

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 Method Selection for New and Existing Devices

May 23, 2024

Medical Device Sterilization Town Hall:

Sterilization Method Selection for New and Existing Devices

Today's Panelists

CDR Tamara Rosbury, PhD

Health Scientist-Detail / EtO Incident Response

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



Christopher Dugard, MS

Assistant Director

Office of Health Technology 4
Office of Product Evaluation and Quality



Nadia Kadry, PhD

Biologist

Office of Health Technology 3
Office of Product Evaluation and Quality



Stephen Anisko, MS

Team Lead

Office of Health Technology 4
Office of Product Evaluation and Quality



Additional Panelists

Jon Weeks, PhD

Acting Assistant Director

Division of Biology, Chemistry, and Materials Science
Office of Science and Engineering Laboratories



Paulo R. Laranjeira, PhD

Senior Staff Fellow

Office of Health Technology 4
Office of Product Evaluation and Quality



Aftin Ross, PhD

Deputy Director

Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation



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

CDR Tamara Rosbury, PhD

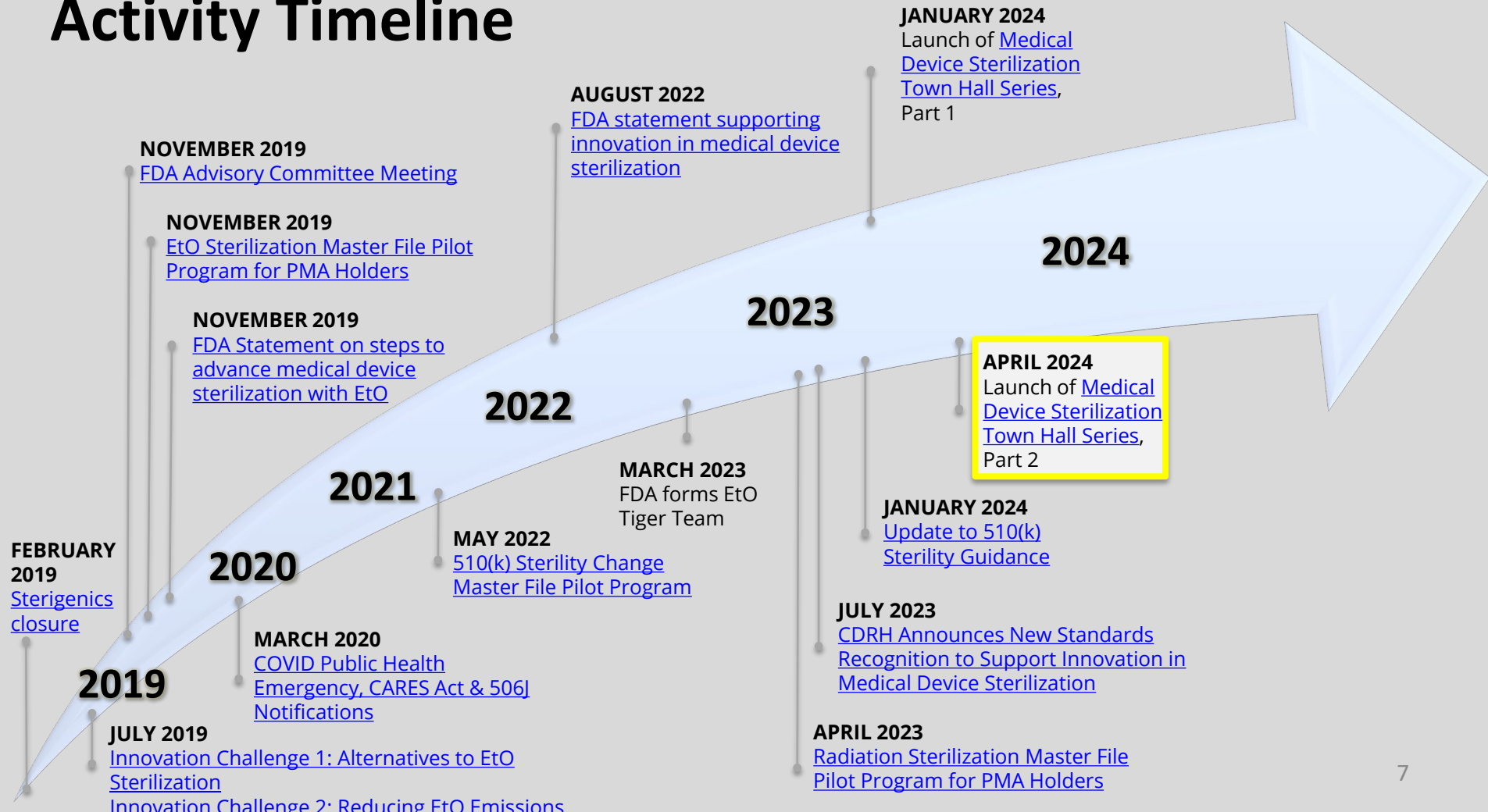
Health Scientist-Detail / EtO Incident Response

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

Activity Timeline

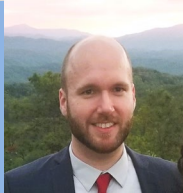


Panel Discussion

- Topic 1: Technical Considerations when Selecting or Changing a Sterilization Modality
- Topic 2: Maintaining Sterility Throughout the Product Lifecycle
- Topic 3: Challenges and Considerations during New Product Design and Development and Transitioning to an Alternate Modality
- Topic 4: Collaboration Opportunities and Additional Information for Decision-Making

