



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

**Tuesday, October 08, 2019**

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

\*Times and topics subject to change



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**Wednesday, October 09, 2019**

8:00 am	Registration Begins- Lumiere room
8:30 am	<b>Radiation Sterilization Basics- Martell Winters, Nelson Laboratories, LLC</b>
9:00 am	<b>Process Definition Part 1- Sterilization Dose Establishment- Martell Winters, Nelson Laboratories, LLC</b>
10:00 am	Morning Break
10:15 am	<b>Radiation Sterilization Validations- Martell Winters, Nelson Laboratories, LLC</b>
11:15 am	<b>Dose Audits and Wrap Up- Martell Winters, Nelson Laboratories, LLC</b>
12:00 pm	Lunch
1:00 pm	<b>Packaging- Designed for Sterilization, Materials Selection, Product Combinations and Distribution- Wendy Mach, Nelson Laboratories, LLC</b>
2:30 pm	Break
2:45 pm	<b>Packaging- Test Method and Validation, case studies- Wendy Mach, Nelson Laboratories, LLC</b>
3:45 pm	Break
4:00 pm	<b>Cleaning Validations of Single Use Devices- Audrey Turley, Nelson Laboratories, LLC</b>
5:00 pm	End of Seminar Day 2

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**Thursday, October 10, 2019**

8:00 am	Registration Begins- Lumiere room
8:30 am	<b>Reprocessing Validations of Reusable Medical Devices- Alpa Patel, Nelson Laboratories, LLC</b>
10:30 am	Break
10:45 am	<b>Biocompatibility ISO 10993- Audrey Turley, Nelson Laboratories, LLC</b>
12:00 pm	Lunch
1:00 pm	<b>Introduction to Chemical Characterization Basics- Sophie Michel, Nelson Labs Europe</b>
2:15 pm	Break
2:30 pm	<b>Chemical Characterization Basics continue- Sophie Michel, Nelson Labs Europe</b>
3:15 pm	<b>Toxicological Assessments for Chemical Characterization- Audrey Turley, Nelson Laboratories, LLC</b>
4:00 pm	<b>ISO 10993 Case Studies (biocompatibility failures as well)- Audrey Turley, Nelson Laboratories, LLC</b>
5:00 pm	End of seminar

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