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, Series Updates and Impact, Wrap Up and Next Steps

December 4, 2024

Medical Device Sterilization Town Hall:

Sterilization Short Topics, Series Updates and Impact, Wrap Up and Next Steps

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

Today's Panelists

Suzanne Schwartz, MD, MBA
Director

Office of Strategic Partnerships and Technology Innovation

Lisa Simone, PhD
Senior Health Scientist / EtO Incident Lead

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

Jon Weeks, PhD
Assistant Director

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

CDR Tamara Rosbury, PhD
Health Scientist / EtO Incident Response

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

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

Today's Panelists, continued

Bella Pelina
Policy Analyst

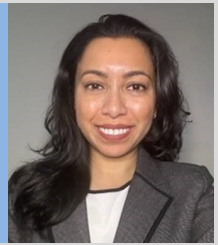
Clinical and Scientific Policy Staff
Office of Product Evaluation and Quality

Jennifer Berg
Senior Staff Fellow

Office of Health Technology 4
Office of Product Evaluation and Quality

Jhumur Banik
Team Lead / Biomedical Engineer

Office of Regulatory Programs
Office of Product Evaluation and Quality



David Saylor, PhD
Research Materials Engineer

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

Yunzhi (Bonnie) Liu, PhD
Research Scientist

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

Today's Panelists, continued

CDR Scott Steffen, PhD
Senior Program Management Officer /
EtO Incident Lead

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

Tammy Beckham, DVM, PhD
Director

Office of Supply Chain Resilience
Office of Strategic Partnerships and Technology Innovation

Aftin Ross, PhD
Deputy Director

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

Opening Remarks

Suzanne Schwartz, MD, MBA
Director

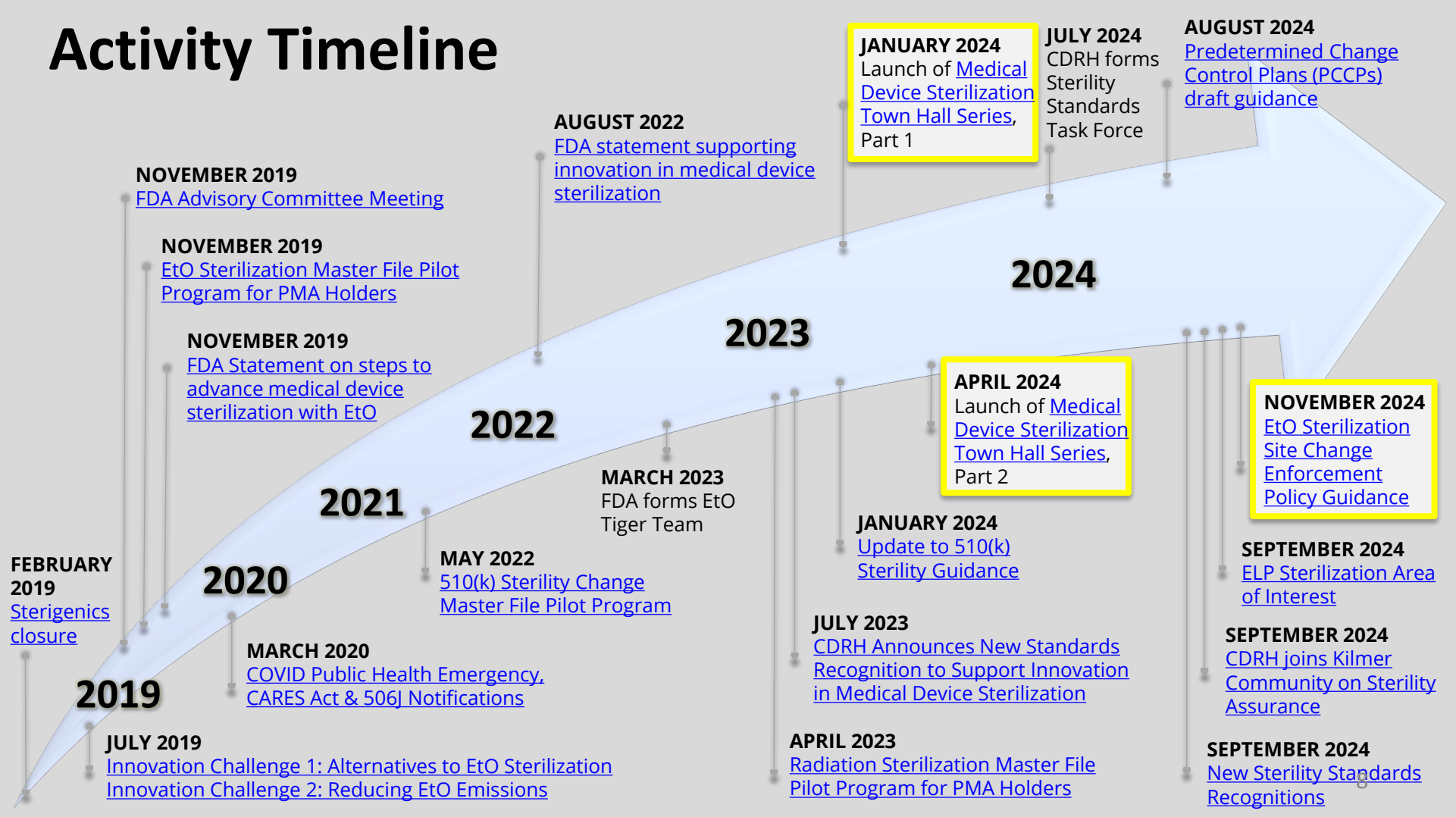
Office of Strategic Partnerships and Technology Innovation

