Medical Device Sterilization Town Hall: Sterilization Short Topics and Open Q&A
October 9, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello, everyone. Thanks for joining us for our 12th Medical Device Sterilization Town Hall. This is Commander Kim Piermatteo of the United States Public Health Service and I serve as the education program administrator in the Division of Industry and Consumer Education within FDA's 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 will begin with a segment on what we heard from you. Then our panelists will provide discussions on the topic of Predetermined Change Control Plans or PCCPs and then we will have our live question and answer segment, where we look forward to hearing from you. If you have a comment or question 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 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: Dr. Lisa Simone, Senior Health Scientist and EtO Incident Lead within the Office of Readiness and Response and CDRH's Office of Strategic Partnerships and Technology Innovation; Dr. Jessica Paulsen, Associate Director for Digital Health within CDRH's Office of Product Evaluation and Quality, or OPEQ; and Dr. Jason Ryans, Policy Analyst on the Regulation, Policy, and Guidance staff within OPEQ. Thank you all for participating in our town hall today.

I would now like to turn it over to Lisa to start us off.

Lisa Simone: Thanks, Kim. And thanks, everyone, for joining us for our 12th Sterilization Town Hall. Before we get started with our topic today, we'd like to take the opportunity to discuss some questions we received in our mailbox.

Question 1, "How can a manufacturer take advantage of the master file program or get partnered with a qualified sterilizer?"

Answer, while FDA can't facilitate partnering between sterilizers and manufacturers, there may be actions that both the sterilizer or a potential customer may take. Sterilizers with a master file could make it clear to customers or potential customers that they have a master file in place. They can also clarify the scope of the master file and potentially share the value or impact to the customer in using

that master file. For any of the master file pilot programs, potential customers could also visit the FDA sterilization website to see who is participating and then reach out to any of those participants and ask about the type of devices that might fall within the scope of their master file.

We are aware that some participants include this information on their websites and may offer their own webinars or educational information that are designed to explore the potential value of the master file to those potential customers.

And there is a second question, and that is, "What data or submission information is no longer needed for product review when using a master file to switch sterilization methods, cycles, or locations?"

And the answer to this question depends on the device and the specific pilot program. For devices that are in the scope of a sterility master file accepted into one of the two pilots targeting PMA devices, their current sterilization process may be changed to the one in the master file without the need to submit a PMA supplement. Instead, they can inform us of the change in an annual report. Per the Federal Register Notice for the two PMA-focused pilots, we ask that the annual report from the device manufacturer supporting such a change include the following three pieces of information: one, the name, address, and FEI number of the proposed sterilization facility; two, the master file number in which the reference sterilization procedures are described, with a signed right-of-reference from the master file holder; and three, the devices to be sterilized, identified by manufacturer, trade name, model number, and PMA number.

On the other hand, for devices that are in the scope of a sterility master file accepted into the pilot's targeting 510(k) devices, their current sterilization process may be changed to the one in the master file without the need to submit a new 510(k). Instead, they would document the change and all supportive information internally. No submission would be needed for a change within the scope of this pilot.

For all three pilots, all of the technical information supporting the sterilization changes, including the validation work, should be maintained in records as part of the internal change management and, like other product manufacturing or change information, may be requested as a part of inspectional activities. And we do think it would be helpful if one of the first conversations between a device manufacturer and the master file holder about potentially using a sterility master file is to clarify the scope and the applicability of the master file.

We also want to clarify that the sterility master file needs to already have been accepted into one of the pilot programs, in order to leverage it in the manner that I described. If you have specific questions about utilizing one of the pilot programs or how to use an accepted sterility master file in one of the pilots for a specific scenario, we do invite you to use our Q-Submission Program to discuss those specific questions with us.

We've shared this timeline previously, and we've added a few new entries. Highlighted on the left are the three existing links for our master file pilot programs that I mentioned earlier when I responded to the mailbox questions. Highlighted on the right, you'll see four new entries. At the top, in August, we published the Predetermined Change Control Plans draft guidance, which our panelists will discuss today.

In September, we added three new recognized consensus standards to our database related to sterilization, including ISO 11737 part 3, 2023, for bacterial endotoxin testing; the complete recognition of ISO 11140 part 1, 2014, for chemical indicators; and ISO 13004, 2022, for radiation substantiation of dose. I'm also very pleased to announce that last month, CDRH updated our collaborative community website to announce our membership in the Kilmer community on sterility assurance.

