

Greetings,

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

exploring accelerator-based sterilization alternatives

September 21, 22, & 23, 2022.

Just a reminder that the 4th Annual Medical Device Sterilization Workshop is just over a month away.

This [virtual event](#) is being offered at no expense and will take place in the morning each day (CDT). Please remember: [Registration closes September 7](#). There will be no opportunity for late registration.

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 an example of how to interact with the FDA most effectively. The 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 from the bio-process industry on their efforts to incorporate X-ray sterilization into their processes
- Update from Team Nablo – Data from direct comparisons of material performance in gamma, x-ray, and e-beam
- New developments in modeling and simulation to reduce in-beam qualification times
- Comparison of European and US regulatory processes
- A discussion on irradiation equipment (needs and purchasing expectations)

These workshops offer many opportunities for interaction and 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.

[Registration](#) is now open.

Sincerely,
The Organizing Committee:

Debbie Cotton (Retired)
Thomas Kroc (Fermilab)
Vu Le (Abbott)
Mark Pasmore (Baxter)
John Williams (Medtronic)