Welcome

Lisa Simone, PhD
Senior Health Scientist / EtO Incident Lead

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

Activity Timeline



Discussion Topics

Topic 1: Discuss the new Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices Guidance and a brief comparison to the existing PDA/HDE enforcement policies

Topic 2: Share research and modeling on diffusion of vaporized hydrogen peroxide (VH2O2) through select polymeric materials and discuss the potential impacts

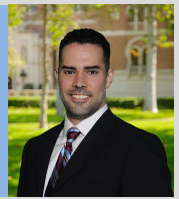
Topic 3: Discuss the scope and impact of the Sterilization Town Hall series and related FDA activities, and explore potential next steps in the continued effort to reduce reliance on ethylene oxide for sterilization of medical devices

Topic 1: Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices Guidance

Why was the Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices Guidance developed?

MODERATOR:

Ryan Ortega, PhD
Regulatory Advisor
OPEQ, Regulatory Policy and Combination Products



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OPEQ, Clinical and Scientific Policy Staff

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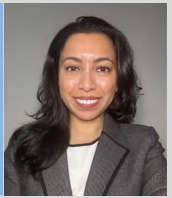
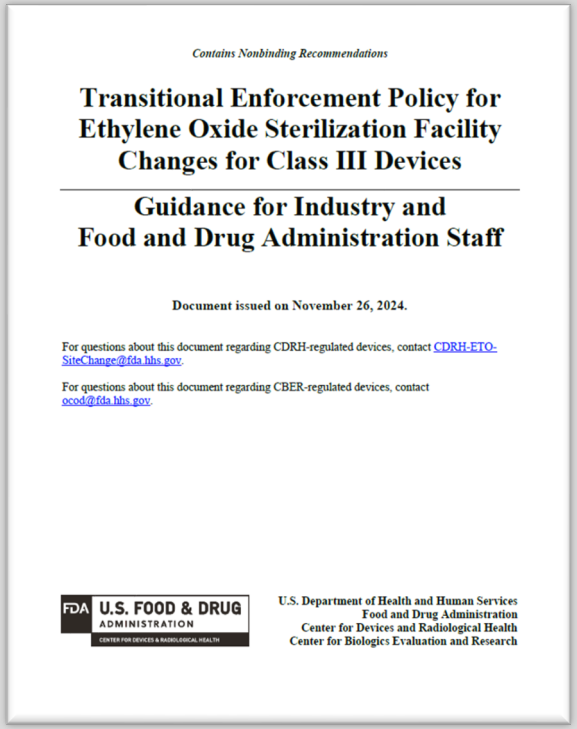
OPEQ, Surgical and Infection Control Devices

Jhumur Banik
Team Lead / Biomedical Engineer
OPEQ, Office of Regulatory Programs,
PMA/HDE/Q-Sub and Device Lifecycle Tracking



EtO Sterilization Site Change Enforcement Policy Guidance



Contains Nonbinding Recommendations

Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on November 26, 2024.

For questions about this document regarding CDRH-regulated devices, contact CDRH-ETO-SiteChange@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

This guidance is intended to communicate FDA's policy regarding sterilization site changes for EtO sterilized PMA and HDE devices.