And finally, the last link is to our experiential learning program, describing a new sterilization-related area of interest that we've announced to help further our staff's education. And, as always, the links for each of these appear in the resources slide at the end of today's presentation.

In today's town hall on medical device sterilization, we're taking the opportunity to discuss predetermined change control plans with our sterilization and regulatory subject matter experts. This year, we've responded to emailed and live questions in town halls three, four and five. And due to the sustained interest, we felt it might be valuable to spend a bit more time on the topic today.

So, our panelists today will talk about the purpose of PCCPs, how one might be used, the general content of a PCCP, and then they'll explore some sterilization-related modifications that may be appropriate for a PCCP. And now, let me turn it over to Jessica and Jason to start the discussion.

Jessica Paulsen: Great. Thank you so much, Lisa. And thanks to everyone for joining us today to discuss PCCPs and how you may be able to leverage this new approach to device modifications. So today, Jason and I will provide some high-level information about PCCPs, based on the draft guidance, as Lisa mentioned, that was published in August of this year. Just a general reminder that the draft guidance is not for implementation at this time. And we are currently seeking public comment on the draft guidance.

So today we're also going to highlight our current authority to authorize devices with PCCPs. This is based on Section 515C of the Food, Drug, and Cosmetic Act. And then, finally, we will briefly discuss a couple of sterilization related modifications that could be appropriate for a PCCP. So if you'd like a deeper dive into PCCPs, we'd encourage you to read the draft guidance. It's titled Predetermined Change Control Plans for Medical Devices and listen to the recording that's available from the corresponding webinar that we held on September 3rd.

Alright, Jason, so let's first start with the basics. Can you share a little bit about what is a PCCP?

Jason Ryans: Yeah, thanks, Jessica. The framework for PCCPs is that manufacturers would be able to provide documentation in their marketing submission that details specific future modifications that could be made to the device and how those modifications would be validated before implementation without the need for a new marketing submission, like a new 510(k).

FDA would review the PCCP document and could authorize the PCCP as part of the final decision for the marketing submission. Once the PCCP is authorized, the manufacturer would then be able to validate and implement those modifications from the authorized PCCP sometime in the future.

Jessica Paulsen: Okay, great. Yeah, and I'd also like to highlight just the value of a PCCP. So for manufacturers, the value is really that ability to iterate their device more quickly and reduce the need for subsequent additional marketing submissions for each of those planned modifications that are

included in the PCCP. And then from the FDA perspective, it can also be least burdensome for us just by reducing the number of new submissions for such modifications in the future.

So, Jason, can you share a little bit about just where the concept of PCCPs came from?

Jason Ryans: Yeah, so PCCP terminology was originally introduced in a 2019 FDA discussion paper to address the rapid evolution of AI-enabled devices and resulted in a separate draft guidance that was published in April of 2023 that discusses PCCPs specifically for AI-enabled devices. And we're hoping to have that guidance finalized soon.

The PCCP concept then really expanded with the Food and Drug Omnibus Reform Act in 2022. This added section 515C to the Food, Drug, and Cosmetic Act, which allowed for the authorization of PCCPs for any device type, not just AI-enabled devices. Importantly, the provision includes that PCCPs describe planned changes that be made to the device and that would otherwise require a PMA supplement or a 510(k).

So the provision is self-executing and in effect. So we can authorize devices for PCCPs now. And we actually already have authorized more than 20 devices with PCCPs so far.

Jessica Paulsen: That's great. Yeah, so you mentioned a little bit about how FDA's authority in section 515C allows for PCCPs to be authorized in a marketing submission today. Can you share a little bit more about how this happens?

Jason Ryans: Sure thing. First, it's important to mention that a PCCP can only be reviewed and established as part of a marketing authorization, so this would be a 510(k), a PMA, or a De Novo. No other pathway is appropriate to authorize a PCCP.

Second, the types of modifications that are appropriate for a PCCP as described in the draft guidance, uses a risk-based approach, and could depend on a number of factors, for example, whether the modifications change the intended use of the device or whether the changes introduced new risks to the device. In the case of a PCCP submitted in a 510(k), the modifications must also allow the device to remain substantially equivalent to the predicate.

