U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Medical Device Sterilization Town Hall: The Value and Use of Recognized Consensus Standards in Premarket Submissions

March 21, 2024

Medical Device Sterilization Town Hall:

The Value and Use of Recognized Consensus Standards in Premarket Submissions

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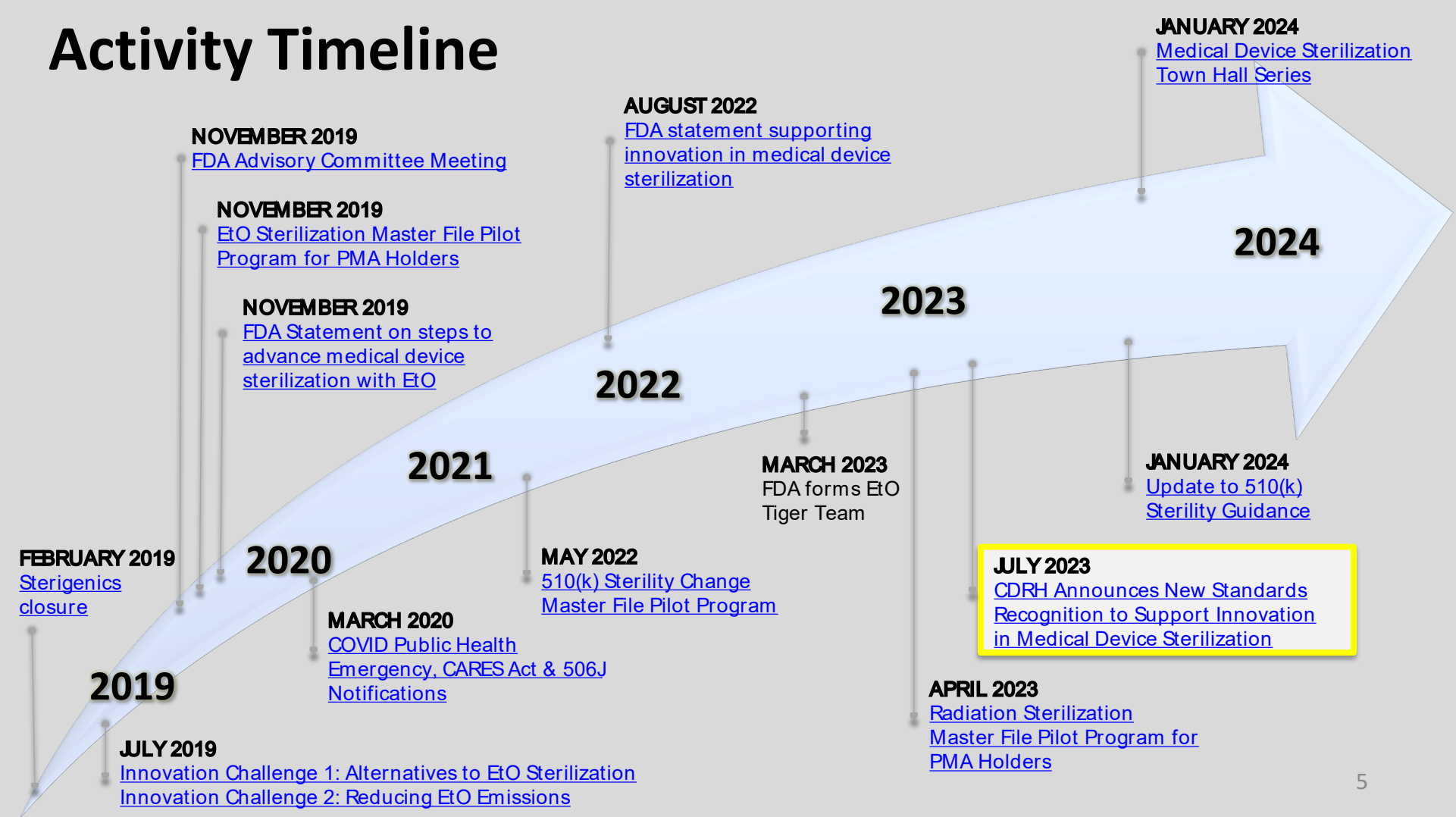
What we heard from you last time