EtO Sterilization Site Change Enforcement Policy Guidance

Why was the Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices Guidance developed?

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Team Lead / Biomedical Engineer
OPEQ, Office of Regulatory Programs,
PMA/HDE/Q-Sub and Device Lifecycle Tracking

What is the enforcement policy being introduced?

MODERATOR:
Ryan Ortega, PhD
Regulatory Advisor
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OPEQ, Office of Regulatory Programs,
PMA/HDE/Q-Sub and Device Lifecycle Tracking

How is this policy different than other PMA/HDE enforcement policies noted in other guidance documents?

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Senior Staff Fellow

OPEQ, Surgical and Infection Control Devices

Jhumur Banik
Team Lead / Biomedical Engineer
OPEQ, Office of Regulatory Programs,
PMA/HDE/Q-Sub and Device Lifecycle Tracking

Topic 2: Research and modeling on diffusion of vaporized hydrogen peroxide (VH2O2) through select polymeric materials

Modeling vaporized hydrogen peroxide (VH2O2) penetration through medical device materials

MODERATOR:

Jon Weeks, PhD

Assistant Director

OSEL, Biology, Chemistry, and Materials Science

David Saylor, PhD

Research Materials Engineer

OSEL, Biology, Chemistry, and Materials Science

Yunzhi (Bonnie) Liu, PhD

Research Scientist

OSEL, Biology, Chemistry, and Materials Science

FDA/CDRH: Yunzhi Liu, Sara Linden, Iskinder Arsano, David Saylor, Jon Weeks, Michael Eppihimer

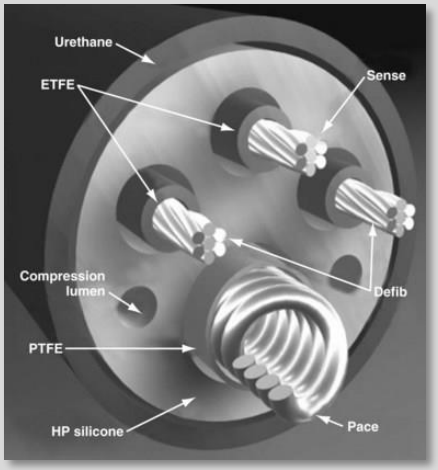
Medtronic: Ioan Gitsov, Maruti Sinha, Angie Hendrickx, Kimberly Chaffin

Motivation and Need

Motivation

- Increase the usability and adoption of alternative gaseous sterilants (e.g., VH2O2).

McEvoy, B. et al. Journal of Applied Microbiology 134, 2023.



https://thoracickey.com/engineering-and-construction-of-pacemaker-and-icd-leads-2/

Need

- While modeling is routinely used to support radiation-based sterilization, gas/vapor-based modalities currently rely solely on empirical evidence.
- Models of VH2O2 permeation could facilitate cycle development and scalability of sterilization parameters.

E.g., Sterilization of enclosed surfaces via permeation through device materials

Approach

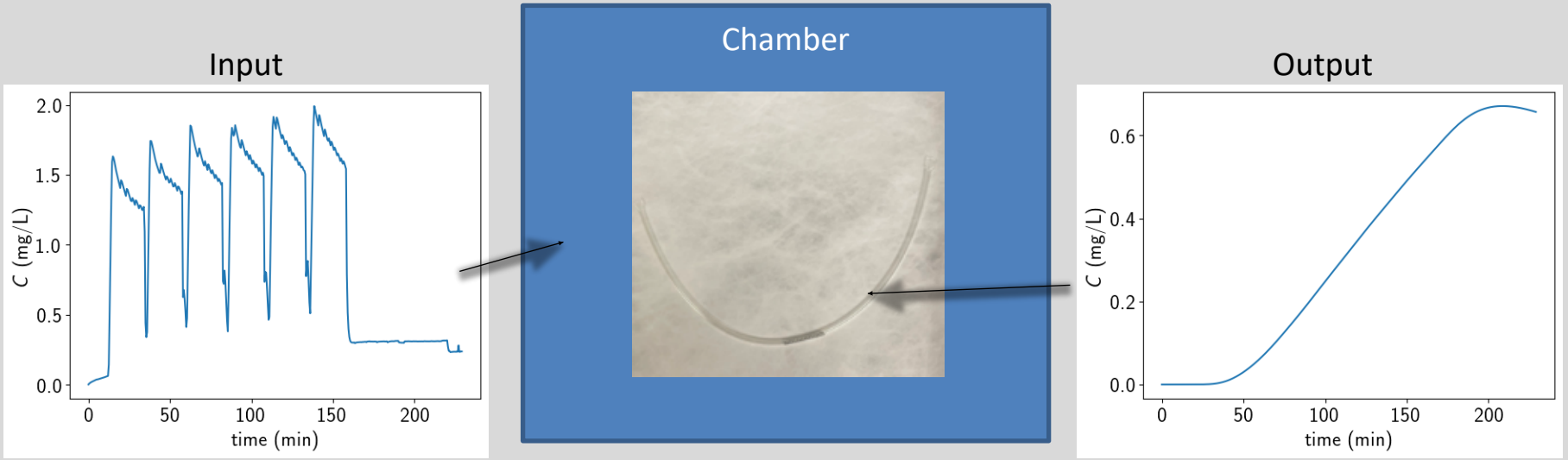
Objective: Develop a physics-based computational model for VH2O2 permeation through medical device polymers

