

Greetings,

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

exploring accelerator-based sterilization alternatives

September 21, 22, & 23, 2022.

Please note that [Registration](#) for the 4th Annual Medical Device Sterilization Workshop **closes on September 7th**! There will be no opportunity for late registration.

This [virtual event](#) is being offered at no expense and will take place in the morning each day (CDT).

The featured event will be a **Mock Pre-submission Interaction with the FDA** with five FDA representatives along with product and regulatory SMEs from industry. This event should be an excellent look into how to effectively interact with the FDA when working on sterilizing your medical devices.

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

Other topics covered will be (see agenda[[link](#)] here):

- 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.

We also note that the Midwest Chapter of the Parenteral Drug Association (PDA) is having a [half day event](#) on September 20th looking at parametric release.

Sincerely,

The Organizing Committee:

Debbie Cotton (retired)

Thomas Kroc (Fermilab)

Vu Le (Abbott)

Mark Pasmore (Baxter)

John Williams (Medtronic)