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:
Overview of Sterilization Landscape and Role of Ethylene Oxide

January 10, 2024

U.S. FOOD & DRUG ADMINISTRATION

Medical Device Sterilization Town Hall

Overview of Sterilization Landscape and Role of Ethylene Oxide

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Opening Remarks

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Learning Objectives

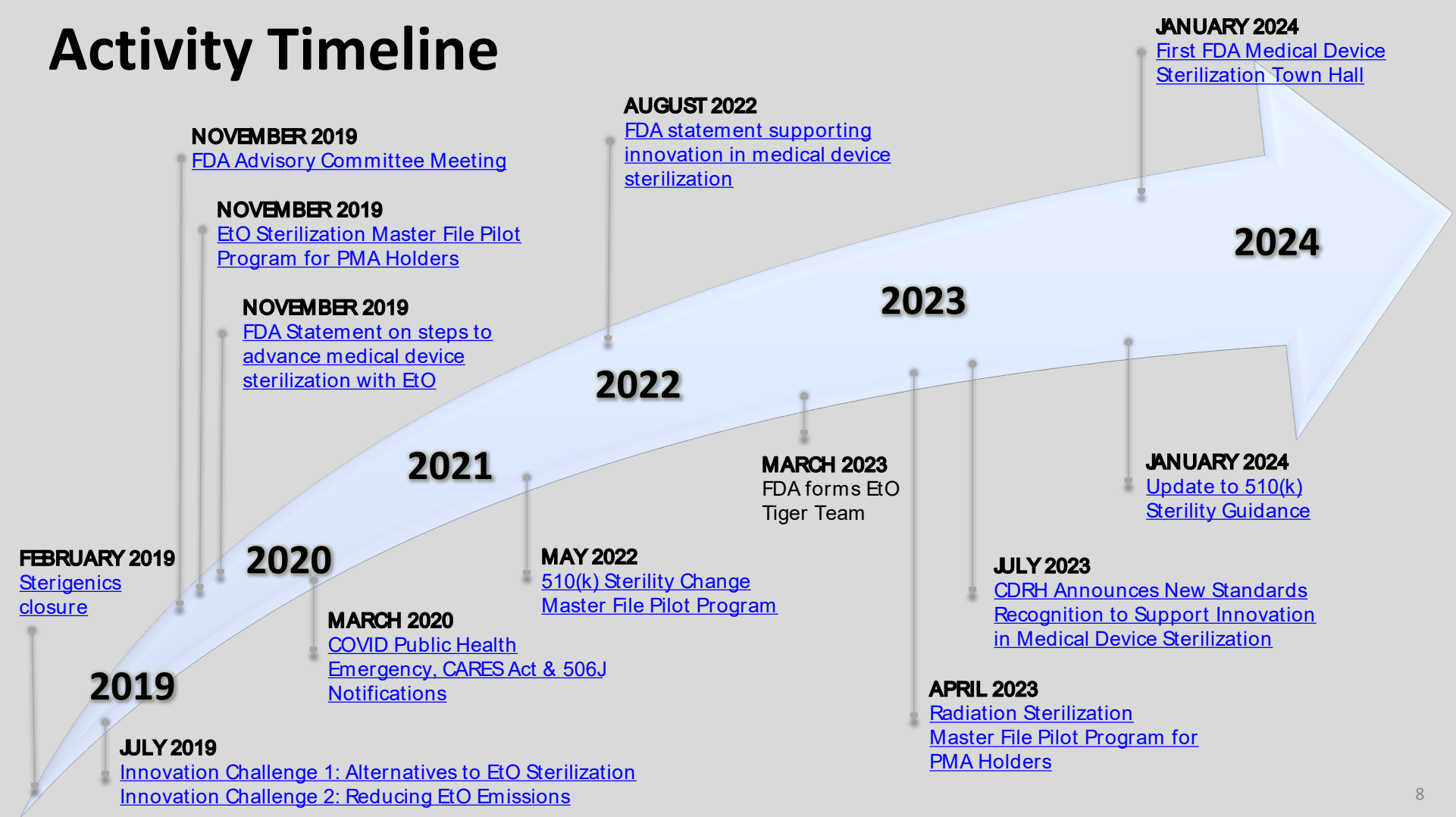
- Discuss medical device sterilization challenges and the activity timeline since 2019
- Describe FDA's 2019 Advisory Committee Meeting and related FDA activities
- Describe the medical device sterilization landscape and supply chain integrity
- Describe the need for forward-looking activities and the role of FDA's new series of sterilization town halls

What happened in 2019 that impacted medical device sterilization?

