a PMA device would be submitting a bundled PMA site change supplement in order to add an alternative sterilization facility for sterilization

of various types of devices and let's say in this example, it's various types of cardiac devices that are all reviewed by the Office of Cardiovascular Devices within FDA CDRH. In this example, you'll note that I specified that the cardiac devices are similar, and they are all reviewed within the same FDA review group in the Office of Cardiovascular Devices. If the same alternative sterilization facility and sterilization processes are utilized for all of the devices such that the supporting data are the same, then the general bundling principles would be met.

Ryan Ortega: Yeah, thanks for sharing those sterilization-related PMA bundling examples, Shani. Do you have anything similar examples for sterilization related bundling in the 510(k) space?

Shani Haugen: Yes. So I'm happy to provide a hypothetical 510(k) example. I will say, though, we don't see as many examples of bundling for sterilization-related changes in 510(k)s as we do in PMAs, given that not all changes to sterilization methods are required to come in with a 510(k).

So I thought it might be helpful. In past Town Halls we've talked about the different categories of sterilization methods described in FDA's 510(k) sterility guidance document. So just to briefly without a lot of detail go through what those different categories are, there's established A, which is a category of method that has a long history of safe and effective use. Sterilization methods might be categorized as established B, which is a category of sterilization method where there isn't an FDA-recognized dedicated consensus standard, but there is published information, and FDA has previously evaluated discrete cycles. And lastly, there are novel sterilization methods which are newly developed methods for which there exist little or no published information, no history of comprehensive FDA evaluation, and no FDA-recognized specific consensus standards.

So, per FDA's guidance document, Deciding When to Submit a 510(k) for a Change to an Existing Device, changes from established category A to established category B or novel generally requires submission of a new 510(k). But on the other hand, changes from one established category A to another established category A method don't necessarily need to come in with a new 510(k). Rather, those changes should be evaluated to see if the change could significantly affect the performance or biocompatibility of the device in determining if a new 510(k) is needed. So, in general, for changes from one established category A method to another established category A method, it's unlikely submission of a new 510(k) is required if the change could not significantly affect the performance or biocompatibility of the device or constitute a major change or modification in the intended use of the device.

So, with that background in mind, a potential hypothetical example of appropriate bundling in a 510(k) would be submitting a bundled 510(k) for a change from EO in a fixed rigid chamber, which is an established category A method, to EO in a flexible bag system, which is an established category B method, for various, let's use gastroenterology devices. And in this case, they would all be reviewed within the same division. Again, I'm emphasizing that the devices are all reviewed within the same review group. In general, the devices should be similar enough that a representative worst case sample could apply to multiple devices or device types. And if the same change in sterilization process applies to all of the devices such that the supporting data are similar, then the general bundling principles would be met.

Ryan Ortega: Yeah. Thank you, Shani, for those excellent examples. And thank you both for this really informative discussion, again, with examples on submission bundling. So, I will pass it back to Tamara to bring us home.

CDR Tamara Rosbury: Thanks, Ryan. Next slide, please.

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

We will summarize the discussion topics. We discussed activities CDRH has in place to support medical device innovators, including early regulatory assistance, funding opportunities, and knowledge sharing. And we discussed the use of bundling for sterility-related submissions.

Before we open the discussion, I'm excited to announce our next Town Hall on November 20, where our panel will discuss short topics, including recent sterility consensus standards, recognitions, and biocompatibility assessment considerations related to sterilization changes.

As always, we'll include the live Q&A on topics identified by the audience and topics provided prior to the event via our MedicalDeviceSterilization@fda.hhs.gov mailbox. Information about the Town Hall series can be found at the link here. Now I'll turn it back over to Kim.

CDR Kim Piermatteo: Thanks, Tamara. And thank you to all of our panelists for providing your discussion on those topics. We will now transition to our question and answer segment for today's Town Hall.

I would like to go over how we will manage this segment and a few reminders. So 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 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.

When asking your question, please remember to limit yourself to asking one question only and try to keep it as short as possible. And as always, we appreciate that you may have a very specific question involving your device, company, or scenario. However, we might not be able to answer such specific questions during the Town Hall, but we may be able to provide a broader response, so keep that in mind.

After you ask your question or provide your comment, please lower your hand and then if you 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.

So, as we wait to receive some of your questions and comments today, I'd like to start us off with a few questions to some panelists. And the first question, I'd like to direct that to Ruth. So, Ruth, the question is, you've shared information about many programs that CDRH offers. Can you provide some insight if we're just not sure where to start?

