Nelson Labs MedTech Lifecycle Seminar: Design, Validation & Regulatory Compliance
Location: San Jose, Costa Rica

October 13, 2026

Day 1: Regulatory Strategy & Quality Systems

Focus: Harmonization and high-level compliance.

- **09:00 AM – 10:30 AM: QMSR Transition.** Strategic roadmap for shifting from FDA Part 820 to the new Quality Management System Regulation- **Jordan Elder**
- **10:30 AM – 10:45 AM**: **Break**
- **10:45 AM – 12:30 PM: ISO 13485 & Audit Readiness.** Case studies on surviving unannounced audits and maintaining a global QMS- **Jordan Elder**
- **12:30 PM – 1:30 PM: Networking Lunch**
- **1:30 PM – 3:00 PM: Risk Management Workshop (ISO 14971).** Hands-on application: Aligning risk files with new EU MDR and FDA expectations- **Jordan Elder**
- **3:00– 3:15 PM: FDA guidance on categories of sterilization processes and changing between sterilization modalities,** AAMI updates to novel sterilization methods- **Martell Winters**
- **3:15 PM – 3:30 PM: Updates to 10993-1 on risk assessments for biocompatibility- Robert Mueller**
- **3:30 PM – 3:45 PM: Break**
- **3:45 PM – 4:45 PM: Single Use Cleaning Validations (ISO 19227). Robert Mueller**
- **4:45 PM – 5:30 PM: Roundtable Discussion.** All Presenters
- **5:30 PM: Evening Welcome Reception**

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Day 2: The Testing & Validation Intensive

Focus: Deep dives into the technical topics requested by over 60% of survey respondents.

- **8:30 AM – 10:00 AM: Biocompatibility Deep Dive (ISO 10993).** Technical session on materials characterization and biological evaluation plans for Class II devices. **Robert Mueller**
- **10:00 AM – 10:15 AM: Break**
- **10:15 AM – 11:15 AM: Biocompatibility Deep Dive (ISO 10993) continued- Robert Mueller**
- **11:15 AM – 12:30 PM: Packaging Validation (ISO 11607).** Hands-on workshop: Design of experiments for shelf-life testing and distribution simulation. **Martell Winters**
- **12:30 PM – 1:30 PM: Networking Lunch**
- **1:30 PM – 3:00 PM: Microbiology & Sterilization Science.** Exploring EO and Radiation validation strategies, including bioburden control and environmental monitoring. **Yesi Frago, Martell Winters**
- **3:00– 3:15 PM: Break**
- **3:15 PM – 4:30 PM: Microbiology & Sterilization Science continued.**
- **4:30 PM – 5:30 PM: Product Lifecycle Case study incorporating all aspects of testing and regulatory- All Presenters**

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Day 3: Infrastructure, Software & Global Access

Focus: Practical application via facility tour and future-proofing.

- **8:30 AM – 10:00 AM: Software Validation & Cybersecurity.** Addressing the challenges of connected devices and SaMD (Software as a Medical Device) **Jordan Elder**
- **Break**
- **10:15 AM – 11:15 AM: Global Market Entry (US/EU/UK/JP).** A technical overview of navigating MDR and UKCA requirements for Class II devices- **Jordan Elder**
- **11:15 AM – 11:45 AM: Final Wrap-up & Q&A.** Closing remarks- **All Presenters**
- **11:45 AM – 12:00 PM: Facility Briefing.** Pre-tour technical briefing on Ethylene Oxide safety and terminal sterilization logistics- **Yesi Frago**
- **12:00 PM – 1:00 PM: Networking Lunch**
- **1:00 PM – 4:30 PM: Sterigenics Site Tour.** The highly requested tour of the Ethylene Oxide facility to see large-scale validation in practice.
- **4:30 PM**: Head back to hotel