- February 15, 2019: Illinois Environmental Protection Agency (EPA) issued a Seal Order to stop the Sterigenics facility in Willowbrook, Illinois from producing ethylene oxide (EtO)-sterilized medical products due to facility emission concerns.

- This closure and the subsequent closure of 5 additional facilities resulted in increased supply chain shortage risks to 100+ types of medical devices.

Activity Timeline



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FDA's 2019 Advisory Committee Meeting and Related FDA Activities

2019 Advisory Committee Meeting

The General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee met November 6-7, 2019

Goal

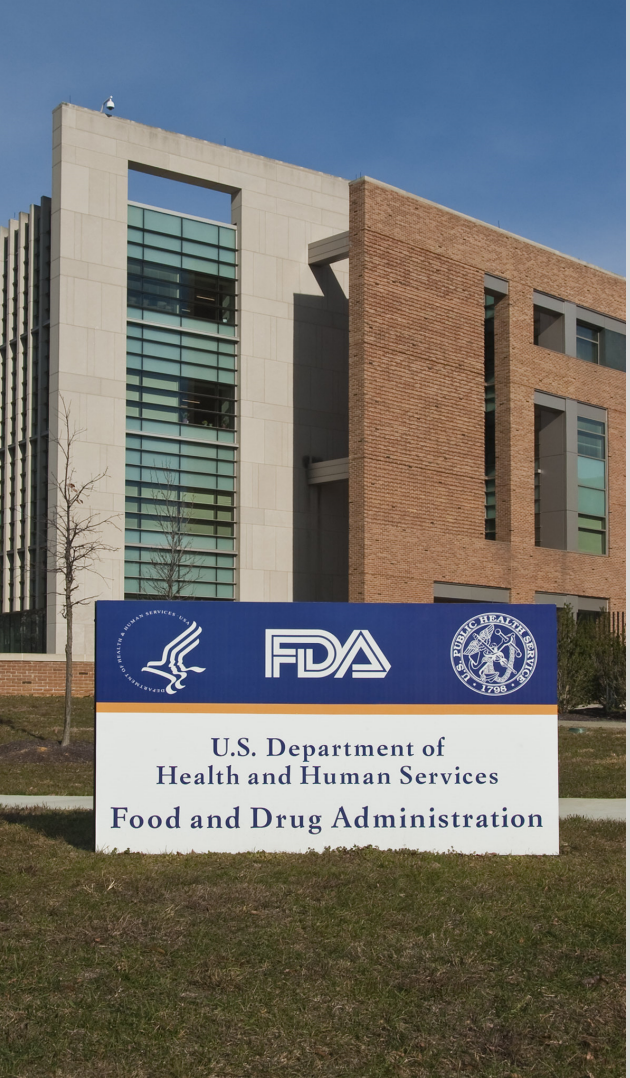
Obtain recommendations on how to reduce or eliminate EtO emissions secondary to medical device sterilization without compromising assurance of sterility for medical devices

Topics

- Overview of EtO sterilization processes
- Methods to reduce EtO emissions
- Alternative modalities
- Shortages, supply chain impacts, clinical impacts

2019 Advisory Committee Meeting Discussion Points

- Patients would suffer from abrupt unavailability of devices sterilized using EtO
- The current sterilization ecosystem cannot absorb additional facility shutdowns
- Promising alternative sterilization methods exist but may have challenges (such as material compatibility, infrastructure needs, packaging)
- Opportunities may exist to optimize EtO cycle time and reduce EtO use (such as using e-labeling to decrease the amount of paper that is sterilized)
- Movement away from EtO would take many years



Incentive Structures and Partnering with Industry Stakeholders

- Sterility Master File Pilot Programs
  - Intended to streamline the regulatory processes for sterilizers and manufacturers to make process changes
    - EtO Sterilization Master File Pilot Program for PMA Holders (2019)
    - 510(k) EtO Sterility Change Master File Pilot Program (2022)
    - Radiation Sterilization Master File Pilot Program (2023)
- Innovation Challenges
  - Challenge 1: Alternatives to EtO Sterilization
  - Challenge 2: Reducing EtO Emissions

Sterilization for Medical Devices | FDA

Tammy Beckham, DVM, PhD
Associate Director
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Current State of Medical Device Sterilization

Sterilization Industry Current State

- In U.S., 50% of medical devices (~20 billion/year) are sterilized using EtO, ~40- 45% gamma, and 5-10% other modalities
  - Other modalities - moist heat (steam), dry heat, E-beam, X-ray, vaporized hydrogen peroxide (VHP), chlorine dioxide (ClO_2), and nitrogen dioxide (NO_2)
- EtO demonstrated performance:
  1. Efficient logistics for sterilization
  2. Supports broad range of material compatibility
- The national capacity for EtO sterilization is constrained
- Challenges exist moving from EtO to other modalities

Balancing Health Concerns

The FDA shares concerns about the release of EtO at unsafe levels into the environment and is interacting collaboratively with EPA and other jurisdictions to identify ways to reduce use of EtO that maintain safe and effective medical device sterilization without compromising patient care.