Activity Timeline



Learning Objectives

- Describe the value of using consensus standards, including their use in premarket review
- Describe the principles of standards development and the role of the CDRH's Division of Standards and Conformity Assessment (DSCA) in recognizing consensus standards.
- Understand the utility of three recently FDA-recognized sterility consensus documents for regulatory submissions
- Describe the value of participating in the collaborative standards development process and how you can help

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The Value of Consensus Standards and their use in Premarket Review

Benefits of Consensus Standards

- Improved quality thanks to the consensus process, tapping into a broad array of experts and expertise
- More efficient than lengthy legal or rule-making approaches
- Encourage innovation and competition among product developers
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Promote regulatory science at national and international levels
- Streamline conformity assessment

Consensus Standards Development Principles

Due process: stakeholders with a material interest have a right to participate by expressing a position and having that position fairly and fully considered. The minimum acceptable criteria for due process are*:

1. Transparency
2. Openness
3. Impartiality and Consensus
4. Effectiveness and Relevance
5. Coherence
6. Development Dimension

* World Trade Organization:
Principles for the Development of International Standards, Guides and Recommendations, Article 2.1-2.6

CDRH strongly encourages the use of standards

Why?

- FDA-recognized standards have FDA's confidence that conformity will support device claims
- Using recognized standards with a declaration of conformity generally reduces documentation needed in the submission
- Fewer Additional Information questions
- Conformity assessment resource used by multiple jurisdictions
- Can provide clearer regulatory expectations, for example:
  - Standardize test methods to eliminate guess work (e.g., ISO 11135:2014 provides recommendations on validation methods for EtO cycles)
  - Provide acceptance criteria
  - Potentially eliminate extraneous tests

Appropriate Use of Voluntary Consensus Standards

Using FDA-Recognized Consensus Standards

FDA strongly encourages the use of FDA-recognized consensus standards in premarket submissions

Declarations of conformity (DOCs) are used with FDA-recognized consensus standards, reducing documentation submitted to FDA

A DOC is a communication tool, conveying key information to review staff in a clear and concise fashion

Appropriate Use of Voluntary Consensus Standards

What is a Declaration of Conformity (DOC)?

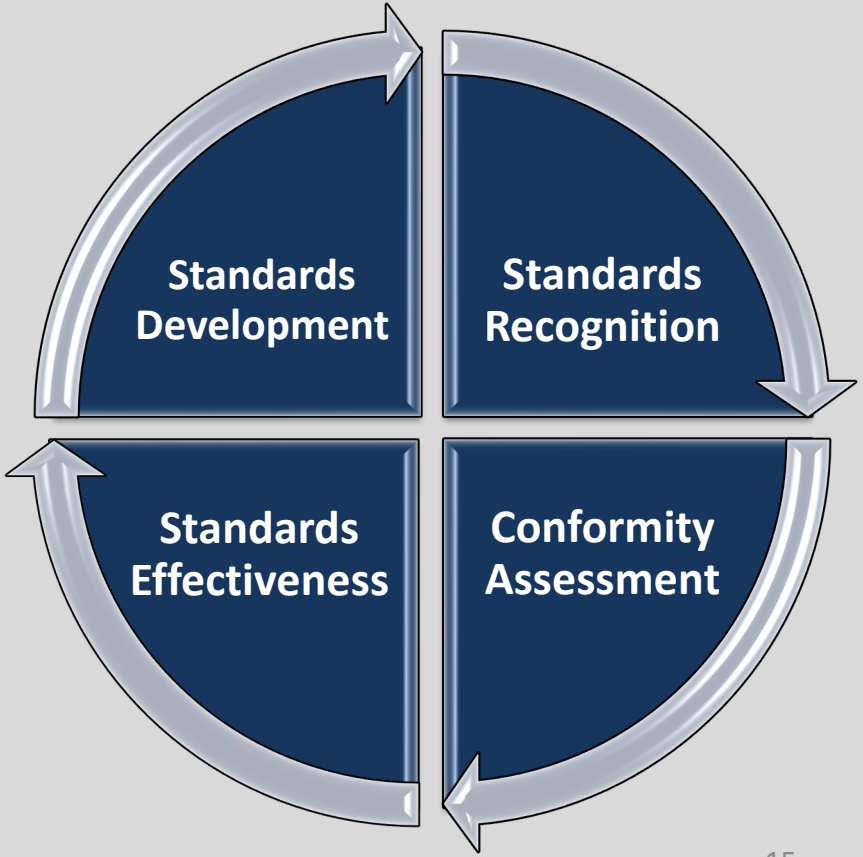
- Attestation that the device conforms with the cited FDA-recognized consensus standard
  - All normative requirements are met
  - All testing has been conducted
  - Testing was performed on finished device or final finished device
- If the manufacturer declares conformity with a recognized consensus standard, a DOC and any associated supporting documentation accompany the submission
- Complete test reports should generally NOT be submitted with a DOC
- eSTAR makes this easy along with filing appropriate supporting documentation
- See the guidance entitled *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices* for details on declarations of conformity and supporting documentation

