



# Sterility Assurance Seminar

Catalonia | Spain

13-15 September, 2022

A close-up, macro photograph of a glass test tube and a pipette. A single, clear liquid drop is suspended at the tip of the pipette, about to fall into the test tube. The background is softly blurred, showing other laboratory glassware. The overall color palette is dominated by light blues and greens, with a white background at the top and bottom. The image is framed by a large, curved green shape at the top right and a blue shape at the bottom.

## Agenda

Tuesday, 13 September 2022

Day One | Sterility Assurance & Regulatory Landscape

- 8:30 – 9:00     **Registration / Coffee**
- 9:00 – 9:15     Welcome / Logistics / Day 1 Learning Objectives
- 9:15 – 9:45     Safeguarding Global Health
- 9:45 – 10:45    **Current events in Sterilization:** Standards Update  
& Emerging Modalities
- 10:45 – 11:00   **Break**
- 11:00 – 12:30    **INDUSTRY BREAKOUTS**
- Medical Device**
- EO Sterilization: Considerations for Neonate Products and Medical Devices & ISO 10993-7
  - Case study – EO-Sterilization Cycle Optimization to Meet Current Environmental and Industry Considerations
- Pharmaceutical**
- Comparison Between Aseptic Processing & Terminal Sterilization
  - Case study – The Effect of Sterilization on Active Pharmaceutical Ingredients
- 12:30 – 13:45   **Lunch**
- 13:45 – 14:45    Basic Microbiology and Sterilization
- 14:45 – 15:45    Facility Processing Capabilities: Ethylene Oxide & Gamma
- 15:45 – 16:00    **Break**
- 16:00 – 16:30    Technology Bingo
- 16:30 – 17:00    Wrap-Up
- 17:30 – 19:30    **Reception**

Note: Talk titles may change. Final version with speakers available shortly.



Wednesday, 14 September 2022

Day Two | Ethylene Oxide (EO) Sterilization Overview & Advanced Topics

- 8:00 – 8:15 Welcome / Day 2 Learning Objectives
- 8:15 – 9:30 Introduction to EO Technology & Regulatory Landscape
- 9:30 – 10:00 Process Definition
- 10:00 – 10:15 EO Packaging Considerations
- 10:15 – 10:30 **Break**
- 10:30 – 12:00 Workshop: Packaging & BI Location
- 12:00 – 13:30 **Lunch**
- 13:30 – 14:30 EO Validation & Cycle Requalification
- 14:30 – 15:15 Parametric Release
- 15:15 – 15:30 **Break**
- 15:30 – 16:15 The 3Rs of EO Sterilization:  
Sustaining the Continued Safe Use of EO
- 16:15 – 17:00 How to be a Mill-EO-naire
- 16:30 – 17:00 Wrap-Up

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Thursday, 15 September 2022

Day Three Radiation Sterilization Overview & Advanced Topics

- 8:00 – 8:15 Welcome / Day 3 Learning Objectives
- 8:15 – 9:30 Introduction to Ionizing Radiation Technology
- 9:30 – 10:00 Standards for Radiation Sterilization of Medical Devices
- 10:00 – 10:15 **Break**
- 10:15 – 10:40 Sterilization processing with Accelerator Technologies: E-Beam & X-Ray
- 10:40 – 12:00 Radiation Sterilization Dose Establishment/  
Dose Audits/Dose Setting Exercise
- 12:00 – 13:00 **Lunch**
- 13:00 – 13:30 Establishing the Maximum Acceptable Dose/Radiation Effect on Materials
- 13:30 – 14:45 Radiation Process Validation (IQ/OQ/PQ)
- 14:45 – 15:30 Radiation Sterilization “Jeopardy”
- 15:30 – 16:00 Wrap-up / Certificates

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