

Validation of Sterile Medical Devices

Location: Chicago, IL

Day 1 – Sterilization Science & Packaging Systems

Tuesday, September 22, 2026

8:00 AM Registration & Breakfast- Armstrong Conference Room	1:00 PM Packaging Test Methods & Validation Logan Luke • Integrity & performance test methodologies • Validation protocol development • Statistical & sampling considerations • Managing worst-case conditions
8:30 AM Introduction to Nelson Labs Mike Pizzi • Course technical objectives & structure	
8:45 AM Microbiology & Sterility Assurance Principles Bryce Telford • Microbial inactivation kinetics & SAL concepts • Bioburden characterization & variability • Engineering implications of microbiological risk • Process lethality fundamentals	1:45 PM Radiation Sterilization Principles Bryce Telford • Radiation modalities & mechanisms • Dose distribution fundamentals • Material compatibility & degradation • Engineering trade-offs
10:00 AM Break	2:30 PM Break
10:15 AM Packaging Systems & Sterilization Compatibility Logan Luke • Sterile barrier system design requirements • Material selection & sterilization interactions • Product–package compatibility risks • Regulatory considerations under ISO 11607	2:45 PM Dose Establishment & Process Definition Bryce Telford • Sterilization dose methodologies • Dose audits & verification • Statistical & microbiological considerations • Regulatory documentation expectations
11:00 AM Packaging Fundamentals & Failure Mechanisms Logan Luke • Critical barrier functions • Seal integrity & performance risks • Common failure modes • Design control considerations	3:45 PM Applied Case Discussions
12:00 PM Lunch- Rickenbacker room	4:15 PM Interactive Workshop: Integrated Sterilization Strategy • Modality selection framework • Case study introduction • Cross-functional decision variables
	5:00 PM- End of Day 1 5:30 PM- Evening Reception- Aldrin Crossfield

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Day 2 – Radiation Sterilization & Reusable Devices Cleaning, Sterilization & Disinfection

Wednesday, September 23, 2026

8:00 AM Breakfast- Armstrong Conference Room	1:00 PM Workshop Session: Applied Technical Decision-Making
8:30 AM EO Sterilization – Technical Foundations Courtney Lang, Dania Cortes • Ethylene Oxide Fundamentals • Cycle Dynamics • Feasibility study design	• EO vs Radiation selection criteria • Validation planning & justification • Packaging integration considerations • Release & lifecycle strategies • Risk management alignment with ISO 14971
9:15 AM EO Cycle Development Courtney Lang, Dania Cortes • Process and Product Definition • Load Configuration & Product Grouping • Process Challenge Device Determination • Cycle parameter optimization	2:30 PM Break
10:15 AM Break	2:45 PM Reusable Devices: Cleaning & Disinfection Validation Griffin Cammack
10:30 AM EO Process Validation & Lifecycle Control Dania Cortes, Dania Cortes • Validation methodologies & acceptance criteria • Data interpretation • Requalification & monitoring strategies	• Regulatory drivers & risk considerations • Soil simulation & test approaches • Acceptance criteria & variability • Engineering challenges
12:00 PM Lunch- Rickenbacker room	4:00 PM Reusable Devices: Sterilization Validation Griffin Cammack
	• Complex device considerations • Reprocessing variability • Advanced validation scenarios • Case-based discussions
	5:00 PM End of Day 2

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Day 3 – Biocompatibility & Chemical Characterization

Thursday, September 24, 2026

8:00 AM

Breakfast- Armstrong Conference Room

8:30 AM

Biocompatibility & Biological Risk Evaluation

Audrey Turley

- Biological risk assessment strategy
- Test selection & justification
- Material & process-driven risks
- Regulatory framework: **ISO 10993**

10:15 AM

Break

10:30 AM

Applied Workshop: Biocompatibility Risk & Failures

Audrey Turley

- Failure analysis case studies

12:00 PM

Lunch- Rickenbacker room

1:00 PM

Chemical Characterization & E&L

Robert Mueller

- Analytical strategy development
- Extractables & leachables considerations
- Worst-case study design
- Data interpretation challenges

2:00 PM

Toxicological Risk Assessment

Robert Mueller

- Toxicological thresholds & safety limits
- Patient exposure considerations
- Integrating chemistry & biology datasets
- Defensible safety justifications

2:45 PM

Break

3:00 PM

Expert Panel: Question & Answer

All Presenters

5:00 PM

End of Training Course