Ruth Bediakoh: Sure. So we understand that it can be very overwhelming. No matter what your question, you can always reach out to the Division of Industry and Consumer Education, or DICE, or D-I-C-E. DICE is your best bet if you are not just sure where to start. As I mentioned earlier, we will direct you to the relevant publicly available information which is contained on our device advice or our CDRH

Learn web pages. If you are looking for specific device information that is not contained on these websites or other medical device web pages, again, DICE will assist you in obtaining that information. For example, DICE may recommend you submit a pre-submission to obtain FDA feedback on specific questions. And if your goal is to help educate FDA, you might consider a Q-Submission information meeting.

CDR Kim Piermatteo: Thanks, Ruth. OK, Lisa, I'm going to come to you for our next question. Lisa, that question is, this Sterilization Town Hall series has provided a broad platform for information related to sterilization, including topics suggested by stakeholders and CDRH activities. The materials available on CDRH Learn represent another resource for innovators. How long will the Town Hall series continue?

Lisa Simone: That's a great question, Kim. We've gotten that question a few times before. We've also gotten a lot of really good feedback from all of you on the value of the series and how it's helped prompt those discussions about what all of us can do to help reduce reliance on EtO and consider those alternative modalities. And I have to admit, this has been quite an experience. We've really enjoyed interacting with stakeholders, sharing our work, exploring how we're going to be addressing these challenges, what we're doing now, what we're thinking of doing, but maintaining the series has been really resource intensive.

So we've decided that the series will go through the end of this year. We do have two more events planned after today's Town Hall. Tamara's just mentioned that the next one is on November 20, and the series will end on December 4th with our 15 event. And that event is going to be titled Sterilization Short Topic, Series Updates, and Impact, Wrap Up and Next Steps.

CDR Kim Piermatteo: Thanks, Lisa. I appreciate that. So, I think at this time we're going to take our first live question, and that is coming to Sandeep. Sandeep, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Sandeep Saboo: Yeah, hi. My name is Sandeep from Merit Medical. The question is on VHP sterilization, which is in the A category. Is FDA planning on issuing a guidance documents on it or a standard is coming out on it? Because the labs don't seem to be too knowledgeable on it, and there doesn't appear to be a guidance document around it.

CDR Kim Piermatteo: Thank you, Sandeep. I'm going to open it up to our panelists to provide a response. I'm not sure if Ronnie, or sorry, Ryan or Shani, would like to start, and then anyone feel free to jump in.

Ryan Ortega: Yeah, I can give a start. So, as you mentioned, we updated our 510(k) sterility guidance to indicate that vaporized hydrogen peroxide is something that we consider an established category, A method with respect to sterilization review in 510(k)s. And so, you asked about VHP-specific guidances or standards. And I definitely want to note that we were able to make that update to our 510(k) guidance in large part because there is a vaporized hydrogen peroxide standards. It's ISO 22441, and that has been recognized by FDA. And so that is really kind of a great starting point for understanding the standardized methodology for validating a vaporized hydrogen peroxide cycle. So, I think that would be the first thing that I would direct you to.

I don't think we currently have specific guidance on individual sterilization modalities. We do have our general guidances about sterilization and other general topics. But for specific modalities, I would definitely direct you to those modality-specific standards. And again, for VHP, that's ISO 22441.

CDR Kim Piermatteo: Thanks, Ryan, and thank you, Sandeep, for your question. OK, actually, Ryan, I'm going to come back to you with another question that we previously received. And that question is, I am making the same sterilization change for several similar devices. Can I utilize one of the master file sterility pilot programs or bundle the changes to the devices together in the same submission? Are there reasons to consider one approach over the other?

Ryan Ortega: Yeah. Thanks, Kim. I like this question because it gives us a chance to disambiguate the sterility master file pilot and the bundling approach. So, I'll dig into that just a little bit.

The sterility master file pilots and submission bundling both present different approaches for managing changes to devices, and different entities are potentially involved in each. So, for example, the sterilizer is explicitly involved in interactions with the agency for a sterility master file in one of the pilots because they're the master file pilot holder. However, both can help to make the review process for changes to previously cleared or approved medical devices more efficient when used effectively. In this case, the change would be a sterilization change.

Bundling is a potential approach to sending submissions for multiple devices together. In this case, for example, consider maybe a number of similar devices from the same manufacturer, and they're all undergoing the same change, the same sterilization change. If the devices are similar, the change is similar and the impact to the devices are similar enough that they can potentially be assessed in one review, bundling the submissions for changes may make a more efficient process and may be a more efficient way to review those changes.