Additionally, FDA may require that a PCCP include certain labeling, notification, or performance requirements, depending on the modifications that are proposed. As you mentioned earlier, I would recommend reviewing the details in the draft guidance we published in August. And for any specific questions, I would really encourage those that are interested to use a Pre-Submission.

Jason Ryans: Okay, now that we've talked some about what a PCCP is and how we got here, let's get into what makes up a PCCP. The draft guidance from August lays out three key elements that FDA recommends be included in a PCCP. These three key elements are the description of modifications, the modification protocol, and the impact assessment. Jessica, do you want to walk us through each of the elements at a high level?

Jessica Paulsen: Yeah, sure. Happy to. So, I do want to stress this will be just a high-level explanation, again, more detail can be found in the draft guidance. So, the first element, the description of modifications, this is the section that includes the specific planned modifications to the device, including

device specifications and performance characteristics. And this is where we recommend that you include a list of the individual proposed device modifications, as well as a description of the specific rationale for each of the device modifications proposed. And, again, these should be really, really specific modifications and not a general laundry list of categorical changes.

And then we have the modification protocol, which is the section that includes the verification and validation activities, including the pre-defined acceptance criteria that would support each of those modifications to ensure that if the modification were implemented, the device would remain safe and effective. So, this should include performance evaluation methods that include the plans to verify and validate the device following implementation of each modification, both individually and collectively. And the section should also include what we're calling update procedures, that describe how manufacturers will implement their validated changes. So this could include updating the labeling, providing notification to users, or even real-world monitoring plans as appropriate based on the modifications being proposed.

And then lastly, we have the impact assessment. This is the section that's, it's really an assessment of the benefits and risks of implementing a PCCP for a device as well as the documentation of the risk mitigations. So, this should include how the individual modification in the PCCP impacts not only the particular device function, but the overall functionality of the device. So, this could include how the PCCP impacts other device software or hardware in the device or, for example, if the device is a combination product, this could include how the PCCP impacts the biologic or the drug constituent part and the combination product as a whole.

Jason Ryans: Thanks. That's really helpful. And I'd like to add that we've gotten a lot of questions regarding how detailed this documentation should be. So, I think a good rule of thumb is that generally the level of detail expected in a PCCP should be the same as it would be submitted in a marketing submission for a particular modification, but minus the test data.

Another topic we've gotten many questions on is about the types of modifications that may be appropriate for a PCCP. I highly recommend you review the draft guidance for more comprehensive information; however, we did want to touch on it a bit; the general thinking about how to evaluate whether your proposed modifications may be appropriate.

First, you can think about evaluating whether the modification is appropriate for a PCCP by determining whether your PCCP would be submitted in a 510(k) or De Novo versus a PMA. Authorization of a PCCP for these premarket pathways, consider different benefit risk evaluations of the proposed modifications and they're intended to harmonize with our existing device modification policies.

Second, no matter the premarket pathway that is pursued with a PCCP, the proposed modifications cannot result in a change to the intended use of the device. Similarly, we believe that most modifications to the indications for use included in a PCCP would be difficult for FDA to assess prospectively. That being said, there may be certain modifications to the indications for use that may be appropriate for inclusion in a PCCP. Jessica, was there anything else you'd like to add?

Jessica Paulsen: Yeah, no, I think you've captured the most important aspects and I'll just add that we do recognize there can be variability when considering the risk of a device. And we intend to consider the totality of the information provided when evaluating proposed PCCP modifications. So, for example,

including the proposed guiding principles that are outlined in the draft guidance, those can be really helpful to think about. We'll also, of course, take into account just the benefit-risk profile of the specific device in front of us, as well as our experience with PCCPs across different device types and with different modification types. So this may result in scenarios where certain modifications that may be appropriate for a PCCP for one device type may not be appropriate for another device type.

Jason Ryans: Agreed. Those are really good points. Now, Jessica, what about including PCCP-related information in other parts of a marketing submission? What are some of the important things to think about?

Jessica Paulsen: Yeah, there's definitely some places we think it is very helpful to include PCCP information and I'll focus on a couple that are tied pretty strongly to transparency. So the first is related to labeling, where we generally recommend that it include a statement that the device has an authorized PCCP. And, as mentioned earlier, when modifications are being implemented, the labeling should be updated as appropriate, so that users may be aware of the modifications that have been implemented that impact use of the device.