Challenge: Collecting data for model calibration and validation is resource intensive; e.g., FDA does not have access to commercial sterilizers

Solution: Industry partnership: FDA and Medtronic

Physics-based model

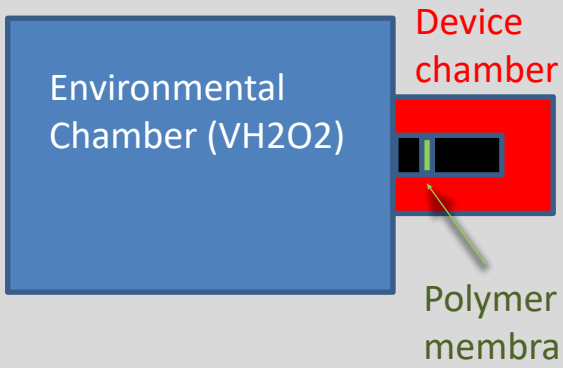
- Links applied concentration (chamber) to concentration at interior surfaces:



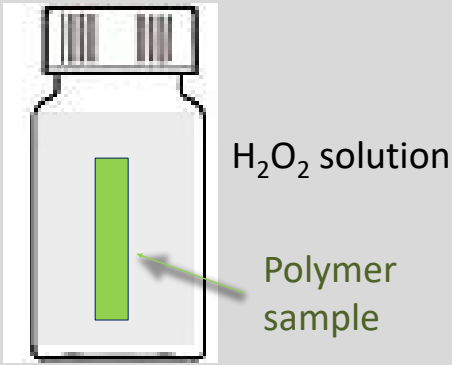
- Requires geometric information and material specific parameters