We talked about the master file pilot programs in detail at our Town Hall on September 11th. So, I would definitely invite folks to go back and listen to that recording of the session if you were unable to attend. You can also visit our website, Sterilization for Medical Devices, for more information on master files.

And again, if found eligible, the advantage of the master file pilot programs is that a sterilization provider could submit a master file upfront for our review. And if that master file is accepted into the pilot, in the PMA case, the PMA holder with a device that's in scope of the master file can just reference that master file in a post-approval report rather than in a PMA supplement. Or in the 510(k) space. the 510(k) holder can just reference the master file in their internal documentation rather than submitting a new 510(k).

CDR Kim Piermatteo: Great. Thank you for that information, Ryan. Alright, our next question is coming from Maris. Maris, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Maris D: Hi. Thank you for doing this Q&A. My name is Maris from Globix Corporation here in LA. I have a question regarding ELP. So could a manufacturer with a medical device sterilization process that is considered novel in the US but already established internationally take part in the FDA's ELP? And if so,

would the manufacturer also be able to submit a Q-submission at the same time if they are looking to introduce this process to the US market?

CDR Kim Piermatteo: Thank you, Maris, for that question. Shani, I'm going to turn it over to you, if you want to start us off?

Shani Haugen: Yeah, absolutely. So I heard a couple of different things in your question. So one is, would it be possible to submit an ELP for a sterilization method that might be novel in the U.S. and maybe not novel outside of the U.S. And to answer that question, yes, absolutely. If we do consider it a novel method, that would be new information to us. We would love to learn more about that sterilization modality. So yes, please do feel free to check out our ELP website. And once the next open period is available, then please do go ahead and submit something for us.

You also asked about submitting a Q-Sub at the same time. And I do want to make sure that we're separating out that Q-Sub from ELP. ELP visits should not have any kind of regulatory decision associated with them. They really are learning opportunities. But they can be independent. You could submit for an ELP during the next open period and there's nothing stopping you from submitting a Q-Sub to get us interested in or get us aware of your novel sterilization method. But again, they would need to be very, very separate processes and information.

CDR Kim Piermatteo: Thank you, Shani, and thank you, Maris, for your question. OK, I'm going to come back to Mary with a question that we received that I want to ask. So, the question I have for you is, or that came in is, I have 510(k)s where I want to update some aspect of the sterilization. However, I also don't want to submit all the other changes that have been building up. I just want to share that in a bundle of 510(k)s that all have the same sterilization change. Would that be permissible?

Mary Wen: Thank you. That is a really good question. So please note that FDA's 510(k) modifications guidance states when a new 510(k) is submitted for a device with multiple changes, that 510(k) should describe all changes that trigger the requirement for submission of a new 510(k).

To help ensure that FDA has a complete understanding of the device under review, that 510(k) should also describe the other changes since the most recently cleared 510(k), in other words, those changes that didn't require submission of a new 510(k) that would have been documented as part of the first 510(k) for that device.

So, in other words, if the other minor changes that have been building up wouldn't normally require a new 510(k), you'd still need to inform us of those other changes when submitting the bundle for the devices so that FDA has a complete understanding of all of the devices under review. Given this, lots of devices with minor changes might preclude an effective bundling strategy if those other minor changes cannot be efficiently addressed by one review group within a single review.

CDR Kim Piermatteo: Thanks, Mary. Alright. I am going to call on our next live attendee, and that is coming from BTP3. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Brian Perry: Hi, my name is Brian Perry, and I work at Mass General Hospital in Boston. I have a question regarding the FDA. Are they working on or have started or have guidelines for 3D-printed medical devices that would be manufactured in a hospital setting?

CDR Kim Piermatteo: Thank you, Brian, for that question. I'm going to open it up to any of our panelists. I know 3D printing may be outside of the scope of today's Town Hall. Did anyone on the, any panelists want to comment on that?

Ryan Ortega: I'll just say it is a little bit outside the scope, but I think, it's not my specific area, but I think we put out a public white paper with some initial thoughts on 3D printing and some questions. So, I believe that's publicly available, if you want to search for that.

Mary Wen: Yes, this is Mary. I just wanted to add that FDA does also have a website on 3, or maybe I should say web page on 3D printing of medical devices. And so if you just search for 3D printing of medical devices, FDA web page, that should pop up. And you're absolutely right, Ryan, about the discussion paper. That discussion paper is also linked on that website.