And then the other section to highlight that we believe PCCP information should be included in, is the public decision summary for a submission. So this is something like a 510(k) summary, for example. So generally, we think the PCCP should be described in sufficient detail to support transparency to users of the assessment of reasonable assurance of safety and effectiveness, or for 510(k)s, the substantial equivalence determination for the device, excluding, of course, all trade secret and confidential commercial information.

Jason Ryans: Okay, so let's shift gears a bit and discuss what types of sterilization-related modifications may be appropriate for a PCCP. There's a lot of information in the draft guidance about the types of modifications that generally may or may not be appropriate for a PCCP. So today we wanted to highlight a few example modifications to help folks begin to think about the types of modifications related to sterilization that they may consider in a future submission.

This is by no means an exhaustive list of examples. So, to begin, I'll share some examples of sterilization-related modifications that may be appropriate for inclusion in PCCP and some that may not be appropriate.

For PCCP modifications in a 510(k), FDA generally believes that changes in sterilization, packaging, transport, or expiration dating may be appropriate when using well-established methods. For a PCCP modification and a PMA submission, we generally believe that it would be limited to more minor changes in sterilization, packaging, transport, and expiration dating. For more in-depth example, consider a non-absorbable polyethylene surgical suture. For this specific device, we believe a change to a different non-novel sterilization method, let's say from a category A to a category B method, could be appropriate for a PCCP.

For an example of a modification that we generally don't think is appropriate, would be something like a change from a device labeled "for single use only" to a device labeled as reusable. Jessica, were there any other examples you wanted to highlight?

Jessica Paulsen: Yeah, sure. So maybe to elaborate a little bit more on PMA. So in the draft PCCP guidance, we propose that PMA manufacturing changes or those types of changes that are appropriate for 30-day notices may be appropriate for inclusion in a PCCP. So two examples of that type of change from the 30-day notice guidance include, first, a change to the test site for sterilization test samples, where the specifications are unchanged. And then the second example being a change to the aeration time used at a sterilization site. So, we definitely keep in mind, manufacturing changes for PMA devices in this space as an area where there may be good opportunity to proactively propose modifications in a PCCP.

So hopefully these examples are helpful as you consider thinking about how you might leverage PCCPs for your devices. We'd really encourage folks, again, to read the draft guidance, listen to the recorded external webinar for additional information on our proposed approach for determining the types of modifications that may be appropriate for a PCCP. I will note, the docket is open. The link is in the resources slide. And so, we really are looking forward to receiving your comments regarding the draft guidance.

And I will just wrap up by emphasizing the importance of early interaction with FDA if you're considering submitting a PCCP for your device. So to date, we have not yet authorized a device with a PCCP related to sterilization modifications. So, we're pretty eager to see manufacturers consider how they may propose a PCCP in this space. And I will say that doing a Pre-Sub to receive FDA feedback on your proposed PCCP is highly encouraged and it can be a really helpful way to gain alignment. So with that, I am going to pass it back to Lisa.

Lisa Simone: Thanks, Jason, and Jessica, for exploring this topic in a lot more detail. This slide and the next include resources that were mentioned earlier in the presentation, along with the full URLs that you can access after the presentation.

Today's short topic discussion centered around the purpose of a predetermined change control plan, how one is used, the general content, and then our panelists talked about some sterilization-related modifications that may be appropriate for a PCCP. We hope that this discussion has highlighted the potential of PCCPs as a more proactive approach in bringing safe and effective devices to the market in a timely manner.

And before we open it up to discussion, I am excited to announce our next town hall on October 30th, where our panel will discuss short topics, including activities to support medical device innovators and bundling sterility submissions. And, as always, we'll include the live Q&A on topics identified by our audience and topics provided prior to the event via our medical device sterilization mailbox. Information about the town hall series can be found at the link here. And now I'll turn it back to Kim.

CDR Kim Piermatteo: Thank you Lisa. And thank you Jessica and Jason. What great information. So, we will now transition to our question-and-answer segment for today's town hall.

Joining our panelists today, we have a few returning panelists from our previous town halls, and that includes: Dr. Ryan Ortega, Regulatory Advisor on the Regulatory Policy and Combination Products Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ; Dr. Shani Haugen, Assistant Director for the Gastroenterology and Endoscopy Devices Team within the Office of Health Technology Number 3

in OPEQ; and Dr. Paolo Laranjeira, Senior Staff Fellow on the Sterility Devices Team within the Office of Health Technology Number 4 within OPEQ. Thank you all for joining us.

