U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Program

Thanks for joining us!
We'll get started in a few minutes

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

Lisa Simone, PhD

Senior Health Scientist / EtO Incident Lead

Division of All Hazards Preparedness and Response

Office of Readiness and Response

Office of Strategic Partnerships and Technology Innovation

Center for Devices and Radiological Health, FDA

CDR Scott Steffen, PhD

Senior Program Management Officer / EtO Incident Lead

Division of All Hazards Preparedness and Response

Office of Readiness and Response

Office of Strategic Partnerships and Technology Innovation

Center for Devices and Radiological Health, FDA

Ryan Ortega, PhD

Regulatory Advisor

Regulatory Policy and Combination Products Staff

Office of Product Evaluation and Quality

Center for Devices and Radiological Devices, FDA

Christopher Dugard, MS

Assistant Director

Office of Health Technology 4

Office of Product Evaluation and Quality

Center for Devices and Radiological Health, FDA

Nahid Ilyas, PhD

Chemist

Office of Health Technology 4

Office of Product Evaluation and Quality

Center for Devices and Radiological Health, FDA

Johannetsy (JoJo) Avillan, PhD

Microbiologist

Office of Health Technology 4

Office of Product Evaluation and Quality

Center for Devices and Radiological Health, FDA

Stephen Anisko, MS

Team Lead for Sterility Devices Team

Office of Health Technology 4

Office of Product Evaluation and Quality

Center for Devices and Radiological Health, FDA

Victoria Rodriguez, PhD

Biomedical Engineer

Office of Health Technology 2

Office of Product Evaluation and Quality

Center for Devices and Radiological Health, FDA

Today's Agenda

1. Discuss background information for the mock pre-submission exercise
2. Perform the mock pre-submission exercise
3. Debrief the mock pre-submission exercise

BACKGROUND INFORMATION FOR THE MOCK PRE-SUBMISSION EXERCISE

Discussion Topics

Topic 1: Testing considerations when moving from EtO to another modality (gas/chemical sterilant)

Topic 2: Testing consideration moving from EtO to radiation

Topic 3: Design considerations and modifications factoring into sterilization

Topic 4: Impact of adding a class III device

Setting the Stage – The Fictional Device

- Asymmetric
- Enclosed spaces
- Numerous crevices
- Lumen and tubing
- Multiple materials (polymers and metal)
- Microchips
- Single – use
- Considerations for Class II vs. Class III device
- One device within a large product family

FDA Q-submission Program Guidance

Fictional Firm Roles:

Ryan Ortega - CEO

CDR Scott Steffen - SME

FDA Review Team Roles:

Christopher Dugard
Assistant Director

Nahid Ilyas
Lead Reviewer

Johannetsy (JoJo) Avillan
SME

Victoria Rodriguez
SME

Stephen Anisko
SME

MOCK PRE-SUBMISSION EXERCISE

Fictional Firm and FDA introductions, device description and agenda

Question 1

We have provided proposed testing to be conducted to support the transition from EtO to a different gaseous, chemical sterilant for our previously cleared device and to modify the device.

Does FDA find this testing sufficient, and do you have additional recommendations?

Question 2

We are also considering the option of using radiation as a sterilization modality.

Are there additional sterilization validation or other considerations that differ from the considerations mentioned for Question 1 if we were to use radiation?

Question 3

We are in early design stages for the modification – does FDA have any input on challenge features or material compatibility concerns with respect to device performance?

What other things should we consider when developing our device with regards to sterilization?

Question 4

We are considering adding an additional indication to the device similar to what we see in some existing class III devices. Does FDA agree with the proposed scope of testing and information to be submitted to the agency?

Is there additional information we need to provide with respect to sterility if this additional indication pushed the device into class III?

Pre-submission Meeting Wrap Up

DEBRIEF OF THE MOCK PRE-SUBMISSION EXERCISE

Exercise Debrief

- Pre-subs do not equal pre-review and separate pre-subs are recommended if new topics are presented during a meeting or for in-depth subject matter review.
- When changing sterilization method (modality), consider any impact from design and manufacturing processes, such as compatibility of materials and packaging and the potential need of additional testing.
- Complete test reports should typically be provided for FDA review of Class III devices.
- Clear information about your proposed testing or regulatory approach combined with specific, focused questions facilitate effective pre-sub interactions.