Ryan Ortega: Yeah. thanks for checking that, Mary. You can also reach out to DICE for more information, too. They might be able to help you out, too.

Lisa Simone: This is Lisa. We do have a guidance, and I'm not sure that it's applicable. It's called "Technical Considerations for Additive Manufactured Medical Devices." It might be outside the scope, but that might be something else that might be helpful.

CDR Kim Piermatteo: OK, thanks, Brian.

Brian Perry: I'm not sure if you answered my question.

CDR Kim Piermatteo: I'm sorry. Can you repeat that? I'm sorry. I didn't hear you.

Brian Perry: Oh, thank you. No, thank you very much.

CDR Kim Piermatteo: OK. Alright, so the next question, it looks like we're coming back to Sandeep. Sandeep, I'm unmuting your line. Please unmute yourself and ask your comment or ask your question or provide your comment.

Sandeep Saboo: So, with respect to the previous question, I did see on the FDA's website that there is a guidance planned for next year for the 3D-printed devices made at the hospital or doctor's setting.

CDR Kim Piermatteo: OK. OK, thank you, Sandeep. So, I think what Sandeep is saying is that on FDA's website there is, I'm guessing it's listed as a planned guidance, it's not final or draft or anything. It's just a planned guidance. So maybe that's something else to look into, Brian. I think that's what he's following up on that.

Sandeep Sobo: Yeah, in 2025, yeah.

CDR Kim Piermatteo: OK. Thank you, Sandeep. Alright, it looks like we have another question or comment coming from TA858. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Sierra: Hi, my name is Sierra. I also work at Mass General Hospital in Boston. I saw that manufacturers still need to communicate any of the minor changes for the 510(k) but not necessarily a new 510(k). If there are changes that are exempt from reporting requirements, are there any requirements posed by the FDA to the manufacturer for communicating with the end user that may have that device?

CDR Kim Piermatteo: Thank you for that question. So I'm not sure if Ryan or Shani want to start or ask for clarification on the question. I think, I didn't fully understand that, so if the panelists need to clarify, maybe you could rephrase that question. I think your question was about does the manufacturer of a medical device need to provide sterilization updates to a device that's already, I'm guessing, in use or purchased by the hospital? Is that what your question is framed around?

Sierra: Yeah.

CDR Kim Piermatteo: OK.

Mary Wen: Yeah, so this is Mary. I am not quite sure if I fully understood the question, but I would suggest that you take a look at FDA's 510(k) modifications guidance. Or if you'd like to, feel free to email DICE with additional specifics. But the 510(k) modifications guidance does talk about minor changes and minor changes that may trigger the requirement for submission of a 510(k) or those that may not. And there are some that the guidance describes that would trigger the requirement for a 510(k) and others that would not and would just be documented.

I also hear a question about whether the manufacturer has to notify the end user of sterilization changes. Could you elaborate a little bit more?

Sierra: Yeah, if there was a change in the IFU, would they then have to like this change was made to the IFU to the end user? Is there any regulations around that?

Mary Wen: Generally, if it is a change to the IFU in, do you mean indications for use or instructions for use?

Sierra: Instructions for use.

Mary Wen: OK, and is this for a reprocessed device or not?

Sierra: Yes, reprocessed.

Mary Wen: Got it. I will let some of our sterilization SMEs talk about this.

Shani Haugen: I can jump in a little bit. So there's probably a lot of really important details that we would need to understand to be able to fully address your question. But I do think that if a device has reprocessing changes, meaning that the device manufacturer determined that reprocessing instructions needed to be changed, then I think we would expect that the device manufacturer is notifying users of

that reprocessing change. But again, the details are going to matter, so if you do have a specific question, please do reach out to DICE. DICE is both for industry as well as consumers, and they may be able to provide you with more information.

Sara/Sierra: OK, thank you.

CDR Kim Piermatteo: Thanks for that question. And thank you, Mary, and Shani, for providing a response. So appreciate that. OK, our next question is coming from Shawn. Shawn, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Shawn Flynn: Yes, it's more of a comment related to the previous question. I, too, am on the clinical side and do some consulting related to medical device reprocessing. And there are occasions when we run into containment devices that historically over a period of years have changed their IFUs to include things like dry time, terminal sterilization, when, in fact, the indications for use statement or when the device was cleared was indicated for immediate use steam sterilization. And now they're using the doc, or they're using the product and marketing the product as a terminal sterilization, which retains moisture in the container. And so that's just one example of when should a company refile? And it does cause confusion in the industry. So just more of a comment, but that's a real-time example of how a device can change over a period of years that has deviated far from the original clearance or their indications for use statement.