So I'd 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 then we appreciate that you may have a very specific question involving your device or scenario; however, we might not be able to answer such specific questions during today's town hall. Therefore, we will try to provide a broader response.

After you ask your question or provide your comment, please lower your hand in Zoom. And if you have another question or comment, please raise your hand again 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 that we've previously received.

And the first question, I'll direct that to Jessica. So, Jessica, the question is, has FDA authorized any PCCPs for devices, and what information is publicly available?

Jessica Paulsen: Yeah, thanks so much, Kim. So, yes, is the short answer. FDA has authorized PCCPs for more than 20 devices or so. So to share a little bit more detail about these authorizations, I will say that the PCCPs span most device-specific offices, or OHTs as we call them. And they include 510(k)s, De Novos, as well as PMA submissions. And the modifications in the authorized PCCPs include various disciplines and types of changes, including AI-related changes, hardware and component changes, software changes, and even some limited changes in indication for use, for example. So, if anyone's looking for more information, devices that have an authorized PCB can be identified by information in the marketing decision letter and the public summary information that's available on FDA's website.

CDR Kim Piermatteo: Thanks, Jessica. Okay, next, I'm going to come to Jason with another question. Jason, the question is, for devices subject to 510(k) requirements, how do I compare my device with a PCCP to a device that does or does not have an authorized PCCP?

Jason Ryans: Thanks, Kim. So, for devices subject to 510(k) requirements, the determination of substantial equivalence includes, among other requirements, a comparison between the technological characteristics of the predicate device and the subject device, both of which may or may not have a PCCP. As described in the draft PCCP guidance, FDA considers the PCCP to be part of the technological characteristic of the device. Therefore, comparison of a device with a PCCP to a device that does or does not have an authorized PCCP is consistent with the current 510(k) paradigm for the comparison between the technological characteristics of the predicate and the subject device.

CDR Kim Piermatteo: Thanks, Jason. Again, I encourage our attendees today to please raise your hand in Zoom. Take advantage of our panelists today and ask them any questions you might have about PCCPs related to the topic today. But I'm going to go back to Jessica. This is a question, I think, that we get quite often, but can you expand on what is the value of a PCCP?

Jessica Paulsen: Yeah, happy to. So implementation of modifications to a device through a PCCP can really help facilitate and support device innovation and iteration. So, by including a PCCP in a marketing submission for a device, a manufacturer may be able to reduce the need for subsequent additional marketing submissions for each of those planned modifications to the device that are included in the PCCP, while also allowing FDA to make sure that the device is going to stay safe and effective. And again, it's also least burdensome for FDA. So, there's a lot of potential value here, but it definitely does require that proactive planning as you think about modifications you intend to make in the future to your product.

CDR Kim Piermatteo: Thanks so much, Jessica. Alright, Jason, I'm going to come back to you for another question that I think is of value as well, and that is, how do you submit a PCCP for a device?

Jason Ryans: Sure. So as we mentioned a little bit earlier, the PCCP is submitted as part of a marketing submission, so either within a 510(k), De Novo, or PMA. And we mentioned the three key elements of the documentation, the description of modifications, modification protocol, and impact assessment; those are the content that we recommend. But for submitting it in a marketing submission, we recommend that the PCCP included as a standalone section with a title and version number. And if you're going to use the eSTAR submission method, there's actually a mechanism to signify that your submission has a PCCP under the device description section, under the device attributes. And it will also trigger the ability to attach your PCCP document there.

CDR Kim Piermatteo: Great. Thanks so much, Jason. Okay, Shawn, I see that your hand is raised. Shawn, I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Shawn Flynn: Yes. Thank you. My name is Shawn Flynn. I'm the CEO of Bedrock Surgical. Thank you for hosting this discussion. We're developing a novel instruments as a service platform, which utilizes AI and some advanced sensing technology. But it's basically a reprocessing as a service for hospitals, ambulatory surgery centers, and, in some cases, our medical device manufacturers.

So, really, my question is, given that sterility is a critical step in our process, and we are constantly evaluating the best modalities to ensure patient safety, could you elaborate on how the FDA's predetermined change control plans can support innovative companies like ours in implementing alternative sterilization methods, while maintaining regulatory compliance and supply chain integrity? And additionally, how can emerging technologies like AI and real time data integration be better leveraged to enhance sterilization, efficacy, and compliance monitoring within the regulatory framework?

