

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

Today's Panelists



Lisa Simone, PhDSenior 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, PhDSenior Health Scientist / EtO Incident Lead

Office of Readiness and Response
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What we heard from you last time

AUGUST 2024 IULY 2024 Activity Timeline JANUARY 2024 Predetermined Change CDRH forms Launch of Medical Control Plans (PCCPs) Sterility **Device Sterilization** draft guidance Standards Town Hall Series. **AUGUST 2022** Task Force Part 1 FDA statement supporting innovation in medical device **NOVEMBER 2019** sterilization FDA Advisory Committee Meeting **NOVEMBER 2019 EtO Sterilization Master File Pilot** 2024 **Program for PMA Holders** 2023 **NOVEMBER 2019** FDA Statement on steps to **APRIL 2024** advance medical device Launch of Medical sterilization with EtO 2022 **Device Sterilization** Town Hall Series, **MARCH 2023** Part 2 2021 FDA forms FtO **JANUARY 2024 Tiger Team** Update to 510(k) **MAY 2022 SEPTEMBER 2024 FEBRUARY Sterility Guidance** 2020 510(k) Sterility Change **ELP Sterilization Area of** 2019 Master File Pilot Program Interest **Sterigenics JULY 2023** closure **CDRH Announces New Standards MARCH 2020 SEPTEMBER 2024** Recognition to Support Innovation COVID Public Health Emergency, CDRH joins Kilmer Community 2019 in Medical Device Sterilization **CARES Act & 506l Notifications** on Sterility Assurance **IULY 2019 APRIL 2023 SEPTEMBER 2024** Innovation Challenge 1: Alternatives to EtO Sterilization Radiation Sterilization Master File **New Sterility Standards** Innovation Challenge 2: Reducing EtO Emissions Pilot Program for PMA Holders Recognitions



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
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 13



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 <u>Sterilization for Medical Devices</u> webpage that includes town hall dates and links to town hall materials.

Medical Device Sterilization Town Hall Series

www.fda.gov/medical-devices/general-hospitaldevices-and-supplies/sterilization-medicaldevices#town-halls





Additional Panelists

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Regulatory Advisor

Regulatory Policy and Combination Products Staff
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Assistant Director

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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: <u>MedicalDeviceSterilization@fda.hhs.gov</u>

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: <u>MedicalDeviceSterilization@fda.hhs.gov</u>
- Upcoming Town Halls & Webinars
 - www.fda.gov/CDRHevents

Start Here/The Basics! (Updated 10/3/2024) <u>MDUFA Small Business Program, Registration and Listing</u>			
How to Study and Market Your Device - (Updated module 9/11/24) 510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification			
Postmarket Activities (Updated 9/17/24) Quality System, QMSR, Exporting, Device Recalls, MDR, Inspection - Global Harmonization	~		
In Vitro Diagnostics - (Updated 9/27/24) IVD Development, CLIA, and Virtual Town Hall Series	~		
Unique Device Identification (UDI) System	~		
Specialty Technical Topics - (Updated 9/19/24)	~		
Radiation-Emitting Products	~		
510(k) Third Party Review Program (for Third Party Review Organizations)	~		
Industry Basics Workshop Series	~		



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