Appropriate Use of Voluntary Consensus Standards

Standards Development and FDA Recognition

Division of Standards and Conformity Assessment (DSCA)

- ***Standards Development:*** leadership and participation to optimize consensus standards for regulatory use
- ***Standards Recognition***: robust formal program to advance use of consensus standards
- ***Conformity Assessment:*** DOCs and programs like Accreditation Scheme for Conformity Assessment (ASCA)
- ***Standards Effectiveness***: ongoing evaluation of current consensus standards



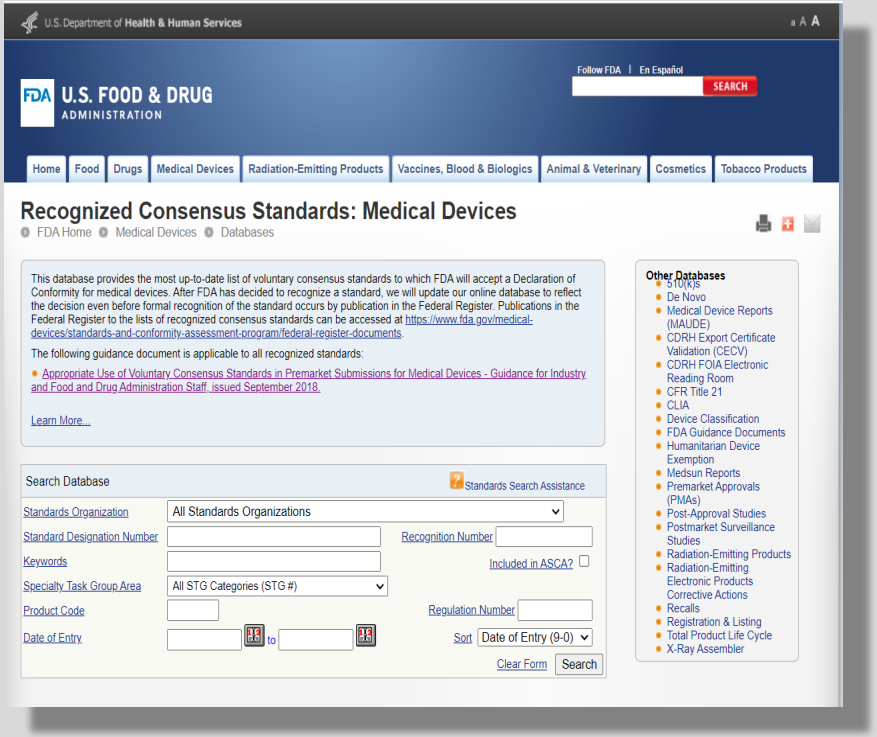
Division of Standards & Conformity Assessment

Standards Recognition Program

‘Recognition’ - FDA’s formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (using a declaration of conformity) to meet relevant requirements.