CDR Kim Piermatteo: Thank you, Shawn, for that question. I'm going to turn it back over to Jessica first and then, Jason, if you have anything to add on, please feel free to chime in.

Jessica Paulsen: Sure. Yeah, no. Thanks so much for the question and glad to hear what you're working on in this space. It sounds exciting. So, I think PCCPs in general can be really valuable in identifying the changes that you intend to make. Whether, I think your example may have been something about changing from one method to another. So, one of the things that we've thought about in this space is if you're changing from an established method to another, again, that established track record of a

method can be a potentially valuable place to start when thinking about changes that may be appropriate for a PCCP.

It's difficult to get into specifics, obviously, for a specific product or space, but I do hope you'll think about what we've shared today and what's in the draft guidance as you consider where your product is today and maybe going in the future and how you can proactively specify the types of modifications, the methods to qualify them, the acceptance criteria. And come and talk to us in a Pre-Sub so that we can give you feedback on whether that may be appropriate in a PCCP. Anything else from the team to add?

Ryan Ortega: Hey, yeah. This is Ryan. I have maybe a little to add about the AI for manufacturing and sterilization part of that question. I think, looking in the future, it would be interesting to see the role that AI might play in manufacturing in terms of monitoring different processes as a part of change control, as a part of systems designs. I think, in general, we've been thinking about that as well. And I would maybe point you in the direction of a couple of our resources. If you looked for the FDA resources on advanced manufacturing, you might find some interesting and helpful information there. For example, some of our previous statements, information about advanced manufacturing, including what the role of AI might be.

Another thing that you could looked for is potentially some information about, again, advanced manufacturing, the use of AI for monitoring and things like that within CDRH's Case for Quality program and the related web pages. Both those web pages might be useful resources for you if you're looking for more information, particularly information from FDA sources.

CDR Kim Piermatteo: Thank you, Ryan. And thank you, Jessica. And, of course, thank you, Shawn, for your question. I don't think anyone else has anything to add, so again, thank you, Shawn.

I'm going to go ahead and move down to our next question, which is coming from Kiran. I have unmuted your line. Please unmute yourself and ask your question or provide your comment.

Kiran: Yeah. Thanks for allowing me to speak here. So, one short question, can we include non-sterile devices in a PCCP of an application in which the sterile device has been made?

CDR Kim Piermatteo: Thank you for that question. So just to clarify on my end, so that I hear you, that we hear you correctly, you're asking if a non-sterilized device can be included in the PCCP of a sterilized device? I'm sorry, can you rephrase that question, maybe?

Kiran: Yes, yes. Suppose I'm filing a 510(k) for a sterile device, for a sterile implant. But I want to introduce also a non-sterile implant for the same. So can I submit a PCCP in that same application?

CDR Kim Piermatteo: So, I'm going to open it up to our panelists. I think we understand that you're asking about including a PCCP for a sterilized device with a non-sterile device?

Kiran: Yes.

CDR Kim Piermatteo: Okay. So I'd like any of our panelists to chime in. I think maybe that's not what we're talking about here, but I'll turn it over to any of our panelists who want to chime in.

Jessica Paulsen: Yeah, this, oh go ahead please.

Jason Ryans: So, I was going to say, generally, I think the PCCP is meant to be for one device. So the submission, your 510(k) for that device, your PCCP is going to be tied to that device. And as we mentioned earlier, changing a device from sterile to non-sterile through just the PCCP mechanism is likely not going to be appropriate. Jessica, do you have anything you wanted to add?

Jessica Paulsen: Yeah, no. I'll just say, again, we might sound like a broken record, here, but if you've got a specific proposal, I would encourage you to come to us and get some feedback on what you're thinking about doing for a PCCP, so that we can help best point you in the right direction before you submit your marketing application. So, a Pre-Sub is a really valuable tool.

Kiran: Okay. Thank you.

CDR Kim Piermatteo: Thank you. Thank you for that question. And thank you, Jessica, and Jason. Okay, I actually want to circle back to Jessica for another question that we've previously received. And, Jessica, that question is, as a user, how do I know if modifications have been implemented using a PCCP for a device?

