Nelson Labs® A Sotera Health company Sterigenics® A Sotera Health company

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

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

10:00 AM
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**

11:00 AM
Packaging Fundamentals & Failure Mechanisms
Logan Luke

- Critical barrier functions
- Seal integrity & performance risks
- Common failure modes
- Design control considerations

12:00 PM
Lunch- Rickenbacker room

1:00 PM
Packaging Test Methods & Validation
Logan Luke

- Integrity & performance test methodologies
- Validation protocol development
- Statistical & sampling considerations
- Managing worst-case conditions

1:45 PM
Radiation Sterilization Principles
Bryce Telford

- Radiation modalities & mechanisms
- Dose distribution fundamentals
- Material compatibility & degradation
- Engineering trade-offs

2:30 PM
Break

2:45 PM
Dose Establishment & Process Definition
Bryce Telford

- Sterilization dose methodologies
- Dose audits & verification
- Statistical & microbiological considerations
- Regulatory documentation expectations

3:45 PM
Applied Case Discussions

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

Validation of Sterile Medical Devices
Location: Chicago, IL
Day 2 – Radiation Sterilization & Reusable Devices Cleaning, Sterilization & Disinfection
Wednesday, September 23, 2026

8:00 AM
Breakfast- Armstrong Conference Room

8:30 AM
EO Sterilization – Technical Foundations
Courtney Lang, Dania Cortes

- Ethylene Oxide Fundamentals
- Cycle Dynamics
- Feasibility study design

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

10:15 AM
Break

10:30 AM
EO Process Validation & Lifecycle Control
Dania Cortes, Dania Cortes

- Validation methodologies & acceptance criteria
- Data interpretation
- Requalification & monitoring strategies

12:00 PM
Lunch- Rickenbacker room

1:00 PM
Workshop Session: Applied Technical Decision-Making

- EO vs Radiation selection criteria
- Validation planning & justification
- Packaging integration considerations
- Release & lifecycle strategies
- Risk management alignment with **ISO 14971**

2:30 PM
Break

2:45 PM
Reusable Devices: Cleaning & Disinfection Validation
Griffin Cammack

- Regulatory drivers & risk considerations
- Soil simulation & test approaches
- Acceptance criteria & variability
- Engineering challenges

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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Validation of Sterile Medical Devices
Location: Chicago, IL
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
Lee Wence, PhD

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

2:00 PM
Toxicological Risk Assessment
Lee Wence, PhD

- 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