CDR Kim Piermatteo: Thank you, Shawn, for providing those comments and feedback. I think our panelists will take note. I do think that it's something that is good to be brought to our attention. Did any panelists or anyone want to provide any additional comments? I know that was outside of scope of today's specific webinar, or sorry, Town Hall and topic, but I'll give it a second to see if any of the panelists want to comment.

Lisa Simone: Sure. This is Lisa. I will say that we've gotten a couple of questions to our mailbox that have been in the same vein. And even though the reprocessing IFU is outside the scope of this particular Town Hall, if you'd like, you can go ahead and put that in an email and send it to the email that's on the screen right now, and we can redirect it to the folks who have been looking at some of those questions internally. And we'd appreciate that additional context.

CDR Kim Piermatteo: Great. Thanks, Lisa. And thanks again, Shawn. I'm going to come back to Brian. Brian, I have unmuted your line. Please unmute yourself and ask your comment or ask your question or provide your comment.

Brian Perry: I'm sorry, I thought I'd lowered my hand, but you've already answered everything that I needed to know. Thank you.

CDR Kim Piermatteo: OK, thanks. Alright. I'm actually going to come back to you, Lisa. I'm going to come back to you for another question that we've previously received. And that question is, if we receive, if FDA receives an additional information request and we are wondering how to respond to specific questions in that AI request, how do we approach asking our review team our questions or talking about our proposed response? Do we submit a Pre-Sub in that case?

Lisa Simone: Thanks, Kim. That's a really good question that does involve some timeline discussion. So, if you'd like input on your approach to addressing an FDA deficiency, you can submit a specific type of Q-Submission called a submission issue request, or SIR. And you can request either written feedback or a meeting. But it's important to understand the timelines for an SIR. If you've recently received FDA's marketing submission letter requesting additional information and you are able to submit a submission issue request within 60 days of that letter, then we will respond within 21 days as resources permit. Otherwise, the timeline for FDA's response to a submission issue request received outside of that time frame is 70 days as resources permit. And if that sounded a little confusing, Ryan had mentioned a bit about the different types of Pre-Subs earlier in this presentation. And it's all outlined in the guidance document that's in the Resources page.

CDR Kim Piermatteo: Thanks, Lisa. Alright, at this time, I do not see any more raised hands, so I'm going to make one more call-out. Alright. I have seen Azul. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Azul Cohlmia: Hi there. Can you hear me, OK?

CDR Kim Piermatteo: Yes, we can.

Azul Cohlmia: Oh, fantastic Thank you. I work for a medical device manufacturer startup, and I just had a question regarding steam sterilization. The question that we had here was if we were to validate for the ISO standards for sterility of a medical device, would we, I guess is it OK to use a 510(k)-approved steam sterilizer in-house to perform that sterilization long-term for our device?

CDR Kim Piermatteo: Thank you as well for that question. It seems to be very specific, but I think I'm going to turn it to maybe Shani, if you want to just provide a broader response or maybe sort of broader information for him?

Shani Haugen: Sure. So I think I heard the question was you're wanting to sterilize your device using steam sterilization and wanting to use a 510(k)-cleared steam sterilizer in-house to sterilize your device. So in general, using a 510(k)-cleared steam sterilizer for a device that's provided sterile is acceptable. I do want to note, though, that there's a lot that is involved with validating a sterilization cycle. In addition to the type of microbiological testing that we often talk about, we often refer to it as IQ, OQ, PQ. You want to be controlling your installation process. You want to be controlling how your device is operating. And so, I just want to point that out to you so it's additional information for you to think about as you go about validating your sterilization cycle.

Azul Cohlmia: Thank you. I really appreciate that information. That was very helpful. And we have gone through that validation process with a contract sterilizer. And what we're just considering now is to potentially bring that steam sterilization process in-house as we increase our production volume.

I guess there's one additional question that I have now, which is when I'm looking at the 510(k)-approved steam sterilizers through the FDA registration search, they are coming up as general hospital use, typically. Does a medical device manufacturer fall within the scope of that classification?

Ryan Ortega: Maybe I can hop in here and provide some insight. So, one thing where it's important to make the distinction between a health care sterilizer and an industrial sterilizer. Health care sterilizers,

as you mentioned, they're in our registration listing database, you can find 510(k) clearances for health care sterilizers. They are themselves medical devices when used in that context.

