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:
Sterility Master Files and Effective Use in Premarket Submissions

September 11, 2024

Medical Device Sterilization Town Hall:

Sterility Master Files and Effective Use in Premarket Submissions

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

Today's Panelists

CDR Scott Steffen, PhD
Senior Program Management Officer /
EtO Incident Lead
Division of All Hazards Preparedness and Response
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

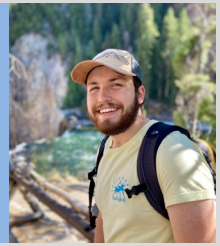
Ángel A. Soler-García, Ph.D.
Lead Microbiologist
Lead, Incontinence and Female Urological Devices Team
Office of Health Technology 3
Office of Product Evaluation and Quality

Ryan Ortega, PhD
Regulatory Advisor

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

Matthew Beckwith
Lead Reviewer/General Engineer

Office of Health Technology 2
Office of Product Evaluation and Quality



Today's Panelists, continued

Christopher Dugard, MS
Assistant Director

Office of Health Technology 4
Office of Product Evaluation and Quality

Mitali Patil, PhD
General Engineer

Office of Health Technology 2
Office of Product Evaluation and Quality

Anita Khatiwara, PhD
Biologist

Office of Health Technology 2
Office of Product Evaluation and Quality

CDR Scott Steffen, PhD
Senior Program Management Officer /
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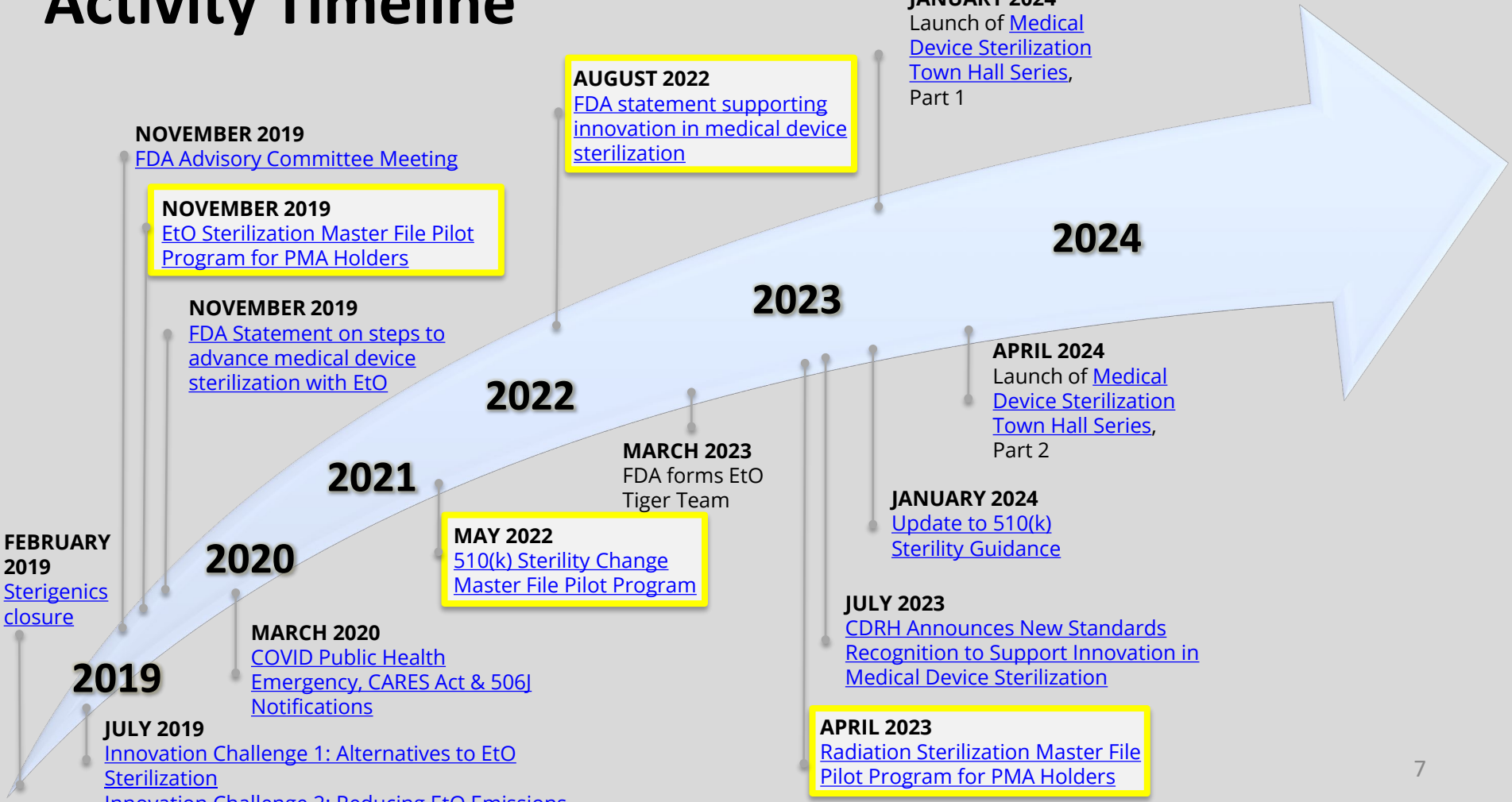
Division of All Hazards Preparedness and Response
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

