

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 Open Q&A

June 12, 2024

Medical Device Sterilization Town Hall: Question & Answer Panel Discussion

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What we heard from you last time

Let's Take Your Questions and Comments



- **To ask a question/share a comment:** A black square icon with a white hand symbol and the text "Raise Hand" below it.
 - 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



Start Here/The Basics! (Updated Module 10/16/2023) <i>MDUFA Small Business Program, Registration and Listing</i>	▼
How to Study and Market Your Device - (Updated 11/20/23) <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i>	▼
Postmarket Activities <i>Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization</i>	▼
In Vitro Diagnostics - (Updated 12/19/23) <i>IVD Development, CLIA, and Virtual Town Hall Series</i>	▼
Unique Device Identification (UDI) System	▼
Specialty Technical Topics - (New module 1/26/24)	▼
Radiation-Emitting Products	▼
510(k) Third Party Review Program (for Third Party Review Organizations)	▼
Industry Basics Workshop Series	▼



Next Town Hall



Date: Wednesday, July 10, 2024

Time: 1:00 – 2:30 pm ET

Potential Topic:

- Mock Pre-Submission for a fictional medical device, exploring regulatory, design and testing considerations regarding a change in sterilization method.

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