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:
Topics and Formats for the Continuing Sterilization Series

April 29, 2024

FDA U.S. FOOD & DRUG ADMINISTRATION

Medical Device Sterilization Town Hall:

Topics and Formats for the Continuing Sterilization Series

Today's Panelists from the CDRH EtO Tiger Team

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Deputy Director
Office of Readiness and Response

Office of Strategic Partnerships and Technology Innovation

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Senior Health Scientist / EtO Incident Lead
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Aftin Ross, PhD
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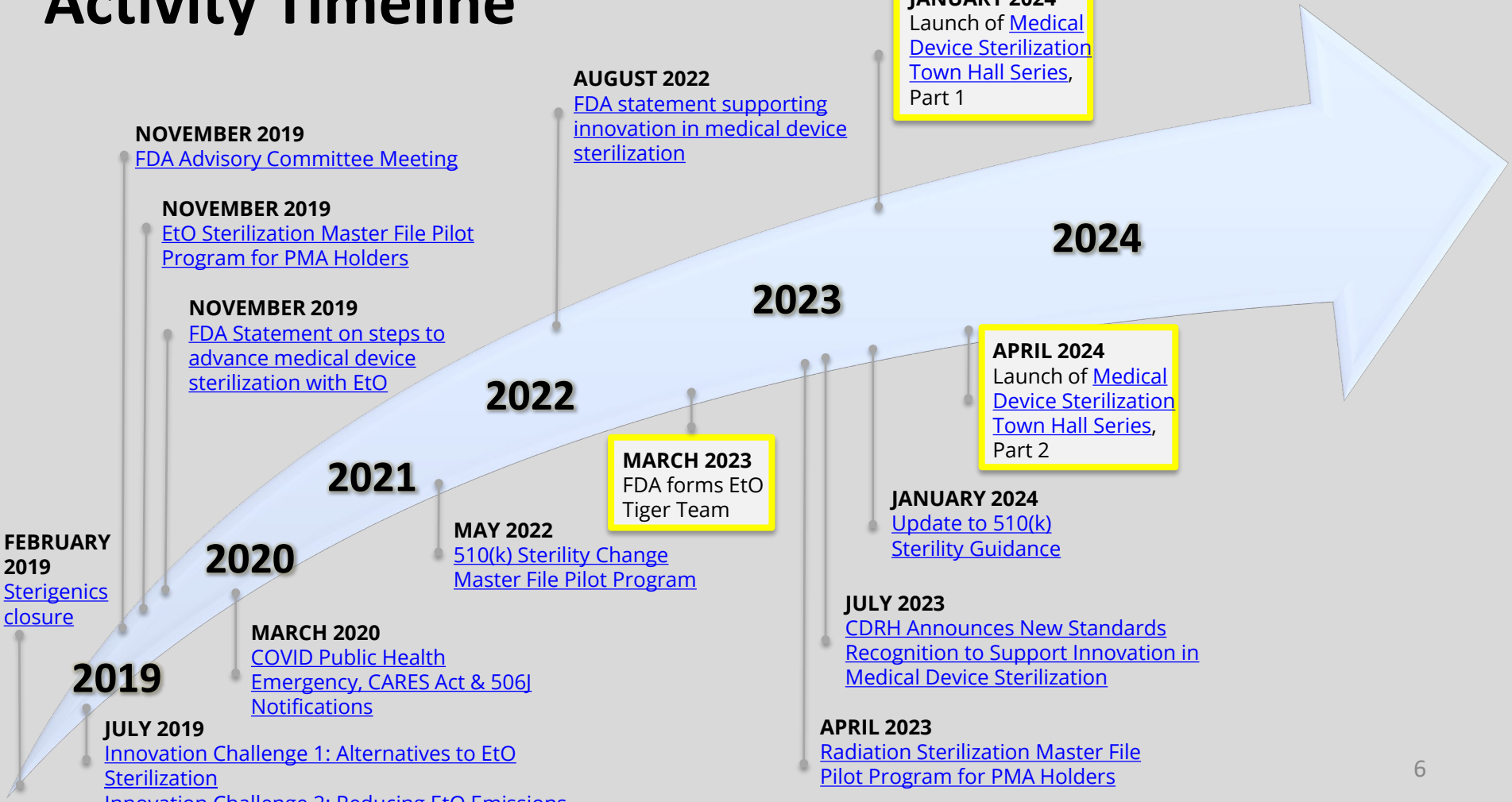
Office of Readiness and Response

Office of Strategic Partnerships and Technology Innovation

What we heard from you last time

Activity Timeline



Discussion Topics

Topic 1: Discuss the suggestions FDA has received regarding potential topics for the sterilization town hall series

Topic 2: Discuss how FDA will pivot the format of the series to support more engaging discussions on topics of interest

Lisa Simone, PhD
Senior Health Scientist / EtO Incident Lead
Division of All Hazards Preparedness and Response
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Topic 1

Feedback on the Sterilization Town Hall Series and potential topics for future events

Suggested Topic Areas of Interest

- Technical topics (e.g., sterilization cycle design)
- Alternate sterilization methods
- Material compatibility
- Review topics (e.g., functional testing, what to submit)
- Mock pre-sub or case study for transition to another sterilization modality
- Incentive Structures
- Master File Pilot programs – value, approaches, challenges
- Engagement with other regulatory jurisdictions
- Additional topics that may arise – anything missing?

