



**The Validation of Sterile Medical Devices: Sterilization, Packaging,
Biocompatibility, Toxicology and Reprocessing**

Location: Frankfurt, Germany

Tuesday, March 24, 2020

8:00 am	Registration Begins – Main I & II
8:30 am	Industry Update & Trends & Introduction to Nelson Labs – Mike Pizzi
8:45 am	Introduction to Microbiology & Sterilization – Martell Winters, Nelson Laboratories, LLC
10:15 am	Morning Break
10:30 am	Ethylene Oxide Sterilization- Background, History and Cycle Development Testing – Stefan Reisbacher, Sterigenics
12:00 pm	Lunch
1:00 pm	EO Sterilization Validations and case studies- Stefan Reisbacher, Sterigenics
2:45 pm	Afternoon Break
3:00 pm	European Union MDRs impact on device manufacturers- Michael Maier, Senior Partner, Medidee Services SA
	Reprocessing of surgical invasive devices, critical timeliness and technical documentation requirements under MDR- Michael Maier, Senior Partner, Medidee Services SA
4:30 pm	End of Seminar Day 1
5:00 pm	Evening Reception

*Times and topics subject to change



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Wednesday, March 25, 2020

8:00 am	Registration Begins- Main I & II
8:30 am	Radiation Sterilization Basics- Martell Winters, Nelson Laboratories, LLC
9:00 am	Process Definition Part 1- Sterilization Dose Establishment- Martell Winters, Nelson Laboratories, LLC
10:00 am	Morning Break
10:15 am	Radiation Sterilization Validations- Martell Winters, Nelson Laboratories, LLC
11:15 am	Dose Audits and Wrap Up- Martell Winters, Nelson Laboratories, LLC
12:00 pm	Lunch
1:00 pm	Packaging- Designed for Sterilization, Materials Selection, Product Combinations and Distribution- Wendy Mach, Nelson Laboratories, LLC
2:30 pm	Break
2:45 pm	Packaging- Test Method and Validation, case studies- Wendy Mach, Nelson Laboratories, LLC
4:00 pm	Break
4:15 pm	Cleaning Validations of Single Use Devices- Thor Rollins, Nelson Laboratories, LLC
5:00 pm	End of Seminar Day 2

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Thursday, March 26, 2020

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| 8:00 am | Registration Begins- Main I & II |
| 8:30 am | Reprocessing Validations of Reusable Medical Devices- Emily Mitzel, Nelson Laboratories, LLC and Melissa Galle, Nelson Labs Europe |
| 10:30 am | Break |
| 10:45 am | Biocompatibility ISO 10993- Thor Rollins, Nelson Laboratories, LLC |
| 12:00 pm | Lunch |
| 1:00 pm | Biocompatibility ISO 10993 Test Options- Thor Rollins, Nelson Laboratories, LLC |
| 2:15 pm | Break |
| 2:30 pm | Introduction to Chemical Characterization Basics- TBD, Nelson Labs Europe |
| 3:45 pm | Toxicological Assessments for Chemical Characterization- Thor Rollins, Nelson Laboratories, LLC |
| 3:45 pm | ISO 10993 Case Studies (biocompatibility failures as well)- Thor Rollins, Nelson Laboratories, LLC |
| 5:00 pm | End of seminar |

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