

Greetings,

The Organizing Committee of the 4th Medical Device Sterilization Workshop is pleased to announce the next meeting for stakeholders exploring accelerator-based sterilization alternatives:

[“Medical Device Sterilization: From Possibilities to Practice”](#)

This virtual event is being offered at no expense and will take place in the mornings (CDT) of September 21, 22, & 23, 2022. Due to uncertainties regarding COVID, this will be a virtual event.

The featured event will be a Mock Pre-Submission Interaction with the FDA. If you are considering utilizing a radiation sterilization modality and you are not familiar with the FDA Pre-Submission feedback process, this will provide a concrete example of how to interact with the FDA most effectively. The mock presentation will provide a mock product sterilization example discussion followed by a panel analysis of the event with an opportunity for Q&A. This will be useful for both scientists and engineers along with regulatory affairs team members looking to learn about FDA interactions.

Our keynote speaker will be Aftin Ross, Senior Special Advisor for Emerging Initiatives at the FDA.

Other topics covered will be:

- Presentations relating to experiences of changing modality
- Update from Team Nablo – Data from direct comparisons of material performance in gamma, x-ray, and e-beam
- New developments in modeling and simulation with the goal of reducing in-beam qualification times
- Comparison of European and US regulatory processes
- Discussion on irradiation equipment (needs and purchasing expectations)

These workshops offer many opportunities for attendees to interact with each other, the presenters, and organizers to express needs and desires and to learn more about the evolution of the sterilization industry. Each day will end with extended Q&A and panel discussions to promote as much dialog as possible among all attendees.

The [Summary Reports](#) from previous workshops are available for review.

We welcome anyone in the sterilization, medical device, and bio-processing industries to participate. Whether in Technology/Science, Business/Logistics/Economics, Standards or Regulatory, this workshop will offer opportunities to address all questions.

Please note: [Registration](#) is now open and will close on September 7th. There will be no opportunity for late registration.

Sincerely,

The Organizing Committee:

Debbie Cotton (Baxter)

Thomas Kroc (Fermilab)

Vu Le (Abbott)

Mark Pasmore (Baxter)

John Williams (Medtronic)