What we heard from you last time

Activity Timeline



Panel Discussion

Topic 1: What is a Master File?: Purpose and Applicability

Topic 2: Master File vs. Sterility Master File Pilot: Similarities and Differences

Topic 3: FDA Experience with the Sterility Master File Pilot: Effective Use in Premarket Submissions

Topic 4: Master File General Guidelines and Best Practices: The Reviewer Experience

Topic 1: What is a Master File?: Purpose and Applicability

MODERATOR:

Ángel A. Soler-García, PhD

Lead Microbiologist, OPEQ, Gastrorenal, ObGyn, General Hospital and Urological Devices

Matthew Beckwith, PhD

Lead Reviewer

OPEQ, Coronary and Peripheral Interventional Device

Anita Khatiwara, PhD

Biologist

OPEQ, Cardiac Ablation, Mapping and Imaging Devices

Topic 2: Master File vs. Sterility Master File Pilot: Similarities and Differences

MODERATOR:

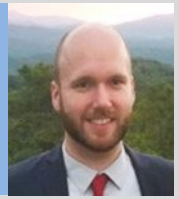
Matthew Beckwith, PhD

Lead Reviewer, OPEQ, Coronary and Peripheral Interventional Devices

Christopher Dugard, MS

Assistant Director

OPEQ, Surgical and Infection Control Devices



Ryan Ortega, PhD

Regulatory Advisor

OPEQ, Regulatory Policy and Combination Products Staff

Topic 3: FDA Experience with the Sterility Master File Pilot: Effective Use in Premarket Submissions

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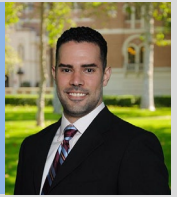

Topic 4: Master File General Guidelines and Best Practices: The Reviewer Experience

MODERATOR:

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

Anita Khatiwara, PhD
Biologist
OPEQ, Cardiac Ablation, Mapping and Imaging Devices

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Ángel A. Soler-García, PhD
Lead Microbiologist
OPEQ, Gastrorenal, ObGyn,
General Hospital and Urological Devices

Resources

Slide Number	Cited Resource	URL
7	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
7	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
7	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
7	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
7, 10, 12	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
7	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
7	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
7	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
7, 10, 12	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
7, 12	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
7	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
7	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
7	FDA Medical Device Sterilization Town Hall Series	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
9	Verbal reference to the 510(k) Modifications Guidance	www.fda.gov/media/99812/download
9, 12	Verbal reference to FDA's Device Master Files website	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/device-master-files
10	Verbal reference to FDA's Sterilization for Medical Devices website	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices
12	Verbal reference to FDA guidance on Master Files Part III	www.fda.gov/media/72543/download
Q&A	Verbal reference to Final Rule regarding sterilization facility registrations	www.federalregister.gov/documents/2012/08/02/2012-18764/implementation-of-device-registration-and-listing-requirements-enacted-in-the-public-health-security

Summary

Today's panel discussion centered around Master Files (MAFs) and their utility as an alternate mechanism to communicate medical device information outside marketing applications. We provided a brief insight into the standard and sterility focused MAF including the following:

- Content and expectations of the different MAF types
- Current Sterility MAFs and their impact in premarket submissions
- Resources to help determine if a MAF could be a way to communicate your medical device information to FDA

Next Town Hall

Date: Wednesday, October 9, 2024

Time: 2:00 – 3:00 PM ET

Potential Topics:

- What we heard from our mailbox
- Short topic discussions, including on Predetermined Change Control Plans (PCCPs)
- 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


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ADMINISTRATION

Let's Take Your Questions and Comments

- **To ask a question/share a comment:**
  

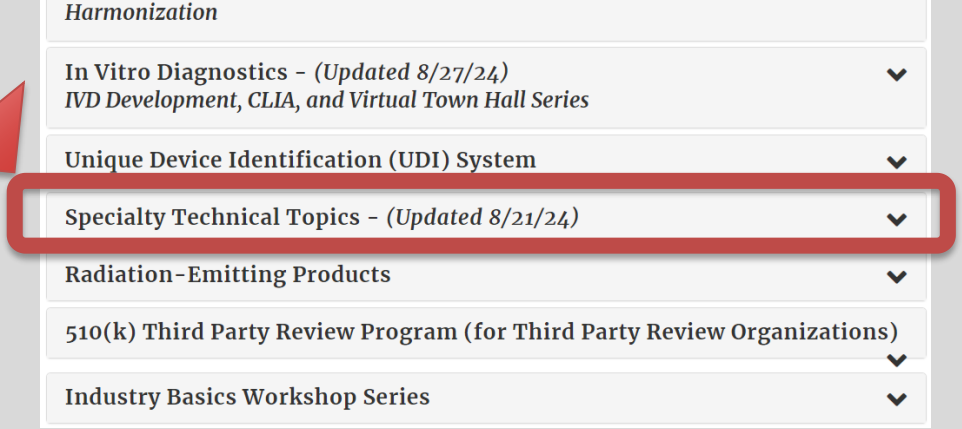
  - Raise your hand in Zoom
  - Moderator will announce your name and invite you to speak
  - Unmute yourself when prompted in Zoom to speak
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment 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



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