



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

Tuesday, October 09, 2018

8:00 am	Registration Begins – Effner II room
8:30 am	Industry Update & Trends & Introduction to Nelson Labs – Mike Pizzi
8:45 am	European Union MDRs impact on device manufacturers- Dr. Christiana Hofmann- TUV
	Reprocessing of surgical invasive devices, critical timeliness and technical documentation requirements under MDR
10:15 am	Morning Break
10:30 am	Introduction to Microbiology & Sterilization – Wendy Wangsgard, PhD
12:00 pm	Lunch
1:00 pm	EO Sterilization Validations- Stefan Reisbacher, PhD
2:30 pm	Afternoon Break
2:45 pm	EO Sterilization Validations cont’d- Stefan Reisbacher, PhD
3:30 pm	EO Sterilization Case Studies- Stefan Reisbacher, PhD
4:00 pm	End of Seminar Day 1
5:00 pm	Evening Reception

*Times and topics subject to change



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Wednesday, October 10, 2018

8:00 am	Registration Begins- Effner II room
8:30 am	Radiation Sterilization Basics- Wendy Wangsgard, PhD
10:00 am	Morning Break
10:15 am	Radiation Sterilization Validations- Wendy Wangsgard, PhD
12:00 pm	Lunch
1:00 pm	Packaging- Designed for Sterilization, Materials Selection, Product Combinations and Distribution- Wendy Mach
2:30 pm	Break
2:45 pm	Packaging- Test Method and Validation, case studies- Wendy Mach
3:45 pm	Break
4:00 pm	Cleaning Validations of Single Use Devices- Thor Rollins
4:45 pm	End of Seminar Day 2

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Thursday, October 11, 2018

8:00 am	Registration Begins- Effner II room
8:30 am	Reprocessing Validations of Reusable Medical Devices- Emily Mitzel
10:30 am	Break
10:45 am	Biocompatibility ISO 10993- Thor Rollins
12:00 pm	Lunch
1:00 pm	Biocompatibility & Introduction to Chemical Characterization Basics- Thor Rollins
2:15 pm	Break
2:30 pm	Chemical Characterization Basics continue- Thor Rollins
3:15 pm	Toxicological Assessments for Chemical Characterization- Thor Rollins
4:00 pm	ISO 10993 Case Studies (biocompatibility failures as well)- Thor Rollins
5:00 pm	End of seminar

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