Evolving Challenges

- Supply limitations and lead time challenges for equipment and monitoring technologies
- Status of technological capabilities for monitoring
- Sterilization capacity and medical device access
- Regulatory considerations

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Looking Ahead

Next Steps

- Since 2019, FDA has dedicated resources to supporting the development of alternatives to EtO and has implemented several programs and initiatives to support innovation in medical device sterilization
- Collaboration is needed to solve these complex challenges and ensure continued availability of safe and effective sterilized medical devices
- In the next town hall, we'll share FDA's 2023 activities, including the creation of a cross-functional Tiger Team to support efforts to reduce reliance on EtO

Medical Device Sterilization Town Hall Series

- FDA intends to host a town hall series focused on various aspects of medical device sterilization
- Town Hall Goals
  - Share FDA activities
  - Discuss potential mitigations
  - Gather input / respond to questions
- Seeking your input on future topics

Resources

Slide Number	Cited Resource	URL
7	Issue a Seal Order	www2.illinois.gov/Pages/news-item.aspx?ReleaseID=19717
8	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
8	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
8	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
8	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
8	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
8	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
8	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
8	FDA statement supporting innovation in medical device sterilization	www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

Resources

Slide Number	Cited Resource	URL
8	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
8	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
8	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
8	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
8	First FDA Medical Device Sterilization Town Hall	www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-sterilization-town-hall-overview-sterilization-landscape-and-role-ethylene-oxide
11	2019 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
13	Sterilization for Medical Devices | FDA	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#MasterFile
16	~20 billion/year	www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures

Summary

- Medical device sterilization challenges have led to many stakeholder activities since 2019 to reduce EtO use and encourage the advancement of EtO alternatives
- FDA has worked collaboratively with industry to develop programs and initiatives to support medical devices sterilization innovation to ensure medical device availability
- FDA intends to continue to engage with stakeholders through a series of town halls on medical device sterilization


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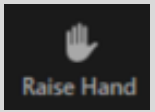
Let's Take Your Questions and Comments

- **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

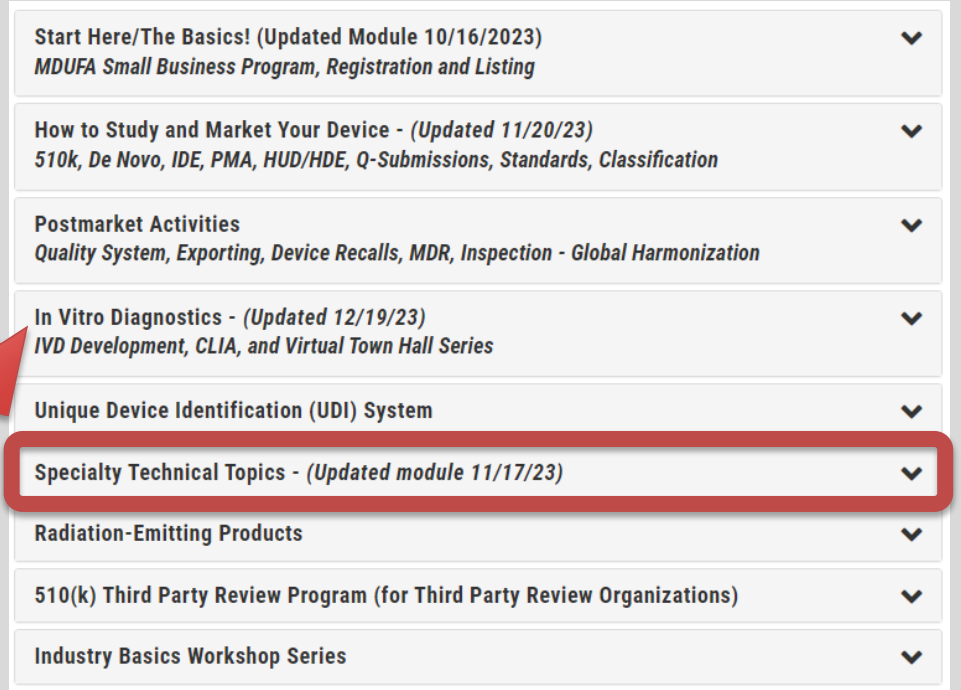


- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions

- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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 Webinars**
  - www.fda.gov/CDRHWebinar

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