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:
Sterilization Short Topics and Open Q&A

August 7, 2024

Medical Device Sterilization Town Hall:

Sterilization Short Topics and Open Q&A

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Today's Panelists

CDR Tamara Rosbury, PhD
Health Scientist / EtO Incident Response

Division of All Hazards Preparedness and Response
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

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

Ryan Ortega, PhD
Regulatory Advisor

Regulatory Policy and Combination Products Staff
Office of Product Evaluation and Quality

Mitali Patil, PhD
General Engineer

Office of Health Technology 2
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Today's Panelists (cont.)

Anita Khatiwara, PhD
Biologist

Office of Health Technology 2
Office of Product Evaluation and Quality

David Craft, PhD
Microbiologist

Office of Health Technology 3
Office of Product Evaluation and Quality

Jennifer Berg
Senior Staff Fellow

Office of Health Technology 4
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

CDR Tamara Rosbury, PhD
Health Scientist / EtO Incident Response

Division of All Hazards Preparedness and Response
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

What we heard from you last time

Short Topics for Discussion

Topic 1: Testing considerations for bioburden testing

Topic 2: Methods and considerations for bacterial endotoxin testing

Topic 3: Testing considerations related to packaging integrity for sterile medical devices

Topic 1: What is bioburden and what are some considerations for testing the bioburden of a medical device?

MODERATOR:

CDR Scott Steffen, PhD

Incident Response Lead

OST, Office of Readiness and Response

Anita Khatiwara, PhD

Biologist

OPEQ, Cardiac Ablation, Mapping and Imaging Devices

Mitali Patil, PhD

General Engineer

OPEQ, Heart Valve Devices

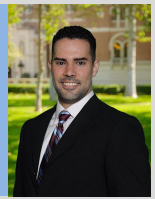
Topic 2: Why is it important to evaluate bacterial endotoxin and what are the considerations for testing a medical device?

MODERATOR:

Ryan Ortega, PhD

Regulatory Advisor

OPEQ, Regulatory Policy and Combination Products



Mitali Patil, PhD

General Engineer

OPEQ, Heart Valve Devices

David Craft, PhD

Microbiologist

OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

Topic 3: What are testing considerations related to packaging integrity for sterile medical devices?

MODERATOR:

CDR Scott Steffen, PhD

Incident Response Lead

OST, Office of Readiness and Response

David Craft, PhD

Microbiologist

OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

Jennifer Berg

Senior Staff Fellow

OPEQ, Surgical and Infection Control Devices

Resources

Slide Number	Cited Resource	URL/Contact Information
6	CDRH's Division of Industry and Consumer Education (DICE)	E-mail: dice@fda.hhs.gov Phone: 1(800) 638-2041 or (301) 796-7100 (9:00 am – 12:30 pm; 1:00 pm – 4:30 pm Eastern Time, Monday – Friday (except Federal Holidays)
8	Verbal reference to ANSI/AAMI/ISO 11737-1: Sterilization of healthcare products – microbial methods	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=43299
8	Verbal reference to Guidance to Industry: Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions	www.fda.gov/media/113230/download
8	Verbal reference to USP 41-NF36:2021 <71>	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=42995
9	Verbal reference to Guidance to Industry: Pyrogen and Endotoxin Testing: Questions and Answers	www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pyrogen-and-endotoxins-testing-questions-and-answers
9	Verbal reference to ANSI/AAMI ST72: Bacterial endotoxins	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=40962
9	Verbal reference to Guidance to Industry: Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile	www.fda.gov/media/74445/download

Resources

Slide Number	Cited Resource	URL
10	Verbal reference to ISO 11607: Packaging for terminally sterilized medical devices	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?&referencenumber=11607
10	Verbal reference to ASTM D4332: Packaging testing	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=43689
10	Verbal reference to ASTM D4169: Performance testing of shipping containers	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=43297
10	Verbal reference to ASTM F1980: Accelerated aging for sterile barrier systems	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=44089
10	Verbal reference to ASTM F1886: Test method for seal integrity	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=35753
10	Verbal reference to ASTM F2096: Test method for detecting gross leaks	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=30649
10	Verbal reference to ASTM F88: Test method for seal strength of flexible barrier materials	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=44773

Summary

Today's short topic discussion centered around microbial test methods used for medical devices that are terminally sterilized. We provided a brief insight on bioburden, bacterial endotoxin and package integrity testing including the following:

- Considerations for testing when conducting bioburden tests on medical devices.
- Testing considerations when evaluating bacterial endotoxin on medical devices.
- Testing for packaging integrity related to terminally sterilized medical devices.

Next Town Hall

Date: Wednesday, September 11, 2024

Time: 1:00 – 2:00 PM ET

Potential Topic:

- Sterility Master Files and Effective Use in Premarket Submissions

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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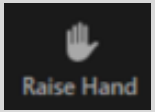
Let's Take Your Questions and Comments

- **To ask a question/share a comment:**
  - Raise your hand in Zoom
  - Moderator will announce your name and invite you to speak
  - Unmute yourself when prompted in Zoom to speak



- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

Additional questions/comments about today's presentation

- Email: MedicalDeviceSterilization@fda.hhs.gov

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/CDRHevents

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