U.S. FOOD & DRUG ADMINISTRATION

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 and Open Q&A

October 30, 2024

Medical Device Sterilization Town Hall:

Sterilization Short Topics and Open Q&A

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

Today's Panelists

CDR Tamara Rosbury, PhD
Health Scientist / EtO Incident Response

Office of Readiness and Response
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

Ruth Bediakoh
Consumer Safety Officer

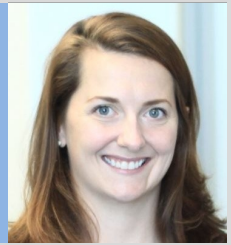
Office of Training and Education
Office of Communication, Information Disclosure, Training and Education (OCITE)

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

Today's Panelists, continued

Kelly Wilkicki, MPP
Senior Advisor for Innovation

Office of Equity and Innovative Development
Office of Strategic Partnerships and Technology Innovation



Shani Haugen, PhD
Assistant Director

Office of Health Technology 3
Office of Product Evaluation and Quality

Mary Wen, PhD
Deputy Division Director

Office of Regulatory Programs
Office of Product Evaluation and Quality

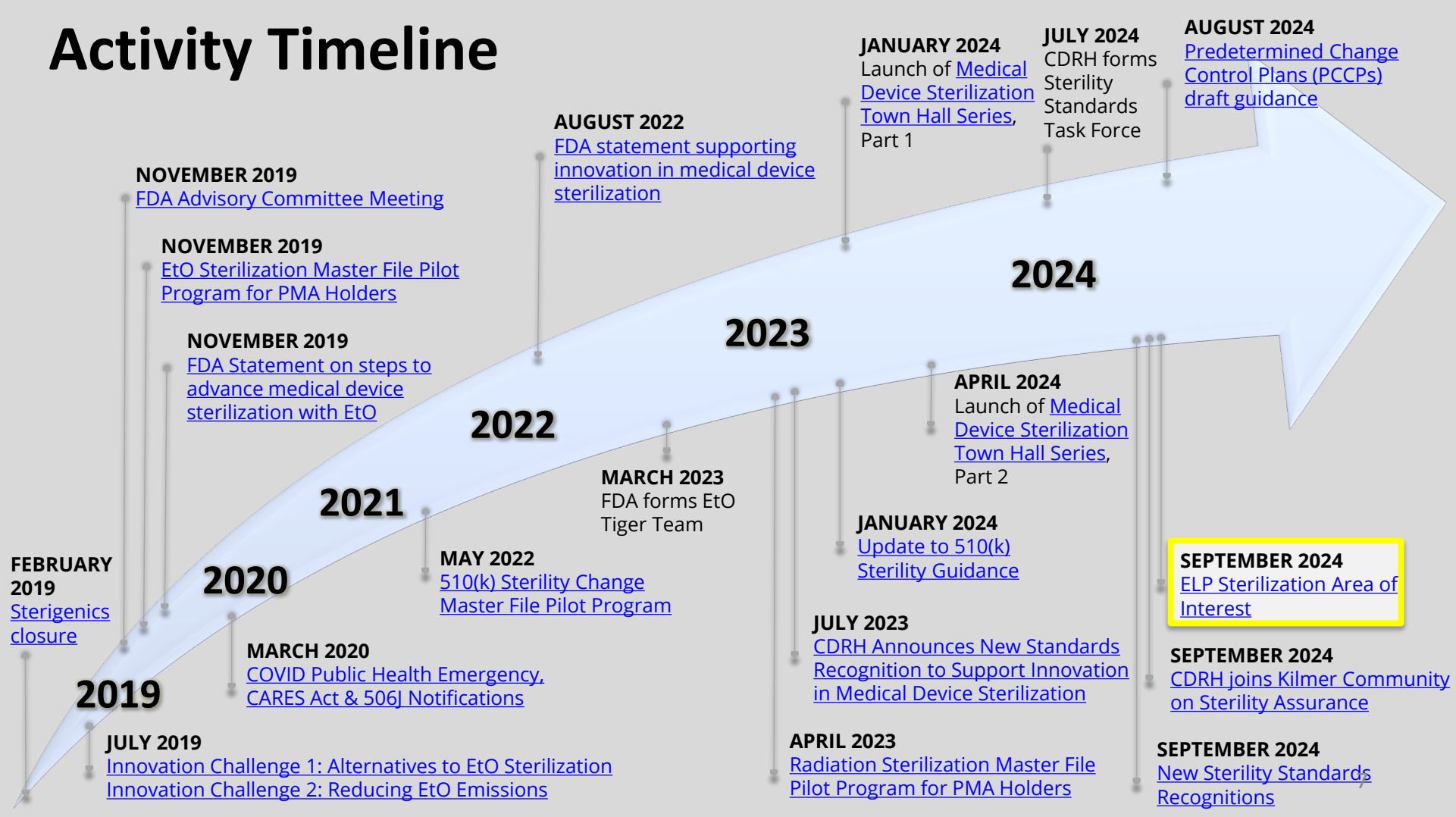
Center for Devices and Radiological Health
U.S. Food and Drug Administration