Poll Question #1

To suggest additional topics, please email us at: MedicalDeviceSterilization@fda.hhs.gov

LCDR Scott Steffen, PhD
Senior Program Management Officer / EtO Incident Lead
Division of All Hazards Preparedness and Response
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Topic 2

Sterilization Town Hall Series Part 2
New interactive formats

Expanded Town Hall Formats

- All events:
  - Open with “What we heard from you last time”
  - Close with Live Q&A

- Town Hall main content options:
  - CDRH activities and information sharing (similar to previous town halls)
  - Mock Pre-submission
  - Interactive Panel
  - Case Study
  - Other?

Poll Question #2

To suggest additional formats, please email us at: MedicalDeviceSterilization@fda.hhs.gov

Town Hall Scheduling and Information

- Announced prior to event
- Included in the Town Hall section of our Sterilization for Medical Devices website
- Approximately every 3 weeks
- Questions welcome at any time at MedicalDeviceSterilization@fda.hhs.gov

Resources

Slide Number	Cited Resource	URL
5	Verbal reference to FDA device labeling website	www.fda.gov/medical-devices/overview-device-regulation/device-labeling
5	Verbal reference to the Establishment Registration & Device Listing Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
5	Verbal reference to the guidance, Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
6	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
6	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
6	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
6	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
6	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
6	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
6	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages

Resources

Slide Number	Cited Resource	URL
6	FDA statement supporting innovation in medical device sterilization	www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
6	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
6	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
6	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
6	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
6	FDA Medical Device Sterilization Town Hall Series	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
16	Medical Device Sterilization Town Hall Series	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
16	Sterilization for Medical Devices	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

Summary

- Shared the feedback we have received related to potential town hall topics, including technical, scientific and regulatory areas
- Shared the pivot in potential delivery formats to allow more engaging exploration of areas of interest

Next Town Hall

Date: Thursday, May 23, 2024

Time: 1:00 – 2:15 pm ET

Potential Topics:

- Panel discussion for what to consider when choosing a sterilization modality or changing sterilization modalities

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

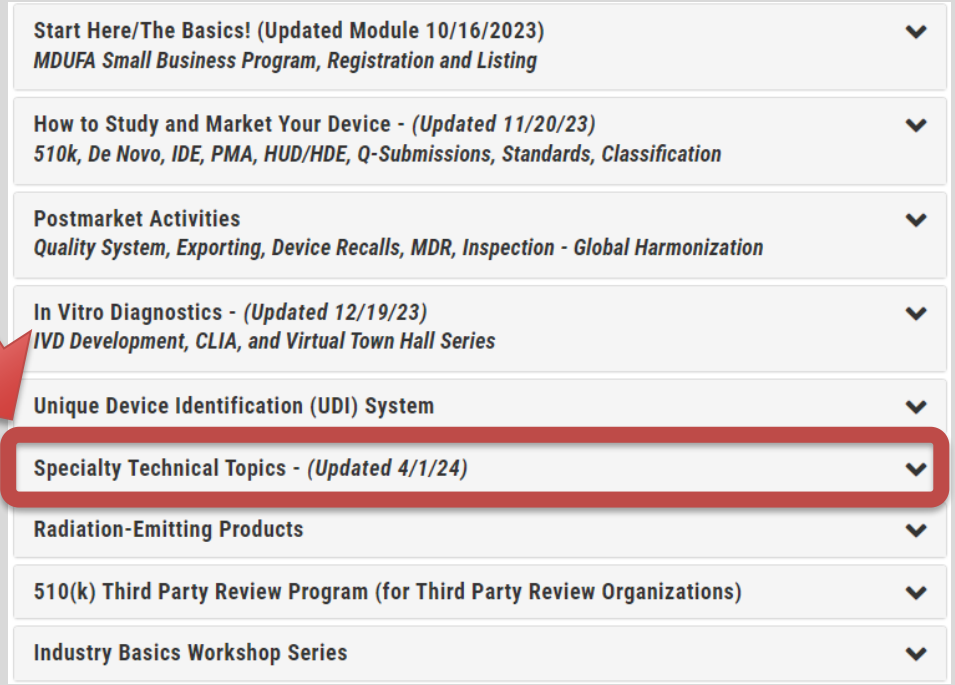
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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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