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 Topic and Open Q&A

October 9, 2024

Medical Device Sterilization Town Hall:

Sterilization Short Topic and Open Q&A

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

Today's Panelists

Lisa Simone, PhD
Senior Health Scientist / EtO Incident Lead

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

Jessica Paulsen, PhD
Associate Director for Digital Health

Office of Product Evaluation and Quality

Jason Ryans, PhD
Policy Analyst

Regulation, Policy and Guidance Staff
Office of Product Evaluation and Quality

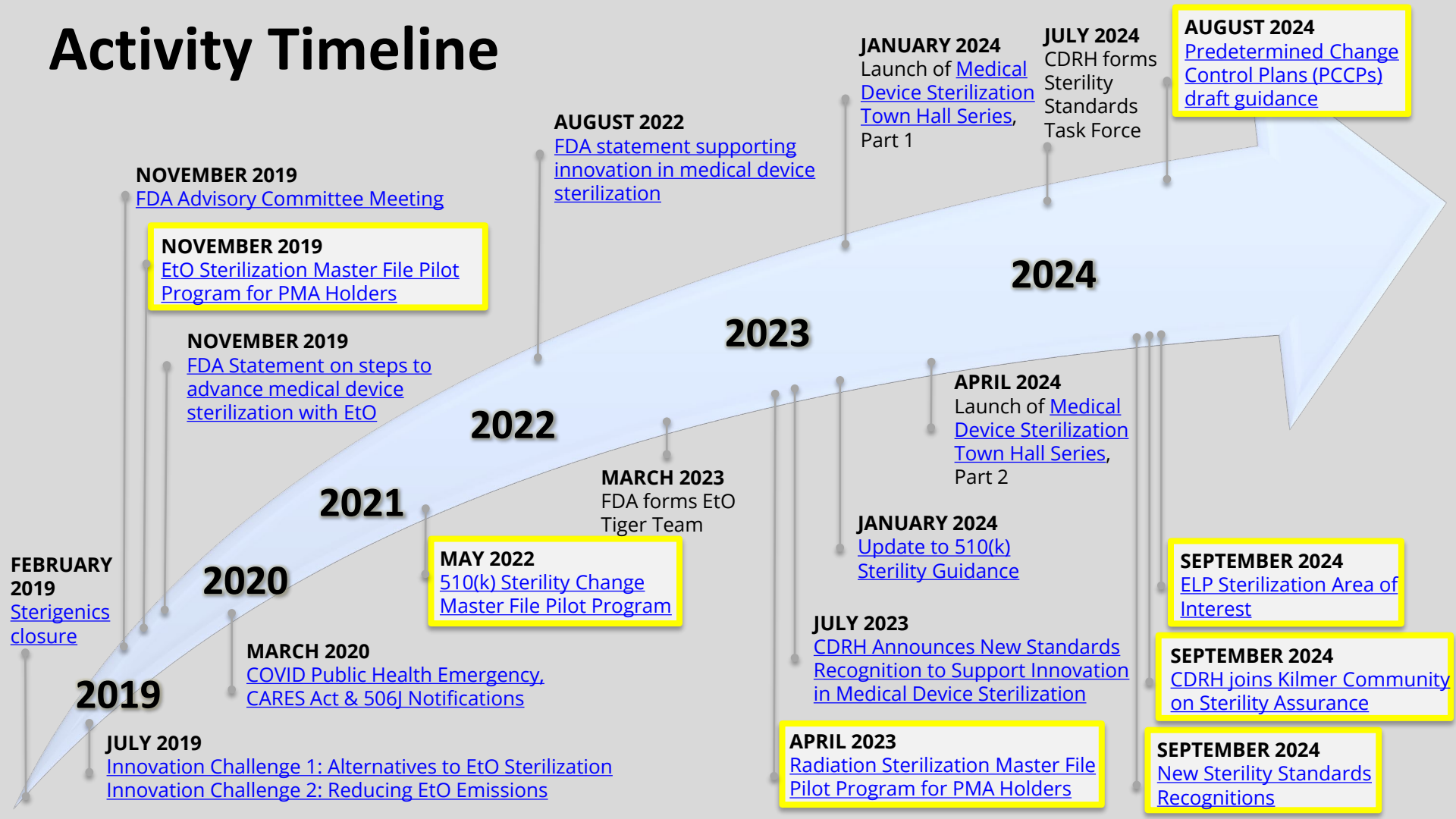
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Lisa Simone, PhD
Senior Health Scientist / EtO Incident Lead

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

What we heard from you last time

Activity Timeline



Discussion Topic

Understand the purpose of a Predetermined Change Control Plan (PCCP), how it is used, the general content, and explore an example of sterilization-related modifications for a PCCP

Predetermined Change Control Plans (PCCPs)

What is a Predetermined Change Control Plan (PCCP) and how is it used?

