

**Pharmaceutical Sterility Assurance, Contamination Control and
Extractables and Leachables: Trends, Test Methods and Current Thinking**

Location: Philadelphia, PA

Tuesday, May 12, 2020

8:00 am	Registration Begins – Borghese Garden room
8:30 am	Introduction to Nelson Labs and Sterigenics– Mike Pizzi
8:45 am	Comparison Between Aseptic Processing and Terminal Sterilization- Annick Gillet, Sterigenics
9:15 am	Terminal Sterilization Concepts – Martell Winters, Nelson Labs
10:00 am	EO Sterilization: Concepts & Applications on Pharmaceutical Products- Annick Gillet, Sterigenics
10:30	Morning Break
10:45	Radiation Sterilization and Concepts– Bart Croonenborghs, Sterigenics
11:30	Concepts from ISO 19930:2017 and AAMI ST 67- Martell Winters, Nelson Labs
12:15 pm	Lunch
1:15 pm	NO₂ Sterilization- David Opie, Noxilizer
1:45 pm	What Does a Sterility Assurance Program Look Like?- Martell Winters
2:45 pm	Afternoon Break
3:00 pm	What Does a Sterility Assurance Program Look Like- continued
3:30 pm	Cleaning & Disinfection Efficacy Validations of Sanitizing Agents – Josef Mastej, Nelson Labs
5:00 pm	End of Seminar Day 1

*Times and topics subject to change

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Wednesday, May 13, 2020

8:00 am	Registration – Borghese Garden room
8:30 am	Endotoxin Control including inhibition and enhancement- Dan Lovero, Nelson Labs Fairfield
9:30 am	Particulate Testing for Pharmaceutical Products- Tonya Morris, Nelson Labs
10:15 pm	Morning Break
10:30 pm	Filtration Sterilization Validation for an Aseptic Process- Tonya Morris, Nelson Labs
12:00 pm	Lunch
1:00 pm	Terminal sterilization using moist heat – Jason Pope, Nelson Labs
2:30 pm	Afternoon Break
2:45 pm	ICH Stability Testing and Method Development- Shiri Hechter, Nelson Labs Fairfield
3:30 pm	Container Closure Integrity Testing – Mass Extraction – Jen Gygi
5:00 pm	End of Seminar Day 2

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Thursday, May 14, 2020

- 8:00 am Registration – Borghese Garden room
- 8:30 am **Introduction to Extractables and Leachables – Anja Cerstiaens, Nelson Labs Europe**
- Definitions
 - General concepts
 - Regulatory landscape
- 9.30 am **Mechanism of Leaching – Dries Cardoen, Nelson Labs Europe**
- Polymers 101
 - Glass 101
 - Mechanism of Leaching
- 10:15 am Morning Break
- 10:30 am **Extractables Studies : Do’s and Dont’s - Dries Cardoen, Nelson Labs Europe**
- Tailor-made study designs
 - Common pitfalls
- 11:45 am **How to Bridge Between Extractables and Leachables Studies - Anja Cerstiaens, Nelson Labs Europe**
- The threshold approach
 - Case study
- 12:15 pm Lunch
- 1:30 pm **Leachables Studies : Do’s and Dont’s - Dries Cardoen, Nelson Labs Europe**
- Tailor-made study designs
 - Common pitfalls
- 2:15 pm **Practical Approaches in E&L - Anja Cerstiaens, Nelson Labs Europe**
- Analytical techniques
- 3:00 pm Afternoon Break
- 3:15 pm **Case Studies - Anja Cerstiaens, Nelson Labs Europe**
- The impact of sterilization on the E&L profile
- 4:15 pm **Q&A – open discussion**
- 4:30 pm End of Seminar

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