

TUESDAY, FEBRUARY 4, 2025 (The times listed are Eastern Time Zone)

8:30 a.m.–8:40 a.m. 8:40 a.m.–8:50 a.m. 8:50 a.m.–9:30 a.m.	Opening Session	Welcome & Introduction	Pamela Arora, AAMI Glenn Wright, PDA
		Forward Look and Keynote Introduction	Conference Chair: Dr. Gerald McDonnell, Johnson & Johnson
		Keynote Address – KILMER 2025	Dr. William Rutala, University of North Carolina

BREAK

10:30 a.m.–10:35 a.m. 10:35 a.m.–10:55 a.m. 10:55 a.m.–11:15 a.m. 11:15 a.m.–11:35 a.m. 11:35 a.m.–11:45 a.m. 11:45 a.m.–12:00 p.m.	Pushing Boundaries	Session Introduction	Session Chair: Amanda Benedict, AAMI
		Disinfectant Efficacy Validation: Selection of Test Materials and In-situ Evaluation	David Collins, Ecolab
		Wicked Stability: Oxidative Induction Time (OIT) Study	Dan Burgess, Boston Scientific
		Accelerating Innovation in Sterility Assurance by Revisiting the Past	John Logar, Johnson & Johnson
		Session Q&A	Session Chair: Amanda Benedict, AAMI
		Polling Session for KILMER Communities	

LUNCH BREAK

1:15 p.m.–1:20 p.m. 1:20 p.m.–1:35 p.m. 1:35 p.m.–1:55 p.m. 1:55 p.m.–2:15 p.m. 2:15 p.m.–2:35 p.m. 2:35 p.m.–2:45 p.m.	Microbiological Quality Level	Session Introduction	Session Chair: Terra Kremer, Johnson & Johnson
		Unlocking the Full Potential of QRM: A Modern Approach to Contamination Control	Amanda McFarland, ValSource
		Microbiology Quality Level (MQL): A Holistic and Proactive Approach to Product Quality	Stephen Langille, ValSource
		Fit for Purpose Contamination Control for ATMP's Based on Quality Risk Management Principles	Dieter Bachmann, Johnson & Johnson
		Microneedle Array Products- How to Establish a Microbiological Quality Level (MQL) for a Novel Dosage Form Without Clinical Experience or Regulatory Precedent	Jessica Chiaruttini, ValSource
		Session Q&A	Session Chair: Terra Kremer, Johnson & Johnson

BREAK

3:45 p.m.–3:50 p.m. 3:50 p.m.–4:10 p.m. 4:10 p.m.–4:30 p.m. 4:30 p.m.–4:50 p.m. 4:50 p.m.–5:05 p.m. 5:05 p.m.–5:15 p.m.	Sterilization Process Modalities	Session Introduction	Session Chair: Suzanne Butler, Medtronic
		Innovation in Understanding Lumen Sterilization in Alternative Sterilization Methods	David Opie, Noxilizer
		Parametric Application to the Validation of Vaporized Hydrogen Peroxide Sterilization	Mayuri Kasaraneni, Intuitive Surgical
		A Case Study on Glucagon-like Peptide-1 (GLP-1) and Epidermal Growth Factor (EGF): Evaluation of Supercritical Carbon Dioxide (scCO ₂) -Based Sterilization for Sensitive Biologic APIs	Ankita Sarkar, NovaSterilis, Inc
		Alternative Sterilization Modalities to Ethylene Oxide: Effects on Common Packaging Materials	Jordan Montgomery, Medtronic
		Session Q&A	Session Chair: Suzanne Butler, Medtronic

WEDNESDAY, FEBRUARY 5, 2025 (The times listed are Eastern Time Zone)

8:30 a.m.–8:40 a.m. 8:40 a.m.–9:25 a.m. 9:25 a.m.–9:30 a.m.	Opening Session	Session Introduction	Session Chair: Mike Sadowski, Sterilexcellence
		Best practice with sterilization MPQ - Panel Discussion and Polling	Mike Sadowski, Sterilexcellence Jeff Martin, SQS Consulting Alexander Stoll, Fresenius Kabi Nicole McLees, Olympus
		Session Q&A	Session Chair: Mike Sadowski, Sterilexcellence

BREAK

10:30 a.m.–10:35 a.m. 10:35 a.m.–10:55 a.m. 10:55 a.m.–11:15 a.m. 11:15 a.m.–11:30 a.m. 11:30 a.m.–11:50 a.m. 11:50 a.m.–12:00 p.m.	Embracing Digital Technology	Session Introduction	Session Chair: Nupur Jain, Intuitive Surgical Inc
		Medical Device Validation with Artificial Intelligence: A New Approach to Family Adoption	Terra Kremer, Johnson & Johnson
		Process Analytical Technology for Inline Microbial Contamination Detection	Karin Bals, Johnson & Johnson
		Big Data Analysis Platform to Improve Sterilizer Performance	Daniel Lasley, Baxter
		Contemporary Three-Pronged Approach to Minimize Microbial Contamination and Maintain Product Quality for Pharmaceuticals and Medical Devices	Sarah Sambolich, Ambrx
		Session Q&A	Session Chair: Nupur Jain, Intuitive Surgical Inc