Summary

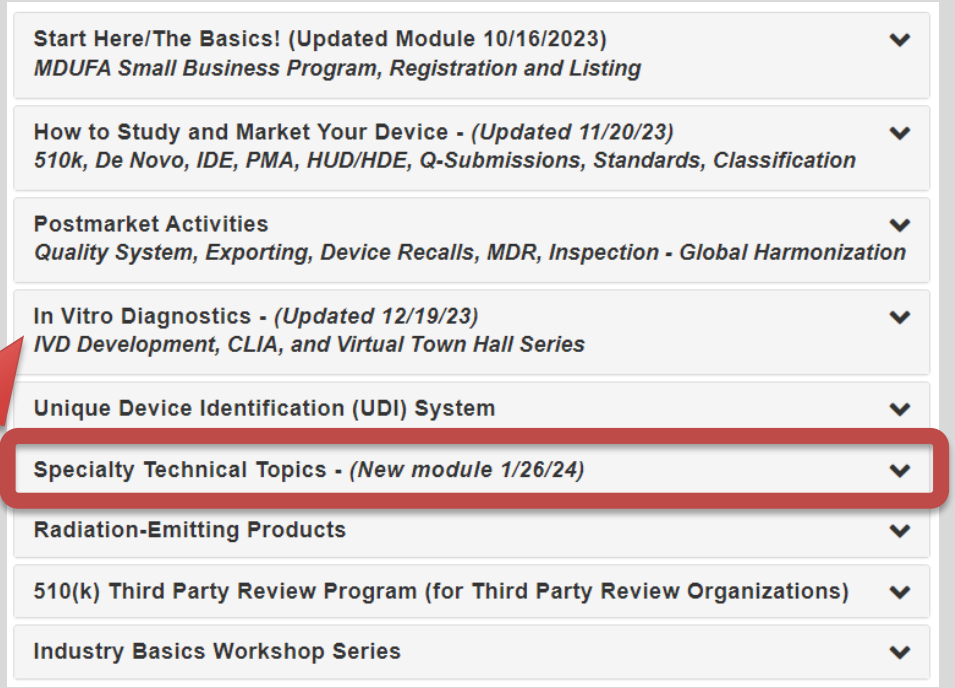
- Discussed background information for the mock pre-submission exercise, including the fictional device and manufacturer, the cast of characters, and the discussion questions
- Performed the mock pre-submission exercise, demonstrating interactive discussions with FDA
- Debriefed the mock pre-submission exercise to convey the scope and key takeaways from the pre-submission exercise

Resources

Section	Cited Resource	URL
Setting the Stage, Question 3	FDA Q-submission Program Guidance	www.fda.gov/media/114034/download
Question 1	AAMI TIR28	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=39387
Questions 1, 2 and 4	510(k) Modifications Guidance	www.fda.gov/media/99812/download
Question 2	ISO 11137 Series	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=1&sortcolumn=pdd&productcode=&category=&title=&supportingdocsyn=off&ascapilotyn=off&organization=&referencenumber=11137&regulationnumber=&recognitionnumber=&effectivedatefrom=&effectivedateto=&PAGENUM=10
Questions 2 and 4	PMA Modifications Guidance	www.fda.gov/media/81431/download
Question 3	AAMI TIR17	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=44569
Question 4	Update to 510(k) Sterility Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
Question 4	PMA Supplement Guidance	www.fda.gov/media/81431/download

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions/comments about today's presentation**
  - Email: MedicalDeviceSterilization@fda.hhs.gov
- **Upcoming Town Halls & Webinars**
  - www.fda.gov/CDRHWebinar



Next Town Hall

Date: Wednesday, August 7, 2024

Time: 2:00 – 3:00 pm ET

Potential Topics:

- What we heard from our mailbox
- Short topic discussions on bioburden, bacterial endotoxin and packaging integrity testing for sterile medical devices
- Open Q&A

See section on our Sterilization for Medical Devices webpage that includes town hall dates and links to town hall materials.

Medical Device Sterilization Town Hall Series

www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls