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

November 20, 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 Scott Steffen, PhD
Senior Program Management Officer /
EtO Incident Lead

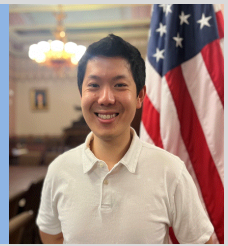
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

Paulo Laranjeira, PhD
Biomedical Engineer

Office of Health Technology 4
Office of Product Evaluation and Quality

Samuel Lum
Standards Advisor, Sterility

Division of Standards and Conformity Assessment
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation



Jianchao Zeng, PhD
Assistant Director

Division of Standards and Conformity Assessment
Office of Readiness and Response
Office of Strategic Partnerships and Technology Innovation

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

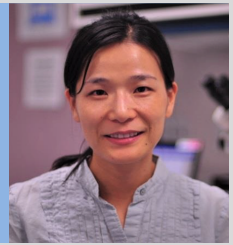
Today's Panelists, continued

Jen Goode
Biocompatibility Program Advisor

Clinical and Scientific Policy Staff
Office of Product Evaluation and Quality

Jinrong Liu, PhD
Polymer Chemist and Team Lead

Office of Health Technology 1
Office of Product Evaluation and Quality



Aprajita (Apra) Garg, PhD
Biologist and Senior Staff Fellow

Office of Health Technology 6
Office of Product Evaluation and Quality

Dale Rimmer, PhD
Chemist and Senior Reviewer

Office of Health Technology 3
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Senior Program Management Officer /
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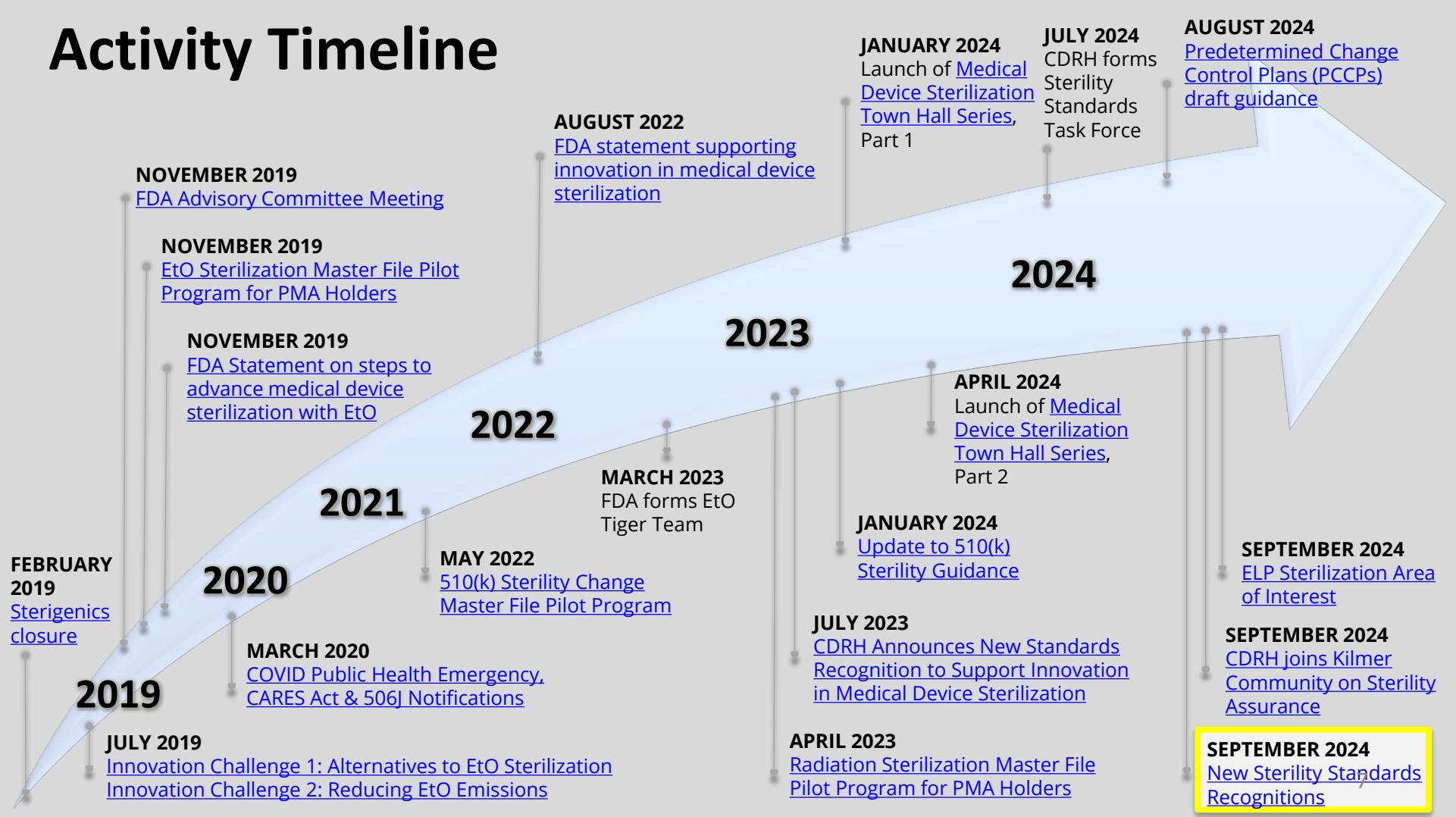
Office of Strategic Partnerships and Technology Innovation

What we heard from you last time

Activity Timeline



Discussion Topics

Topic 1: Discuss the impact and recognition of recent sterilization-related consensus standards

Topic 2: Describe biocompatibility assessment considerations related to sterilization changes

Topic 1: Impact and recognition of recent sterilization-related consensus standards

Why does CDRH strongly encourage the use of recognized consensus standards?

MODERATOR:

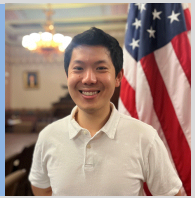
Paulo Laranjeira, PhD
Biomedical Engineer
OPEQ, Surgical and Infection Control Devices

Jianchao Zeng, PhD
Assistant Director

OST, Standards and Conformity Assessment

Samuel Lum
Sterility Standards Advisor

OST, Standards and Conformity Assessment



What consensus standards do we intend to recognize, why did this happen between the regular spring/fall recognition cycle, and what was the process for the early recognition?

MODERATOR:
Samuel Lum
Sterility Standards Advisor
OST, Standards and Conformity Assessment

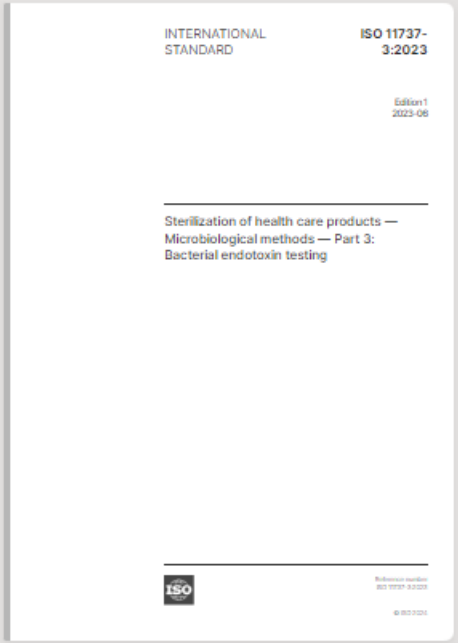
Paulo Laranjeira, PhD
Biomedical Engineer

OPEQ, Surgical and Infection Control Devices

Jianchao Zeng, PhD
Assistant Director

OST, Standards and Conformity Assessment

Bacterial Endotoxin Testing



ISO 11737-3:2023

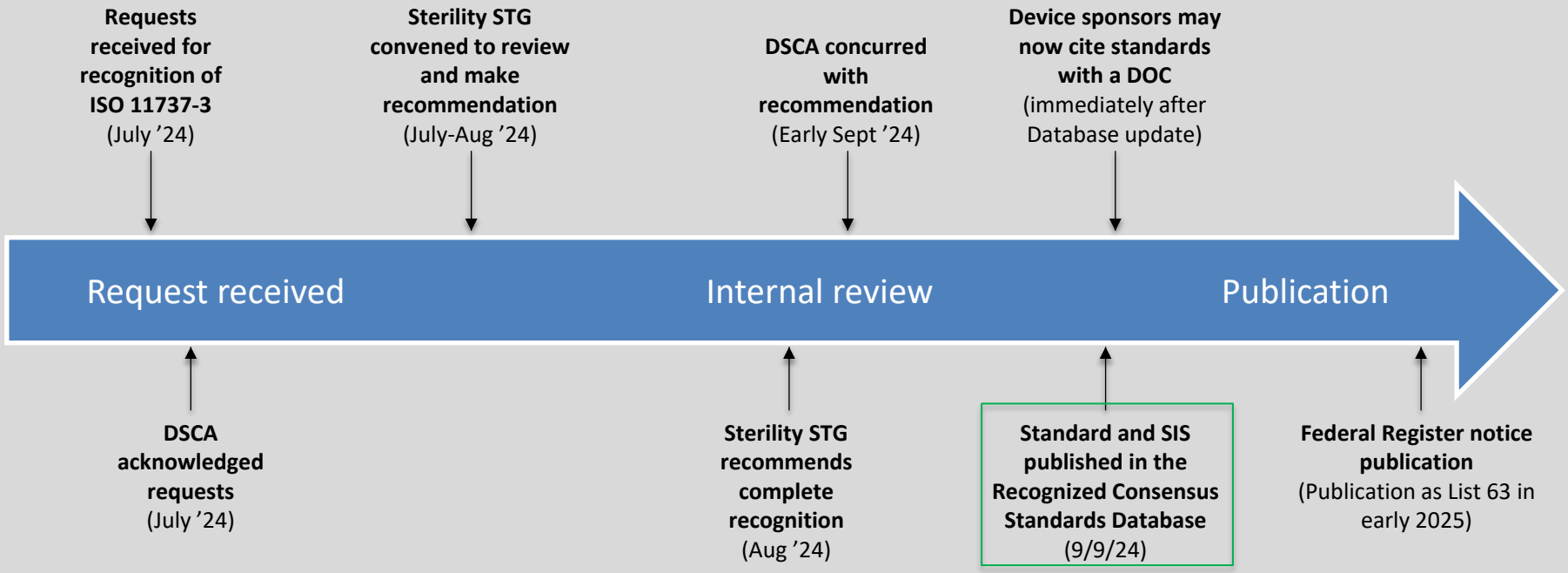
Sterilization of health care products — Microbiological methods

Part 3: Bacterial endotoxin testing

Published (Edition 1, 2023)

Recognition of ISO 11737-3

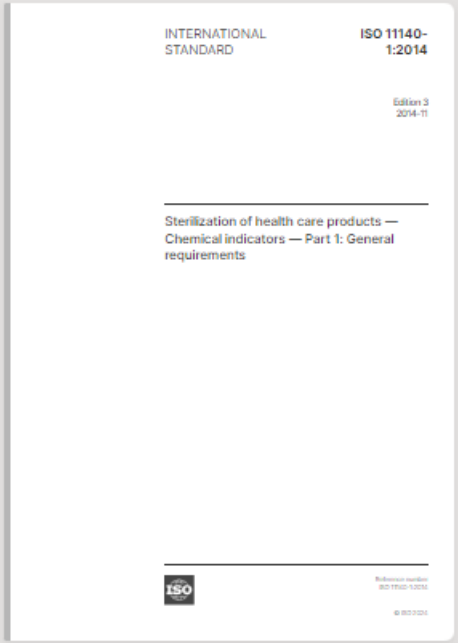
(a case study)



DSCA: Division of Standards and Conformity Assessment
STG: Specialty Task Group
SIS: Supplementary Information Sheet
DOC: Declaration of Conformity

Note: this timeline is not typical, but demonstrates how recognitions can occur quickly if needed

Chemical Indicators



ISO 11140-1:2014

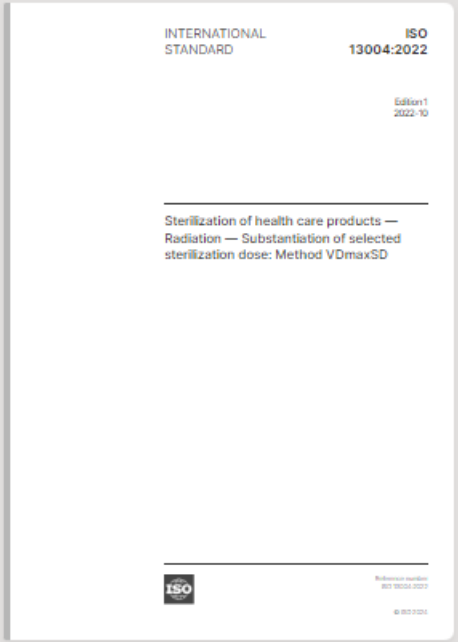
Sterilization of health care products — Chemical indicators

Part 1: General requirements

Published (Edition 3, 2014)

This publication was last reviewed and confirmed in 2021. Therefore this version remains current.

Radiation – Substantiation of Dose



ISO 13004:2022

Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD

Published (Edition 1, 2022)

How has CDRH been involved and how can interested parties get involved in standards development to advance new modalities?

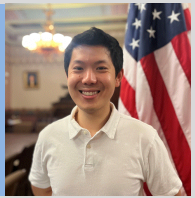
MODERATOR:
Jianchao Zeng, PhD
Assistant Director
OST, Standards and Conformity Assessment

Paulo Laranjeira, PhD
Biomedical Engineer

OPEQ, Surgical and Infection Control Devices

Samuel Lum
Sterility Standards Advisor

OST, Standards and Conformity Assessment



Examples of Recently Recognized Sterility Standards

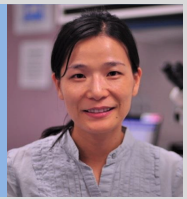
1. ANSI/AAMI ST98:2022 Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.
2. ISO/TS 11137–4: 2020 Sterilization of health care products—Radiation—Part 4: Guidance on process control
3. ISO 22441:2022 Sterilization of health care products—Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
4. AAMI TIR104:2022 Guidance on transferring health care products between radiation sterilization sources
5. AAMI TIR17:2017/(R)2020 Compatibility of materials subjected to sterilization
6. ANSI/AAMI ST108:2023 Water Quality for Processing Medical Devices
7. AAMI TIR28:2016/(R)2020 Product adoption and process equivalence for ethylene oxide sterilization
8. AAMI TIR12:2020/(R)2023 Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
9. ISO 17665:2024 Sterilization of health care products—Moist heat—Requirements for the development, validation and routine control of a sterilization process for medical devices

Topic 2: Biocompatibility assessment considerations related to sterilization changes

What are some general considerations for how sterilization changes may impact biocompatibility?

MODERATOR:
Jen Goode
Biocompatibility Program Advisor
OPEQ, Clinical and Scientific Policy Staff

Jinrong Liu, PhD
Polymer Chemist and Team Lead
OPEQ, Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices



Aprajita (Apra) Garg, PhD
Biologist and Senior Staff Fellow

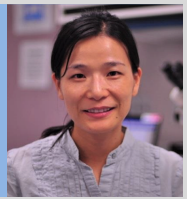
OPEQ, Orthopedic Devices

Dale Rimmer, PhD
Chemist and Senior Reviewer
OPEQ, Renal, Gastrointestinal, Obesity and Transplant Devices

What are some method-specific considerations for how sterilization changes may impact biocompatibility?

MODERATOR:
Jen Goode
Biocompatibility Program Advisor
OPEQ, Clinical and Scientific Policy Staff

Jinrong Liu, PhD
Polymer Chemist and Team Lead
OPEQ, Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices



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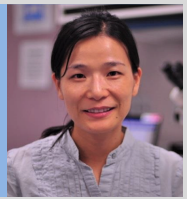
What are some chemical and physical characterization considerations related to sterilization changes that may impact biocompatibility?

MODERATOR:
Jen Goode
Biocompatibility Program Advisor
OPEQ, Clinical and Scientific Policy Staff

Jinrong Liu, PhD
Polymer Chemist and Team Lead
OPEQ, Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices



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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	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	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

Resources

Slide Number	Cited Resource	URL
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
9	Verbal reference to Town Hall 5: "The Value and Use of Recognized Consensus Standards in Premarket Submissions" (3/21/24)	www.fda.gov/medical-devices/medical-devices-news-and-events/medical-device-sterilization-town-hall-value-and-use-recognized-consensus-standards-premarket
9	Verbal reference to Town Hall 10: "Sterilization Short Topics and Open Q&A" (8/7/24)	www.fda.gov/medical-devices/medical-devices-news-and-events/medical-device-sterilization-town-hall-sterilization-short-topics-and-open-qa-08072024
10	Verbal reference to Appropriate Use of Voluntary Consensus Standards guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
10	Verbal reference to Recognized Consensus Standards database	www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards
12	Verbal reference to ISO 11737-3:2023 Sterilization of health care products – Microbiological Methods Part 3: Bacterial Endotoxin Testing	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=45549
14	Verbal reference to ISO 11140-1:2014 Sterilization of health care products – Chemical indicators	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=45569
15	Verbal reference to ISO 13004:2022 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=45570

Resources

Slide Number	Cited Resource	URL
16	Verbal reference to the DSCA mailbox	CDRHStandardsStaff@fda.hhs.gov
17	Verbal reference to Federal Register recently recognized consensus standards	www.fda.gov/medical-devices/division-standards-and-conformity-assessment/federal-register-documents
17	Recognized Consensus Standards Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
19, 20	Verbal reference to AAMI TIR17	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=44569
21	Verbal reference to FDA's Biocompatibility Assessment Resource Center	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/biocompatibility-assessment-resource-center
21	Verbal reference to Biocompatibility Testing of Medical Devices – Standards specific information for the ASCA program	www.fda.gov/media/142388/download
21	Verbal reference to Pyrogen and Endotoxin Testing: Questions and Answers	www.fda.gov/media/83477/download
21	Verbal reference to ISO10993-7	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=42651
21 / Q&A	Verbal reference to FDA Biocompatibility Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	www.fda.gov/media/142959/download

Summary

- Discussed the impact and recognition of recent sterilization-related standards and shared CDRH's additional involvement and the value of industry engagement in standards development to further alternative sterilization modalities
- Discussed biocompatibility assessment considerations related to sterilization changes and described how changes to sterilization methods and packaging may impact biocompatibility

Next Town Hall

Date: Wednesday, December 4, 2024

Time: 2:00 – 3:30 PM ET

Potential Topics:

- Town hall series updates and impact, wrap up and next steps

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

Additional Panelist

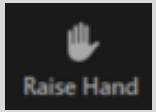
Ryan Ortega, PhD
Regulatory Advisor

Regulatory Policy and Combination Products Staff
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



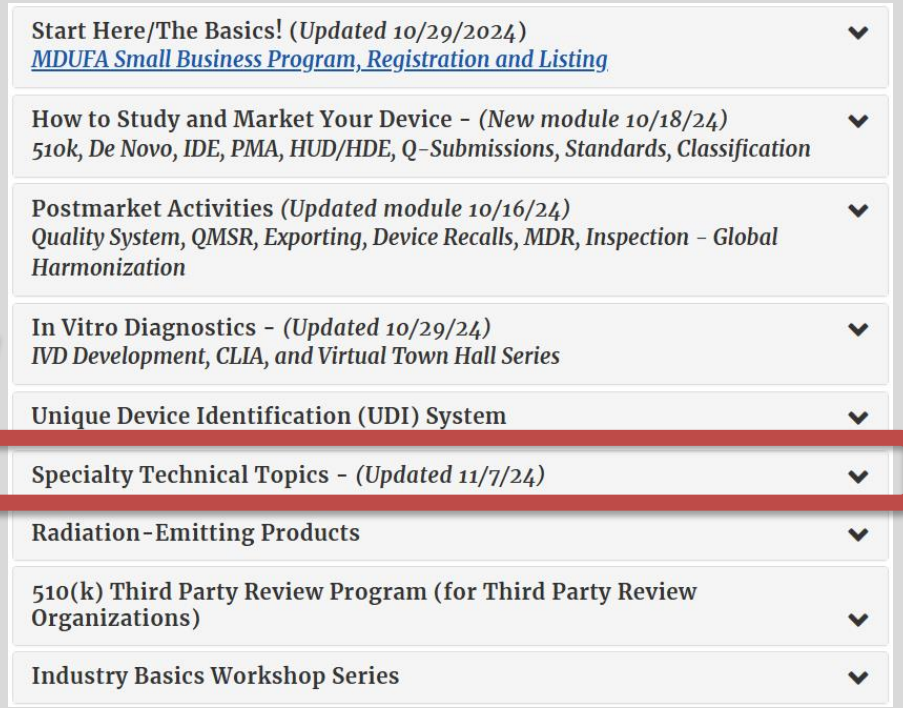
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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



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