Like Shani said, there's nothing necessarily that prevents someone from then taking a health care sterilizer, putting it in an industrial setting, and using that health care sterilizer as a terminal sterilization method for a medical device, as long as it can be validated according to the appropriate standards. And Shani mentioned all of the different types of qualifications as part of what's needed for some of the standards.

So, I think one thing to point out is that just because you're using a health care sterilizer in an industrial setting, it's not like you are, it doesn't necessarily mean that you are using that health care sterilizer as a medical device. In your case and in general when someone takes a health care sterilizer and uses it as a terminal industrial sterilization method, I would say generally you are using that as part of the manufacturing process. It's manufacturing equipment in that case.

Azul Cohlmia: So even if that's not the specific scope of what was approved as part of that device's 510(k), because we're validating the process and doing the IQ, OQ, PQ on the industrial use of that device, we're still within the, I guess, approved, we're creating the approval for the application or the use of that ourselves. And it wouldn't impact, I guess there would not be an issue with us doing that. Am I understanding correctly?

Ryan Ortega: So, there wouldn't be an issue. And it's not so much a matter of an approved or unapproved use because in your case, using it as a piece of industrial equipment, it's not a health care use, so it's not being used for its medical device intended use. It's being used as a piece of manufacturing equipment, like any other piece of manufacturing equipment, say, something on the processing line or that sort of thing. So, in this case, the question of is this following the indications for use, is it following the instructions for use for a health care sterilizer, isn't necessarily what would be looked at. It's more of is this validated as a terminal industrial sterilization method according to the cited standard.

Azul Cohlmia: OK. And then so if every piece of equipment that we're using for our industrial purposes, as long as we are doing our internal validation of that equipment or that process, are there any requirements where we have to use a 510(k)-cleared piece of equipment? Or it's entirely up to our own internal validation process?

Ryan Ortega: There's no requirement for using a 510(k)-cleared health sterilizer for an industrial process. Again, it really comes back to looking at whatever you're using as a piece of manufacturing equipment for industrial terminal sterilization and making sure that it's validated and controlled according to the standard.

Azul Cohlmia: That is incredibly helpful. And I think those are all the questions that I had for you guys. You don't know how many hours of CFR reading you guys have just saved me, so I really appreciate all of that. Thank you so much.

CDR Kim Piermatteo: Thanks, Azul, for that question. And thank you, Shani, and Ryan, for assisting with that. So I'm going to make one last call-out. If anyone has any questions for our panelists today, please raise your hand in Zoom.

OK, seeing none, that will wrap up our question and answer segment then for today. I want to thank you all for your participation. And I'd like to now turn it back over to Tamara to provide her final thoughts for today. Tamara?

CDR Tamara Rosbury: Yep, thanks, Kim. Thank you for joining us for today's Town Hall and for sharing your questions and comments via email and during the live Q&A. We appreciate the questions and robust discussion related to the following topics, interest in vaporized hydrogen peroxide and VHP-specific guidance and standards, which FDA did update earlier this year; scope of the ELP program for a novel sterilization method that may be established internationally; the guideline for 3D-printed devices manufactured in a hospital setting; communication changes and 510(k) submissions; obligations to notify the end user of potential changes in the IFU; and questions about using steam sterilization in-house.

We are very committed to continuing the dialogue on these critical medical device sterilization topics to try to make sure that patients and providers have access to the medical devices they need. Thanks again for attending, and now I'll turn it back over to you, Kim.

CDR Kim Piermatteo: Thanks, Tamara. For everyone's information, printable slides of today's presentation are currently available on the Events page for this Town Hall and on CDRH Learn. A recording of today's Town Hall and a transcript will be posted to the Events page and CDRH Learn in the next few weeks. And a screenshot of where you can find these materials on CDRH Learn is provided on this slide.

If you have any additional questions or comments about today's Town Hall topic, as well as if you have a comment or question for a future Town Hall, please email MedicalDeviceSterilization@fda.hhs.gov. Additionally, you can find a listing of all of our upcoming Medical Device Sterilization Town Halls and other webinars on our CDRH Events page, which is at the bottom of this slide at www.fda.gov/CDRHevents.

And lastly, as Tamara mentioned, I just want to send another reminder that our next Town Hall, will be held on Wednesday, November 20th from 1:00 to 2:30 PM Eastern time. Thanks again for joining us. This concludes today's Town Hall.

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