Material parameters: test methods

Vapor penetration



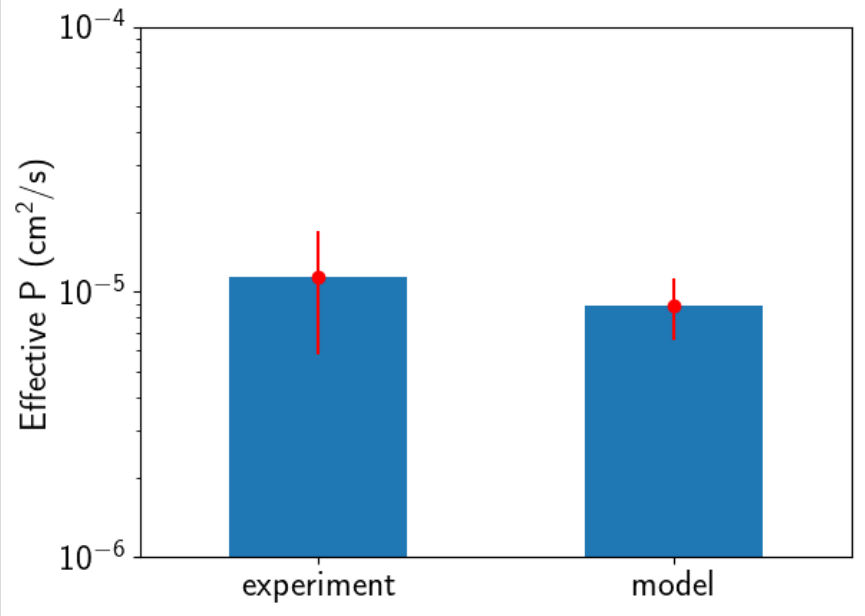
Swelling



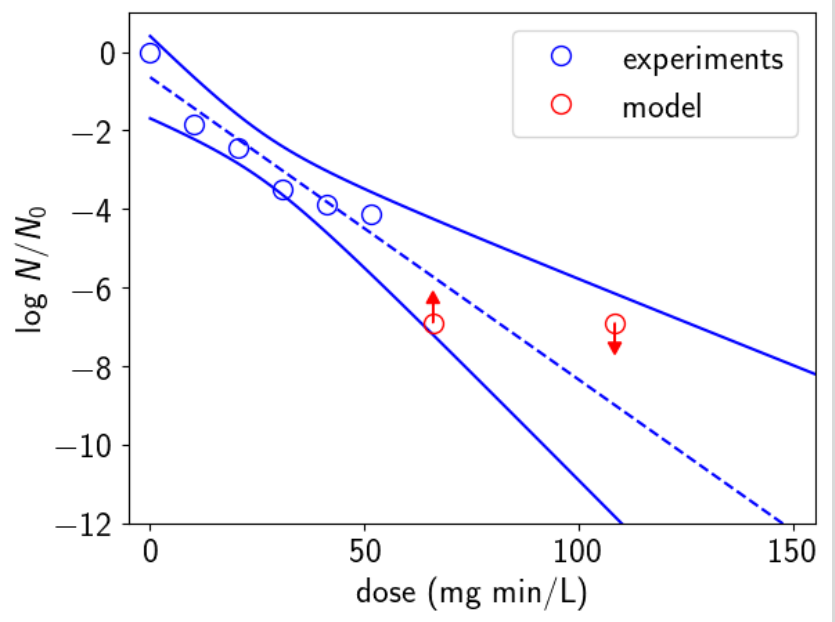
- Validated theoretical link between liquid and vapor phase behavior
- Swelling provides a simple, facile method to evaluate device materials

Validation (preliminary)

Composite material effective permeability (P)



Microbial inactivation kinetics



Considerations for Potential Applications

Inform cycle development: predict if cycle parameters will provide sufficient dose to interior surfaces of device constructs

Material screening: establish conditions and acceptance criteria for simple swelling test to evaluate the suitability of a device material for VH2O2 sterilization

Process control device (PCD) validation: demonstrate that permeation into PCD is more conservative than target device(s)

Topic 3: Activity updates, impact of the Sterilization Town Hall series, and Next Steps

Can you share any further updates about FDA activities?

MODERATOR:

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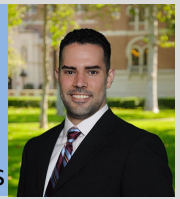
Regulatory Advisor
OPEQ, Regulatory Policy and Combination Products



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Incident Response Lead

OST, Office of Readiness and Response

Christopher Dugard, MS
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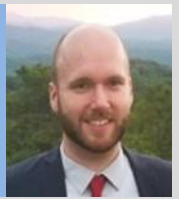

CDR Tamara Rosbury, PhD
Incident Response Lead

OST, Office of Readiness and Response

In what ways did the Sterilization Town Hall Series adapt to help FDA engage industry and inform our activities?

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Incident Response Lead
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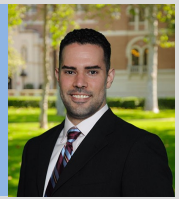
Regulatory Advisor
OPEQ, Regulatory Policy and Combination Products Staff



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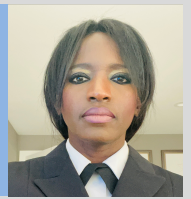