LUNCH BREAK		
1:15 p.m.–1:20 p.m.	Process Control Strategies	Session Introduction <i>Session Chair:</i> Thor Rollins, Sotera Health, LLC
1:20 p.m.–1:40 p.m.		The Role of Data Management in the Transition from Periodic to Continuous Microbial Monitoring in the Control of Manufacturing Processes David Hussong, Eagle
1:40 p.m.–2:00 p.m.		EO Parametric Process Control Daniel Howell, STERIS
2:00 p.m.–2:15 p.m.		Closed-Loop Controlled Sterilization Process Maruti Sinha, Medtronic Patrick Anibaldi, Abbott
2:15 p.m.–2:35 p.m.		What Can We Learn From the Mars Sample Return Mission on Risk Management and Microbial Life Detection? Dr. Gerald McDonnell, Johnson & Johnson Alvin Smith, NASA
2:35 p.m.–2:45 p.m.		Session Q&A <i>Session Chair:</i> Thor Rollins, Sotera Health, LLC
BREAK		
3:45 p.m.–3:50 p.m.	Sustainability	Session Introduction <i>Session Chair:</i> Emily Craven, Boston Scientific Corporation
3:50 p.m.–4:10 p.m.		Sustainable Sterilization: Navigating the Transition to a Circular Economy in Medical Device Sterilization Gillian Cairns, BSI
4:10 p.m.–4:30 p.m.		Implementing x-ray for Single Use Systems Sterilization: What's Next? Samuel Dorey, Sartorius
4:30 p.m.–4:50 p.m.		A Review of Recombinant Endotoxin Reagent Technologies Jason Rogers, STERIS Tonia Bevers, Abbott Melanie Lang, Abbott
4:50 p.m.–5:05 p.m.		Effect of Ethylene Oxide Post-Sterilization Exposure Cycle Design on Fugitive Emissions and Product Residuals Rishabh Jain, BSCI
5:05 p.m.–5:15 p.m.		Session Q&A <i>Session Chair:</i> Emily Craven, Boston Scientific Corporation
THURSDAY, FEBRUARY 6, 2025 (The times listed are Eastern Time Zone)		
8:30 a.m.–8:35 a.m.	Opening Session	Session Introduction <i>Session Chair:</i> Hal Baseman, Valsource, Inc.
8:35 a.m.–9:20 a.m.		Career Development - What is the Industry Need? Jim Vesper, ValSource Neil Rowan, Technological University at the Shannon Wendy Wangsgard, ICU Medical Ann O'Connell, Ibec
9:20 a.m.–9:30 a.m.		Session Q&A <i>Session Chair:</i> Hal Baseman, Valsource, Inc.
BREAK		
10:30 a.m.–11:05 a.m.	Community Continuity	Session Introduction <i>Session Chair:</i> Jen Benolken, DuPont
11:05 a.m.–12:05 p.m.		JeoPARODY John Logar, Johnson & Johnson
12:05 p.m.–12:15 p.m.		Session Q&A <i>Session Chair:</i> Jen Benolken, DuPont
LUNCH BREAK		
1:15 p.m.–1:20 p.m.	Regulatory Science	Session Introduction <i>Session Chair:</i> Marcia Baroni, EBSI
1:20 p.m.–1:40 p.m.		Case Study Review: Lessons Learned Validating Rapid Microbiological Methods Stacey Ramsey, Charles River Labs
1:40 p.m.–2:00 p.m.		Parametric Release Journeys in Mexico and China: A Comparative Analysis of Industry Maturity, Standards, and Regulation of Parametric Release for Products Terminally Sterilized with Moist Heat in Mexico and China Ciara MacSweeney, Baxter
2:00 p.m.–2:20 p.m.		Regulatory Alignment on Risk Evaluation and Implementation of X-ray Sterilization as an Equivalent Alternative to Gamma James Hathcock, Cytiva
2:20 p.m.–2:35 p.m.		Utilizing a Rapid Microbiological Method to Support Annex 1 Requirements for Continuous Viable Monitoring Philip Villari, Modern Microbial Methods Collaboration
2:35 p.m.–2:45 p.m.		Session Q&A <i>Session Chair:</i> Marcia Baroni, EBSI
BREAK		
3:45 p.m.–3:50 p.m.	Closing Session	Session Introduction Pamela Arora, AAMI Glenn Wright, PDA Amanda Benedict, AAMI
3:50 p.m.–4:10 p.m.		Call to Action Dr. Gerald McDonnell, Johnson & Johnson
4:10 p.m.–4:20 p.m.		Poster Awards Amanda, Benedict, AAMI Dr. Gerald McDonnell, Johnson & Johnson
4:20 p.m.–4:30 p.m.		Conference Close Dr. Gerald McDonnell, Johnson & Johnson