The FDA:

- Encourages external and internal stakeholders to nominate standards for recognition
- May recognize all, part or none of the standard
- Will publish the decision rationale
- Regularly updates recognition and non-recognition decisions
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- May withdraw recognized standards, as appropriate



[Recognition and Withdrawal of Voluntary Consensus Standards guidance document]

FDA Recognition Decision Process

- FDA receives and formally acknowledges a request for recognition
- DSCA considers the standard
- DSCA convenes the appropriate FDA Specialty Task Group to formally review the standard and make a recommendation to the program
  - Recognize or not recognize
  - Complete or partial recognition
- Based upon:
  - Scientific, technical, regulatory or other basis

FDA Recognition Decisions

- Recognition decision within 60 calendar days
- Decision, including rationale, sent to requester
- Pending recognition: FDA's determination (partial or complete) appears in the FDA's Recognized Consensus Standards Database
- Non-recognitions listed in the Non-Recognized Standards Database
- Official recognition: publication in the *Federal Register*

**** Manufacturers may submit declarations of conformity within their premarket submission(s) as soon as a standard appears in the Recognized Consensus Standards Database ****

Supplementary Information Sheets (SIS) include:

- Recognition number
- Date of entry into Recognized Consensus Standards Database
- Standards Development Organization (SDO) and designation number
- US identical adoption (if applicable)
- Scope of standard
- Extent of recognition
- Included in ASCA?
- Rationale for recognition or partial recognition
- Transition period (if any)
- Examples of applicable device product codes
- Relevant guidance documents or other publications
- Relevant FDA Specialty Task Group
- Name of contact person

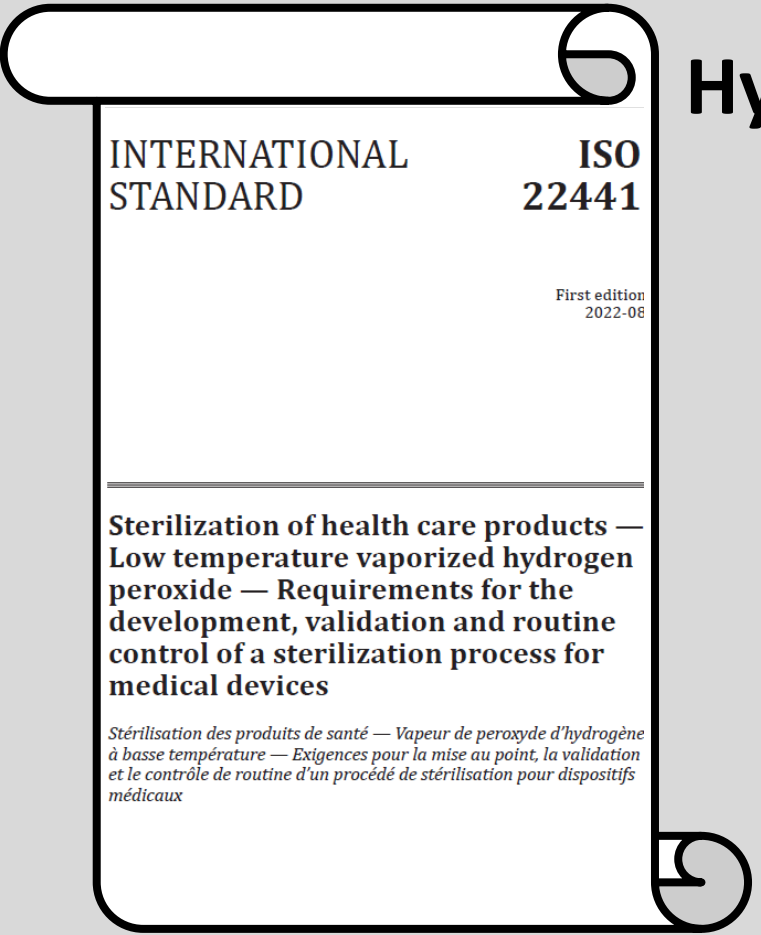
FDA Recognized Consensus Standards Database

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

Office of Product Evaluation and Quality

Recently Recognized Sterilization Consensus Documents and their use in Premarket Submission Review

ISO 22441: Vaporized Hydrogen Peroxide Validation


INTERNATIONAL STANDARD

ISO 22441

First edition
2022-08

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

Stérilisation des produits de santé — Vapeur de peroxyde d'hydrogène à basse température — Exigences pour la mise au point, la validation et le contrôle de routine d'un procédé de stérilisation pour dispositifs médicaux