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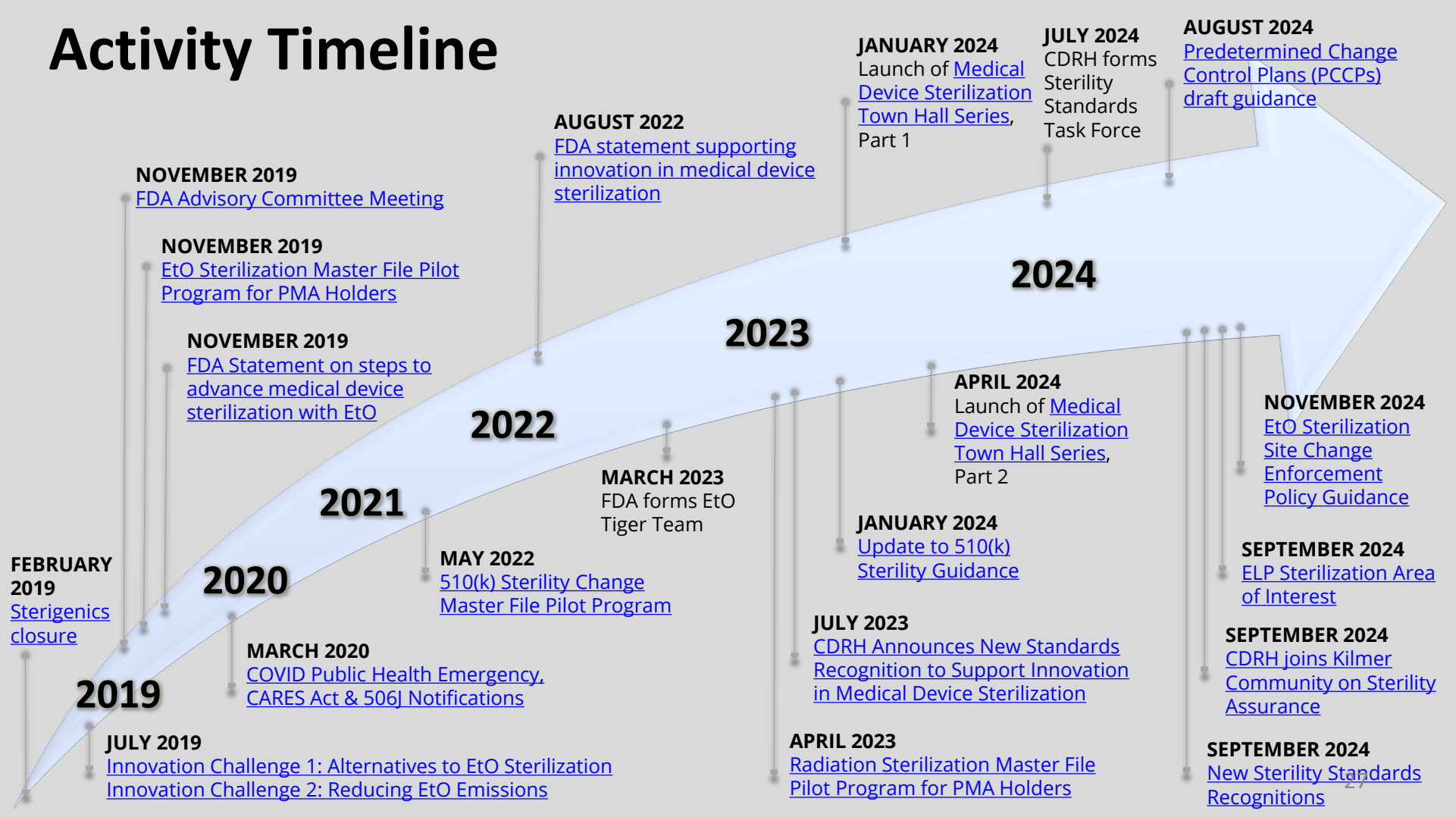
Activity Timeline