Jessica Paulsen, PhD
Associate Director for Digital Health

OPEQ, Digital Health

Jason Ryans, PhD
Policy Analyst

OPEQ, Regulation, Policy, and Guidance

What is the general content of a PCCP?

Jessica Paulsen, PhD
Associate Director for Digital Health

OPEQ, Digital Health

Jason Ryans, PhD
Policy Analyst

OPEQ, Regulation, Policy, and Guidance

What type of sterilization-related modifications may be appropriate for a PCCP?

Jessica Paulsen, PhD
Associate Director for Digital Health

OPEQ, Digital Health

Jason Ryans, PhD
Policy Analyst

OPEQ, Regulation, Policy, and Guidance

Resources

Slide Number	Cited Resource	URL
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
6	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
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

Resources

Slide Number	Cited Resource	URL
6	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
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, Parts 1 and 2	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
6	Predetermined Change Control Plans (PCCPs) draft guidance	www.fda.gov/media/180978/download
6	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
6	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
6	ELP Sterilization Area of Interest	www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/experiential-learning-program-elp-areas-interest#reprocessing
9	Verbal reference to Section 515C of FD&C Act	www.federalregister.gov/documents/2024/03/15/2024-05473/medical-devices-technical-amendments
11	Verbal reference to the PCCP docket for public comment	www.regulations.gov/document/FDA-2024-D-2338-0001

Summary

Discussed the purpose of a Predetermined Change Control Plan (PCCP) and how it is used, described the general content and explored an example of sterilization-related modifications for a PCCP

Next Town Hall

Date: Wednesday, October 30, 2024

Time: 1:00 – 2:30 PM ET

Potential Topics:

- What we heard from our mailbox
- Activities to support medical device innovators
- Bundling sterility submissions
- 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


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Additional Panelists

Ryan Ortega, PhD
Regulatory Advisor

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

Shani Haugen, PhD
Assistant Director

Office of Health Technology 3
Office of Product Evaluation and Quality

Paulo R. Laranjeira, PhD
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

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

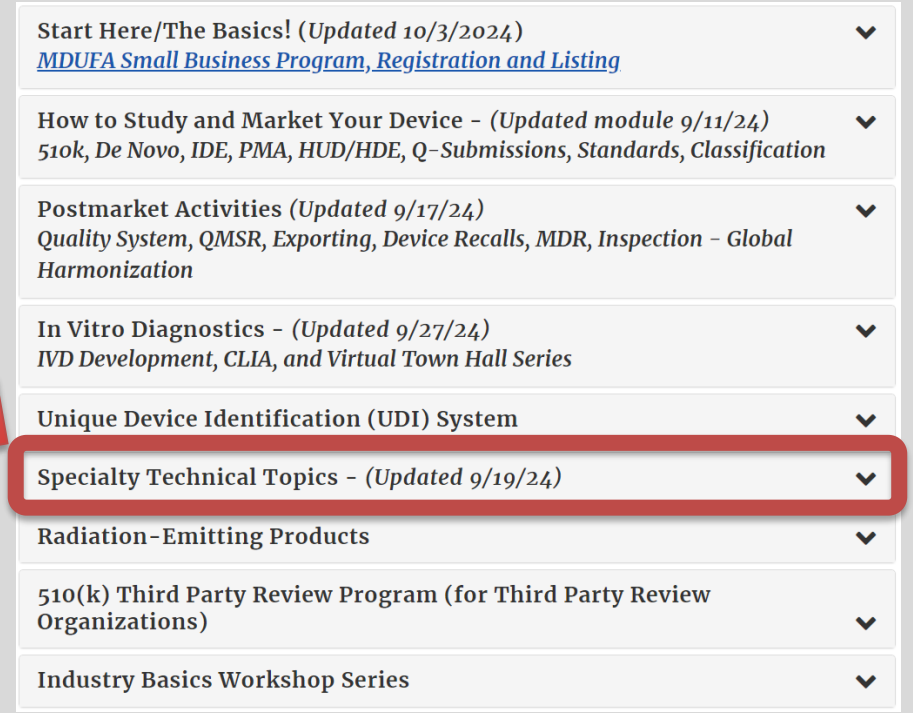
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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



Next Town Hall

Date: Wednesday, October 30, 2024

Time: 1:00 – 2:30 PM ET

Potential Topics:

- What we heard from our mailbox
- Activities to support medical device innovators
- Bundling sterility submissions
- 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