- Vaporized H_2O_2 validation for industrial and healthcare sterilization
  - Development, validation, and routine monitoring and control
  - Microorganism selection, different approaches for process definition, process parameter monitoring
- Manufacturers may submit a DOC in regulatory submissions

FDA Recognized Consensus Standards database

SIS Example
ISO 22441:2022
(complete recognition)

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 060 **Date of Entry** 05/29/2023

FR Recognition Number 14-586

Standard

ISO 22441 First edition 2022-08
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

Scope/Abstract

1.1 Inclusions
1.1.1 This document provides requirements for the development, validation and routine monitoring and control of a low temperature sterilization process for medical devices using vaporized hydrogen peroxide (VH_2O_2) as the sterilizing agent.
1.1.2 This document is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, organizations performing process validation of VH_2O_2 sterilization, and organizations responsible for sterilizing medical devices.
NOTE VH_2O_2 sterilizers can be used in both health care and industrial facilities, and this document acknowledges the similarities and differences between the two applications.

1.2 Exclusions
1.2.1 Processes that use other sterilizing agents, or hydrogen peroxide solution in combination with other chemicals as the sterilizing agent are not addressed in this document.
NOTE See ISO 14937 for guidance on validation of such processes.
1.2.2 This document does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies, e.g. scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.
NOTE Some VH_2O_2 sterilizers have processes that demonstrate some level of inactivation of the causative agents of spongiform encephalopathies, e.g. scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob Disease. However, this inactivation is process, cycle, and test protocol specific, therefore this inactivation is outside the scope of this document, and no specific test methods are provided (see [14], [26], and [30] for more information).
1.2.3 This document does not specify requirements for designating a medical device as sterile.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

NOTE: Defined critical parameters can vary depending on the technology and cycle design of various VH_2O_2 sterilizers. If you are considering releasing product loads using parametric release, please pay attention to process variables [see definition 3.32 and 3.33] to monitor when releasing product loads using parametric release [see definition 3.28]. We encourage you to contact the review division for your device regarding the appropriate parameters to monitor for parametric release of product loads sterilized with VH_2O_2.

Please consider published literatures #1 through #4 listed below.

Relevant FDA Guidance and/or Supportive Publications*

1. USP-NF M7420_01_01 <1229.11> Vapor Phase Sterilization.
2. Dufresne S and Richards T. The first dual-sterilant low-temperature sterilization system. Canadian Journal of Infection Control 2016; 31(3): 169-174.
3. Hultman C, Hill A, McDonnel G. The Physical Chemistry of Decontamination with Gaseous Hydrogen Peroxide. Pharmaceutical Engineering 2007; 27(1): 22-32.
4. Unger-Bürgelt B, Kottke V, Hertel C, Rauschenbach J. The Influence of Humidity, Hydrogen Peroxide Concentration, and Condensation on the Inactivation of Geobacillus stearothermophilus Spores with Hydrogen Peroxide Vapor. Journal of Pharmaceutical Innovation 2008; 3: 123-133.
5. AAMI/TIR17:2017/(R)2020 Compatibility of materials subject to sterilization.
6. Guidance for Industry and Food and Drug Administration Staff: Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 2016.

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued September 2018.

Note extent of recognition and rationale

Note additional relevant documents

AAMI TIR17: Material Compatibility

- Generalized compatibility tables
- Modality-specific material compatibility fundamentals
- Suggestions/considerations for material testing and functionality testing
- Useful for modality selection, sterilization changes for devices, material selection and device design

AAMI TIR104: Transferring Between Radiation Sources

- Suggestions/considerations for source changes (gamma, e-beam, X-ray) and irradiator changes
- Evaluating differences between sources
- Evaluating or re-establishing maximum, verification, or sterilization dose when transferring a product between sources
- Suggestions/considerations for documenting the change
- Useful for planning and implementing a source change and providing support & justification in a regulatory submission

Participating in the Collaborative Standards Development Process

Working together to advance standards

- Investigating new methods for sterilization
- Proposing new standards you feel might be useful
- Getting involved in standards development to drive adoption of additional sterilization modalities
- Proposing sterilization standards for recognition

For questions about standards, their use, and recognition,
please email: CDRHStandardsStaff@fda.hhs.gov