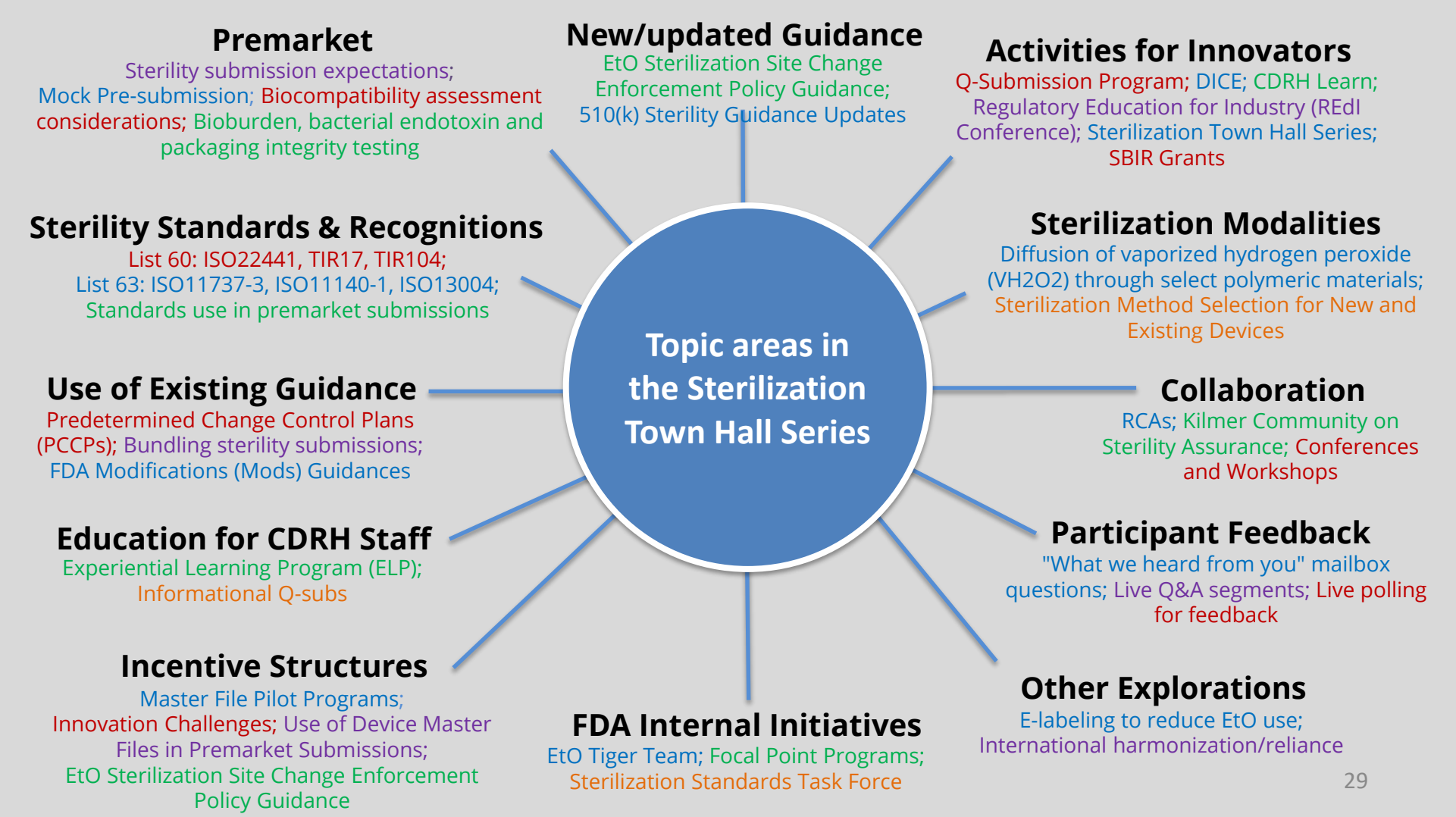


CDRH Learn, “Specialty Technical Topics”, Sterility

Medical Device Sterilization Town Hall Series ***(Updated 11/19/24)***

Series Number	Topic	Date	Materials
01	Medical Device Sterilization Town Hall Overview	01/10/2024	Presentation Transcript Slides
02	FDA's Sterilization Related Activities	01/26/2024	
03	Premarket Pt 1: New submissions & considerations	02/07/2024	
04	Premarket Pt 2: Modifications and Master Files	02/29/2024	
05	Premarket Pt 3: Use of Standards & Standards Development	03/21/2024	
06	Topics and Formats for the Continuing Town Hall Series	04/29/2024	
07	Sterilization Method Selection	05/23/2024	
08	Sterilization Open Q&A	06/12/2024	Presentation Transcript Slides
09	Mock Pre-Submission for Sterilization Method Change	07/10/2024	Presentation Transcript Slides
10	Bioburden, bacterial endotoxin and packaging integrity testing for sterile medical devices	08/07/2024	Presentation Transcript Slides
11	Effective use of Sterility Master Files	09/11/2024	Presentation Transcript Slides
12	Predetermined Change Control Plans (PCCPs)	10/09/2024	Presentation Transcript Slides
13	Supporting medical device innovators and bundling sterility submissions	10/30/2024	Presentation Transcript Slides
14	Recognized consensus standards and biocompatibility assessment considerations	11/20/2024	Presentation Transcript Slides

