



**Introduction to the Validation of Sterile Medical Devices: Sterilization,
Packaging, Biocompatibility, Toxicology and Reprocessing**

Location: Chicago, IL

Tuesday, September 11, 2018

8:00 am	Registration Begins/Continental Breakfast – Hinman Auditorium
8:30 am	Industry Update & Trends & Introduction to Nelson Labs – Mike Pizzi
8:45 am	Introduction to Microbiology & Sterilization – Martell Winters
10:00 am	Morning Break
10:15 am	Packaging- Designed for Sterilization, Materials Selection, Product Combinations and Distribution- Pal Khangaldy
11:15 am	Packaging- Test Method and Validation- Pal Khangaldy
12:00 pm	Lunch
1:00 pm	Packaging- Test Method and Validation cont'd- Pal Khangaldy
1:45 pm	EO Sterilization Validations- Paul Littley and Russ Gonsiorowski
2:15 pm	Afternoon Break
2:30 pm	EO Sterilization Validations cont'd- Paul Littley and Russ Gonsiorowski EO resistance activity- TBD
2:45 pm	EO Sterilization Case Studies- Paul Littley and Russ Gonsiorowski
5:00 pm	End of Seminar Day 1
5:30 pm	Evening Reception

*Times and topics subject to change



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Wednesday, September 12, 2018

8:00 am	Continental Breakfast – Hinman Auditorium
8:30 am	Introduction to Radiation Technology- Kevin O’Hara
9:00 am	Process Definition Part 1- Sterilization Dose Establishment and Dose Audits- Martell Winters
10:00 am	Morning Break
10:15 am	Establishing Dmax, Performance Qualification Dose Mapping and Material Selection- Kevin O’Hara
11:15 pm	Dose Audits and Wrap Up- Martell Winters
12:15 pm	Lunch
1:15 pm	Reprocessing Validations of Reusable Medical Devices – Emily Mitzel
2:45 pm	Break
3:00 pm	Reprocessing Validations of Reusable Medical Devices cont’d- Emily Mitzel
4:00 pm	End of Seminar Day 2

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Thursday, September 13, 2018

8:00 am	Continental Breakfast – Hinman Auditorium
8:30 am	Cleaning Validations of Single Use Devices- Matt Jorgensen, PhD
9:30am	Break
9:45 am	Biocompatibility ISO 10993- Audrey Turley
10:45 am	Morning Break
11:00 am	Biocompatibility & Intro to Chemical Characterization Basics- Audrey Turley/Matt Jorgensen, PhD
12:00 pm	Lunch
1:00 pm	Chemical Characterization Basics continued- Matt Jorgensen, PhD
1:45 pm	Toxicological Assessments for Chemical Characterization- Audrey Turley/Matt Jorgensen, PhD
2:30 pm	Break
2:45 pm	ISO 10993 Case Studies (Biocomp failures as well)- Audrey Turley
4:00 pm	End of seminar

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