Resources

Slide Number	Cited Resource	URL
5	Sterigenics closure	www.epa.gov/il/sterigenics-willowbrook-facility
5	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
5	Innovation Challenge 2: Reducing EtO Emissions	www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions
5	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
5	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
5	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
5	COVID Public Health Emergency, CARES Act & 506J Notifications	www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages
5	FDA statement supporting innovation in medical device sterilization	www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
5	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
5	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
5	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
5	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
5	First FDA Medical Device Sterilization Town Hall	www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-sterilization-town-hall-overview-sterilization-landscape-and-role-ethylene-oxide
10	World Trade Organization: Principles for the Development of International Standards, Guides and Recommendations, Article 2.1-2.6	www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm
11,12,13	Appropriate Use of Voluntary Consensus Standards	www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
13	eSTAR	www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program
15	Division of Standards & Conformity Assessment	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro
16	Recognition and Withdrawal of Consensus Standards guidance document	www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards
19,22	FDA Recognized Consensus Standards Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Summary

- We described the advantages of using recognized consensus standards in regulatory submissions and how they are used in regulatory review
- We described how CDRH's Division of Standards and Conformity Assessment promotes the development, recognition and use of consensus standards in device development
- We described three recent consensus documents and how they can assist industry in adopting new sterilization methods
- We described how participation in the development of consensus standards is a collaborative effort that promotes important inclusivity and transparency principles to 'crowd-source' the best possible standard

Next Town Hall

Date: Monday, April 29, 2024

Time: 1:00 – 2:00 pm ET

Potential Topics:

- Topics of interest for future town halls
- Additional interactive formats for future town halls

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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Additional Panelist(s)

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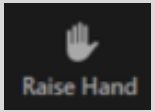
Let's Take Your Questions and Comments

- **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



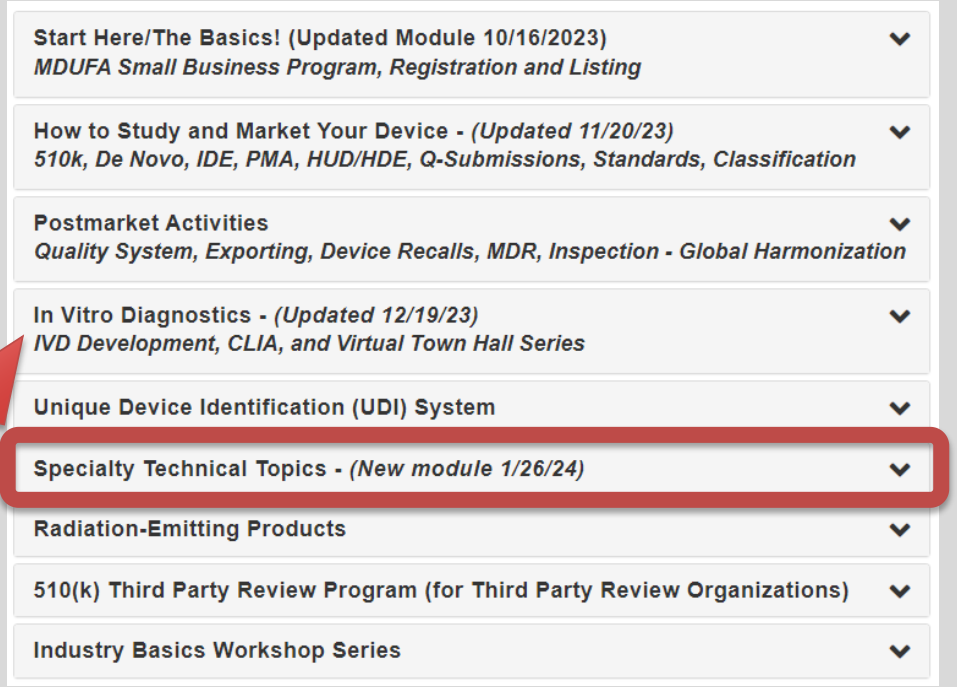
- **When asking a question/sharing a comment:**
  - Keep question/comment as short as possible
  - No questions about specific submissions
- **After question/comment is addressed:**
  - Mute yourself and lower your hand
  - If you have another question/comment - raise your hand again

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/CDRHWebinar



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