Jessica Paulsen: Yeah, no, this is a great one. So in our draft guidance that was released in August, we describe a section of the modification protocol for a device that includes what we call update procedures. So these update procedures should really describe the procedures that manufacturers will use to update the device, to implement the modifications, and communicate that information to users about the modifications that are needed to be able to safely use the device.

So this information may include transparency to users about the modifications, such as through labeling, or perhaps it's updated user training. And as we describe it in a pretty detailed manner in the draft guidance, but, in general, users may see for devices that have authorized PCCPs, that device labeling may include information such as a description of the modifications that have been implemented, a description of how the modifications, how they were implemented and how they would be informed of implemented modifications. Again, maybe it's through instructions for use, or in the software space, we often see a version history. So hopefully that's helpful.

CDR Kim Piermatteo: Thanks, Jessica. Okay, so I think I'm going to pivot just a little bit. And I'm going to come to Shani next for a question. Shani, I have a question. And the question is, do I need to submit a new 510(k) to expand my shelf life?

Shani Haugen: Thanks, Kim. Yeah, I think this is a great question, and in the vein of modifications that we've been talking about today. So FDA has a guidance document titled Deciding When to Submit a 510(k) for a Change to an Existing Device. We sometimes refer to this guidance document as the Mods Guidance, meaning modifications guidance. And that guidance addresses this kind of issue.

So generally, if the same method or protocol described in the previously cleared 510(k) is used to extend the shelf life, then generally a new 510(k) is not needed; however, where methods or protocols that are not described in a previously cleared 510(k) are used to support shelf-life claims, then submission of a new 510(k) is likely required. So, we discussed that Mods Guidance at an EtO town hall back on February

29 of this year. So in addition to going to that guidance, I encourage folks to check out that recording and slides for that town hall on our website for more information.

CDR Kim Piermatteo: Thanks, Shani. Alright, Paulo, I'm going to come to you next with another question. I think this is related to a previous town hall as well. And this question is, when considering a new sterilization modality, can peer-reviewed articles be used to support the scientific rationale to meet AAMI ISO 14937? And should these articles be added to the submission?

Paulo Laranjeira: Hi, Kim. Thank you, thank you for the question. Yes peer-reviewed articles are a scientific source of information that can be used to support a rationale to meet the consensus standards requirement. You should document in your submission what was used from the article in your rationale, and you should provide a complete reference, so we are able to assess the article. You do not need to submit the article with your submission. Thank you.

CDR Kim Piermatteo: Thanks, Paulo. Alright, I'm going to open it up to everyone on the call. If you have a question, please raise your hand in Zoom. Our panelists are here to help answer any questions or provide clarification.

So, I'll give it another minute, but if no one has any other questions or comments, we will move to close the town hall.

Alright, so, Raquel, thank you for raising, uh, no. Okay, Raquel has lowered her hand. Alright, last chance. Anyone have any questions, please raise your hand in Zoom.

Alright, seeing none, Lisa, we're going to go ahead and move to close the town hall. And I'll turn it back over to you to provide closing remarks for today.

Lisa Simone: Sure. Thank you, Kim. And thanks to everyone for joining us for our town hall today and for your earlier questions and suggestions for this topic that led to this event on PCCPs and how they might be leveraged for sterilization-related situations. We had some good conversation today on some new development activities and changing sterilization modalities, questions about leveraging AI to monitor different manufacturing processes and some potential FDA resources, like considering the case for quality.

It was, overall, a really nice town hall today. We were glad that we were able to provide some of this feedback to you. And we're really happy that you were here today and wish you all a very good day, and hopefully we will see you at the next town hall at the end of this month. Thank you. Back to Kim.

CDR Kim Piermatteo: Thanks, Lisa. And a few closing remarks from me, just so everyone is aware that printable slides of today's presentation are currently available on the Events page for this town hall and on CDRHLearn. And we will post a recording of today's town hall and a transcript within the next few weeks. And a screenshot of where you can find all of these town hall materials on CDRH Learn has been 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 remember to send that to MedicalDeviceSterilization@fda.hhs.gov. And, additionally, you can find a listing of all of our upcoming

Medical Device Sterilization town halls and other webinars on our events page, which is listed on this slide as well at www.fda.gov/cdrhevents.

And just another reminder, as Lisa mentioned, we hope you're able to join us for our October 30th town hall, which will be held from 1:00 to 2:00 PM Eastern time.

Thanks again for joining us today. This concludes our town hall.

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