CDR Tamara Rosbury, PhD
Health Scientist / EtO Incident Response

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

What we heard from you last time

Activity Timeline



Discussion Topics

Topic 1: Discuss activities CDRH has in place to support medical device innovators including early regulatory assistance, funding opportunities, and knowledge sharing

Topic 2: Discuss the use of bundling for sterility-related submissions

Topic 1: Activities to support medical device innovators

What kinds of early regulatory assistance does FDA offer medical device innovators?

MODERATOR:

Lisa Simone, PhD

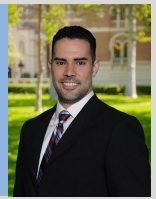
Incident Response Lead
OST, Office of Readiness and Response

Ruth Bediakoh

Consumer Safety Officer
Division of Industry and Consumer Education, OCITE

Ryan Ortega, PhD

Regulatory Advisor
OPEQ, Regulatory Policy and Combination Products



Does CDRH have any funding opportunities to help innovators working in the area of sterilization?

Lisa Simone, PhD

Incident Response Lead
OST, Office of Readiness and Response

Kelly Wilkicki, MPP
Senior Advisor for Innovation
OST, Office of Equity and Innovation
Development

Small Business Innovation Research (SBIR) Grant Background

Health and Human Services (HHS)

- $1.2 Billion
- $275,000
- $1.83 Million
- Grants

SBIR/STTR

Funds health, life science, and biomedical discoveries that could impact the lives of patients and their families.

SBIR Grant Participating Agencies

Examples of CDRH's SBIR Research Priorities

D. Health Equity: Advance the development of knowledge, and safe and effective technologies, to meet the needs of diverse patient populations and consumers, including reducing barriers to participate in evidence generation by diverse populations and the use of medical technologies outside a healthcare setting.

- Health of Women: Explore unique issues related to the performance of medical devices in women, improve analysis and communication of sex- and gender- specific data to better assure the safe and effective use of medical devices
- Human Factors: Explore methodologies to test and report on usability or user experiences with devices in diverse patient populations and consumers.
- Pediatric Medical Device Development: Increase and accelerate medical device development and labelling for the unique and evolving needs of pediatric and special populations, especially younger sub- populations such as neonates and children. Optimize or develop infrastructure that supports safe innovation and development of medical devices designed, evaluated, and labelled for pediatric and special populations.

E. Sterilization: Encourage the development of new approaches to medical device sterilization with a focus on identifying alternatives to ethylene oxide (EtO) sterilization methods, and/or development of strategies to reduce EtO emissions.

HHS Program Descriptions, pg 199

How to apply for an SBIR Grant:

Required Application Instructions

It is critical that applicants follow the SBIR/STTR (B) Instructions in the How to Apply – Application Guide, except where instructed to do otherwise (in this NOFO or in a Notice from the *NIH Guide for Grants and Contracts*).