Topic 1: What aspects of your device need to be considered when you choose a modality, and what technical considerations might you be thinking about to understand/justify the change

MODERATOR:
Christopher Dugard
Assistant Director
OPEQ, Surgical and Infection Control Devices



Stephen Anisko
Team Lead
OPEQ, Surgical and Infection Control Devices



Nadia Kadry
Biologist
OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices



Paulo Laranjeira
Senior Staff Fellow
OPEQ, Surgical and Infection Control Devices




Jon Weeks
Acting Assistant Director; Microbiologist
OSEL, Sterility and Infection Control Program



Topic 2: How to maintain sterility throughout the product lifecycle

MODERATOR:
Nadia Kadry
OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices



Stephen Anisko
Team Lead

OPEQ, Surgical and Infection Control Devices



Christopher Dugard
Assistant Director

OPEQ, Surgical and Infection Control Devices




Paulo Laranjeira
Senior Staff Fellow

OPEQ, Surgical and Infection Control Devices



Jon Weeks
Acting Assistant Director; Microbiologist

OSEL, Sterility and Infection Control Program



Topic 3: What sterilization considerations should be identified during the design and development of new products

CO-MODERATOR:

Stephen Anisko

Team Lead
OPEQ, Surgical and Infection Control Devices



CO-MODERATOR:

Jon Weeks

Acting Assistant Director; Microbiologist
OSEL, Sterility and Infection Control Program



Nadia Kadry

Biologist
OPEQ, Renal, Gastrointestinal, Obesity and
Transplant Devices



Christopher Dugard

Assistant Director
OPEQ, Surgical and Infection Control Devices



Paulo Laranjeira

Senior Staff Fellow

OPEQ, Surgical and Infection Control Devices



Topic 4: What additional information is needed to assist in the decision-making discussed in Topics 1-3

MODERATOR:
Paulo Laranjeira

Senior Staff Fellow
OPEQ, Surgical and Infection Control Devices



Stephen Anisko

Team Lead

OPEQ, Surgical and Infection Control Devices



Christopher Dugard

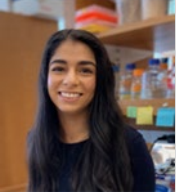
Assistant Director

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Transplant Devices



Jon Weeks

Acting Assistant Director; Microbiologist

OSEL, Sterility and Infection Control Program



Resources

Slide Number	Cited Resource	URL
7	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
7	Innovation Challenge 1: Alternatives to EtO Sterilization	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies
7	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
7	FDA Advisory Committee Meeting	www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee
7	EtO Sterilization Master File Pilot Program for PMA Holders	www.federalregister.gov/documents/2019/11/26/2019-25631/center-for-devices-and-radiological-health-ethylene-oxide-sterilization-master-file-pilot-program
7	FDA Statement on steps to advance medical device sterilization with EtO	www.fda.gov/news-events/press-announcements/statement-new-steps-advance-innovation-medical-device-sterilization-ethylene-oxide
7	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
7	FDA statement supporting innovation in medical device sterilization	www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
7	510(k) Sterility Change Master File Pilot Program	www.federalregister.gov/documents/2022/05/20/2022-10925/medical-devices-510k-sterility-change-master-file-pilot-program

Resources

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7	Radiation Sterilization Master File Pilot Program for PMA Holders	www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-radiation-sterilization-master-file-pilot-program
7	CDRH Announces New Standards Recognition to Support Innovation in Medical Device Sterilization	www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-new-standards-recognition-support-innovation-medical-device-sterilization
7	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
7	FDA Medical Device Sterilization Town Hall Series	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
9	Verbal reference to the 510(k) Modifications Guidance	www.fda.gov/media/99812/download

Summary

The panel discussed four topics, including:

- Technical Considerations when Selecting or Changing a Sterilization Modality
- Maintaining Sterility throughout the Product Lifecycle
- Challenges and Considerations during New Product Design and Development and Transitioning to an Alternate Modality
- Collaboration Opportunities and Additional Information for Decision-Making



Next Town Hall



Date: Wednesday, June 12, 2024

Time: 2:00 – 3:00 PM ET

Potential Topics:

- What we heard from our mailbox
- 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



U.S. FOOD & DRUG
ADMINISTRATION

Let's Take Your Questions and Comments



- **To ask a question/share a comment:** A black square icon with a white hand symbol and the text "Raise Hand" below it.
 - 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



Start Here/The Basics! (Updated Module 10/16/2023) <i>MDUFA Small Business Program, Registration and Listing</i>	▼
How to Study and Market Your Device - (Updated 11/20/23) <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i>	▼
Postmarket Activities <i>Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization</i>	▼
In Vitro Diagnostics - (Updated 5/14/24) <i>IVD Development, CLIA, and Virtual Town Hall Series</i>	▼
Unique Device Identification (UDI) System	▼
Specialty Technical Topics - (Updated 5/9/24)	▼
Radiation-Emitting Products	▼
510(k) Third Party Review Program (for Third Party Review Organizations)	▼
Industry Basics Workshop Series	▼



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