CDRH Learn


Topic areas in the Sterilization Town Hall Series
Premarket
Sterility submission expectations; Mock Pre-submission; Biocompatibility assessment considerations; Bioburden, bacterial endotoxin and packaging integrity testing
New/updated Guidance
EtO Sterilization Site Change Enforcement Policy Guidance; 510(k) Sterility Guidance Updates
Activities for Innovators
Q-Submission Program; DICE; CDRH Learn; Regulatory Education for Industry (REdI Conference); Sterilization Town Hall Series; SBIR Grants
Sterility Standards & Recognitions
List 60: ISO22441, TIR17, TIR104; List 63: ISO11737-3, ISO11140-1, ISO13004; Standards use in premarket submissions
Sterilization Modalities
Diffusion of vaporized hydrogen peroxide (VH2O2) through select polymeric materials; Sterilization Method Selection for New and Existing Devices
Use of Existing Guidance
Predetermined Change Control Plans (PCCPs); Bundling sterility submissions; FDA Modifications (Mods) Guidances
Collaboration
RCAs; Kilmer Community on Sterility Assurance; Conferences and Workshops
Education for CDRH Staff
Experiential Learning Program (ELP); Informational Q-subs
Participant Feedback
"What we heard from you" mailbox questions; Live Q&A segments; Live polling for feedback
Incentive Structures
Master File Pilot Programs; Innovation Challenges; Use of Device Master Files in Premarket Submissions; EtO Sterilization Site Change Enforcement Policy Guidance
FDA Internal Initiatives
EtO Tiger Team; Focal Point Programs; Sterilization Standards Task Force
Other Explorations
E-labeling to reduce EtO use; International harmonization/reliance

Looking forward, what activities might we continue to engage in as an industry, to reduce reliance on EtO and increase resiliency in the sterilization landscape?

MODERATOR:

CDR Tamara Rosbury, PhD
EtO Incident Response
OST, Office of Readiness and Response

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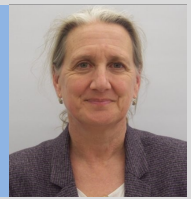

Contacting Us

Follow-ups to this town hall series: MedicalDeviceSterilization@fda.hhs.gov

Office of Supply Chain Resilience (OSCR): Deviceshortages@fda.hhs.gov

Division of Industry and Consumer Education (DICE): DICE@fda.hhs.gov

Medical Device Sterilization website https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

Resources

Slide Number	Cited Resource	URL
8, 27	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
8, 27	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, 27	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, 27	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, 27	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, 27	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, 27	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
8, 27	FDA statement supporting innovation in medical device sterilization	public4.pagefreezer.com/content/FDA/07-09-2023T11:58/https:/www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
8, 27	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, 27	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

Resources

Slide Number	Cited Resource	URL
8, 27	CDRH Announces New Standards Recognition to Support Innovation in Medical Device Sterilization	public4.pagefreezer.com/content/FDA/05-11-2023T15:04/https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-new-standards-recognition-support-innovation-medical-device-sterilization
8, 27	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, 27	FDA Medical Device Sterilization Town Hall Series, Parts 1 and 2	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
8, 27	Predetermined Change Control Plans (PCCPs) draft guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices
8, 27	New Sterility Standards Recognitions	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=1&effectivedatefrom=09/09/2024&effectivedateto=09/10/2024
8, 27	CDRH joins Kilmer Community on Sterility Assurance	www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together#cdrhparticipation
8, 27	ELP Sterilization Area of Interest	www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/experiential-learning-program-elp-areas-interest#reprocessing
8, 27	EtO Sterilization Site Change Enforcement Policy Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices

Resources

Slide Number	Cited Resource	URL
11	Verbal reference to EPA's final rule to amend its National Emission Standards for Hazardous Air Pollutants (NESHAP)	www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities
11	Verbal reference to Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices
15	Verbal reference to Enforcement Policy for Certain Supplements for Approved PMA or HDE Submissions	www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-supplements-approved-premarket-approval-pma-or-humanitarian-device
28	CDRH Learn	www.fda.gov/training-and-continuing-education/cdrh-learn
30	Verbal reference to link for submitting notifications through the 506J process	fda-cdrh.my.salesforce-sites.com/shortages

Summary

- Discussed the new Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices Guidance and a brief comparison to the existing PMA/HDE enforcement policies
- Shared research and modeling on diffusion of vaporized hydrogen peroxide (VH2O2) through select polymeric materials and discussed considerations for potential applications
- Discussed the scope and impact of the Sterilization Town Hall series and related activities, and explored potential next steps in the continued effort to reduce reliance on ethylene oxide for sterilization of medical devices


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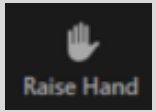
Let's Take Your Questions and Comments

- **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
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