Conformance to all requirements (both in the How to Apply – Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply – Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply – Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

PHS 2024-2 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications

SBIR Funding Opportunity Solicitation

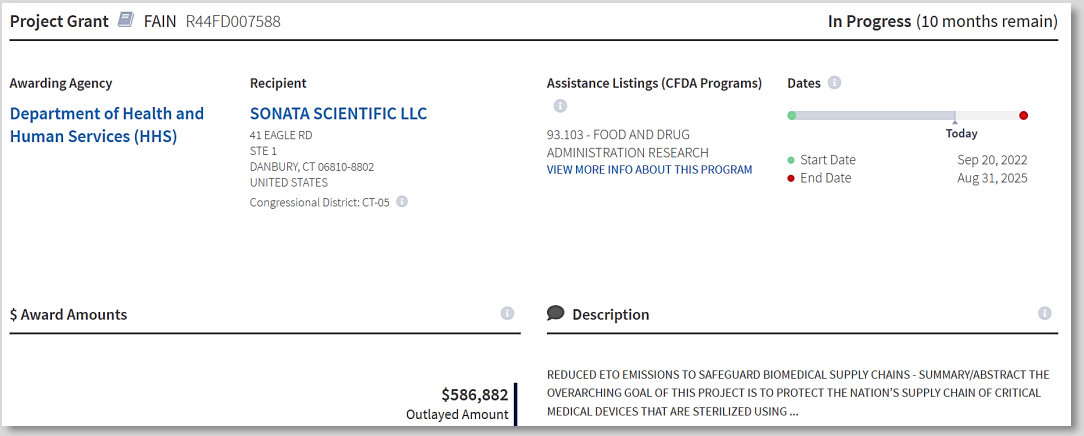
Recent FDA SBIR Grantees

1

Prime Award ID	Recipient Name	Obligations
R44FD007584	TRIPLE RING TECHNOLOGIES INC	$661,773.00
R44FD007588	SONATA SCIENTIFIC LLC	$591,000.00
R43FD007588	SONATA SCIENTIFIC LLC	$200,000.00
R43FD007709	ADVANCED COOLING TECHNOLOGIES IN	$199,997.00
R43FD007805	TRIPLE RING TECHNOLOGIES INC	$199,443.00

[SBIR results 1 (USASpending.gov)]
[SBIR results 2 (USASpending.gov)]
[SBIR results 3 (USASpending.gov)]

2



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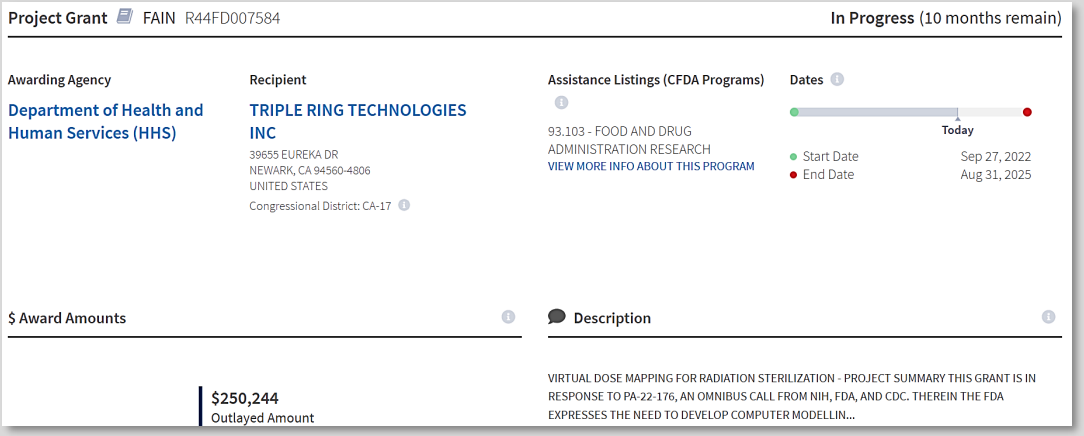


How might industry help FDA staff learn about challenges the device innovators face?

MODERATOR:

Lisa Simone, PhD

Incident Response Lead

OST, Office of Readiness and Response

Shani Haugen, PhD

Assistant Director

OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

Ryan Ortega, PhD

Regulatory Advisor

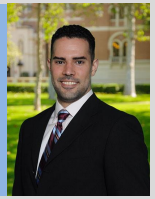
OPEQ, Regulatory Policy and Combination Products

Topic 2: Bundling for Sterility-related submissions

What is bundling and how might it be used to reduce regulatory burden?

MODERATOR:

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

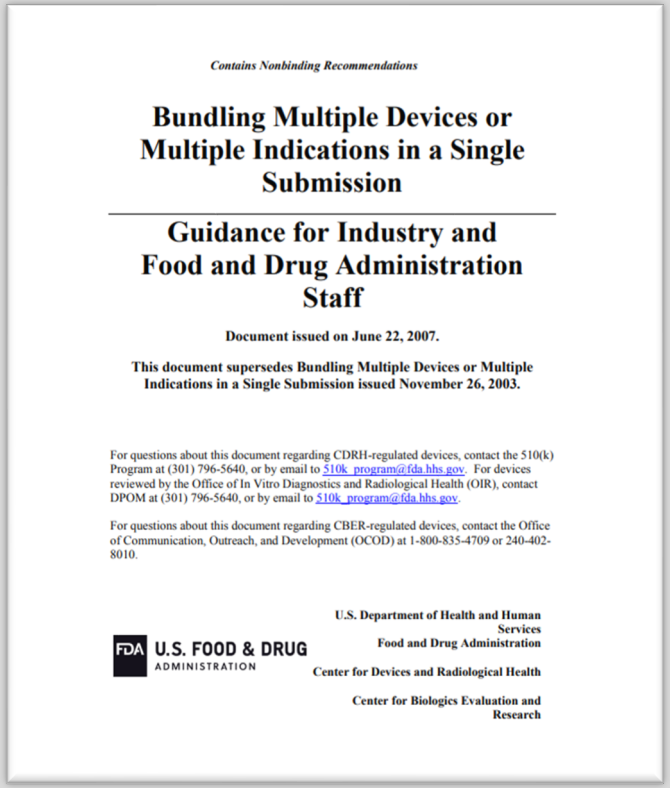


Mary Wen, PhD
Deputy Division Director

OPEQ/ORP, Division of Submission Support

Shani Haugen, PhD
Assistant Director
OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

FDA Bundling Guidance



Contains Nonbinding Recommendations

Bundling Multiple Devices or Multiple Indications in a Single Submission

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 22, 2007.

This document supersedes Bundling Multiple Devices or Multiple Indications in a Single Submission issued November 26, 2003.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Program at (301) 796-5640, or by email to 510k_program@fda.hhs.gov. For devices reviewed by the Office of In Vitro Diagnostics and Radiological Health (OIR), contact DPOM at (301) 796-5640, or by email to 510k_program@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Bundling Guidance

This guidance is intended to assist industry and FDA staff in understanding when bundling may be appropriate.

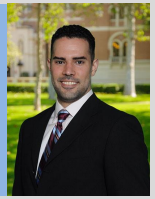
What are the general principles for bundling?

MODERATOR:

Ryan Ortega, PhD

Regulatory Advisor

OPEQ, Regulatory Policy and Combination Products



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Shani Haugen, PhD

Assistant Director

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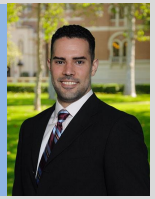
What are some sterilization related examples of bundling?

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



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Assistant Director
OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

Resources

Slide Number	Cited Resource	URL
6	Verbal reference to ISO 14937:2009 Sterilization of health care products	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=36991
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	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

Resources

Slide Number	Cited Resource	URL
7	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	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
7	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
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, Parts 1 and 2	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#town-halls
7	Predetermined Change Control Plans (PCCPs) draft guidance	www.fda.gov/media/180978/download
7	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
7	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
7, 15	ELP Sterilization Area of Interest	www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/experiential-learning-program-elp-areas-interest#reprocessing

Resources

Slide Number	Cited Resource	URL
12	SBIR Grant Participating Agencies	www.sbir.gov/participating-agencies
12	HHS Program Descriptions	seed.nih.gov/sites/default/files/HHS_Program_Descriptions.pdf
13	SBIR Funding Opportunity Solicitation	grants.nih.gov/grants/guide/pa-files/PA-24-245.html
14	SBIR results 1 (USASpending.gov)	www.usaspending.gov/search/?hash=a604f777ace1c95a148b233a15e49026
14	SBIR results 2 (USASpending.gov)	www.usaspending.gov/award/ASST_NON_R44FD007588_7524
14	SBIR results 3 (USASpending.gov)	www.usaspending.gov/award/ASST_NON_R44FD007584_7524
15	Verbal reference to the Experiential Learning Program	www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/cdrhs-experiential-learning-program-elp
18	FDA Bundling Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/bundling-multiple-devices-or-multiple-indications-single-submissions

Summary

- Discussed activities CDRH has in place to support medical device innovators including early regulatory assistance, funding opportunities, and knowledge sharing
- Discussed the use of bundling for sterility-related submissions

Next Town Hall

Date: Wednesday, November 20, 2024

Time: 1:00 – 2:30 PM ET

Potential Topics:

- Recent sterility consensus standards recognitions
- Biocompatibility assessment considerations related to sterilization changes

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
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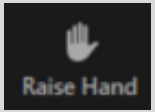
ADMINISTRATION

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



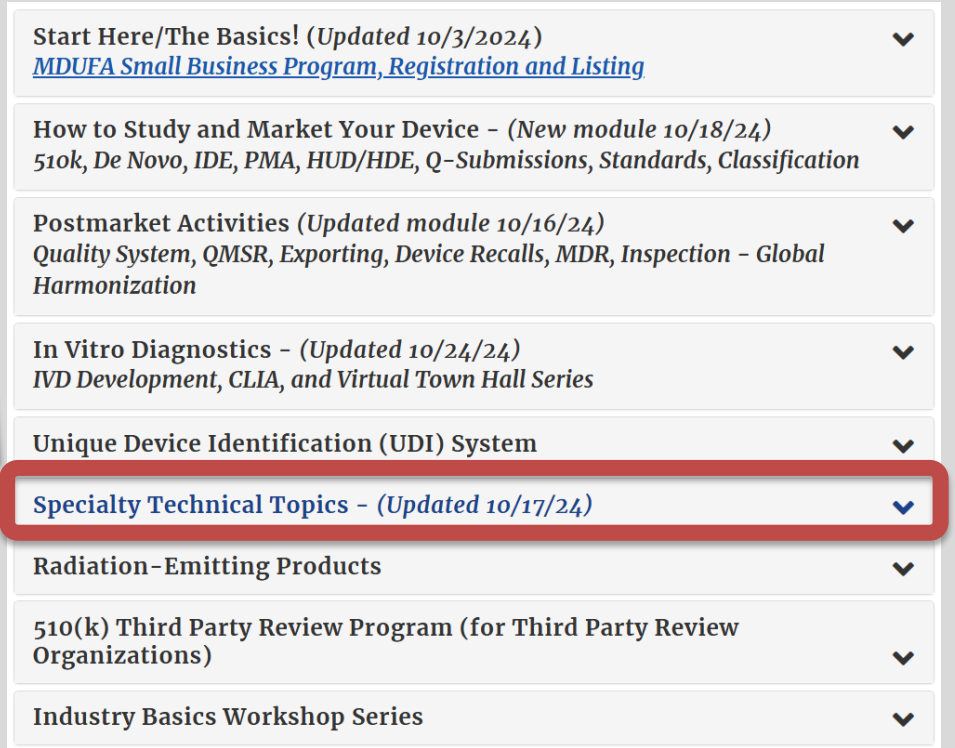
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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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