

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

8:15 a.m.–8:40 a.m.	Opening Session	Welcome & Introduction - NEW START TIME	Pamela Arora, AAMI Glenn Wright, PDA
8:40 a.m.–8:50 a.m.		Forward Look and Keynote Introduction	Conference Chair: Dr. Gerald McDonnell, Johnson & Johnson
8:50 a.m.–9:30 a.m.		Keynote Address – KILMER 2025	Dr. William Rutala, University of North Carolina
BREAK			
10:30 a.m.–10:35 a.m.	Pushing Boundaries	Session Introduction	Session Chair: Amanda Benedict, AAMI
10:35 a.m.–10:55 a.m.		Disinfectant Efficacy Validation: Selection of Test Materials and In-situ Evaluation	David Collins, Ecolab
10:55 a.m.–11:15 a.m.		Wicked Stability: Oxidative Induction Time (OIT) Study	Dan Burgess, Boston Scientific
11:15 a.m.–11:35 a.m.		Accelerating Innovation in Sterility Assurance by Revisiting the Past	John Logar, Johnson & Johnson
11:35 a.m.–11:45 a.m.		Session Q&A	Session Chair: Amanda Benedict, AAMI
11:45 a.m.–12:00 p.m.		Polling Session for KILMER Communities	
LUNCH BREAK			
1:15 p.m.–1:20 p.m.	Microbiological Quality Level	Session Introduction	Session Chair: Terra Kremer, Johnson & Johnson
1:20 p.m.–1:35 p.m.		Unlocking the Full Potential of QRM: A Modern Approach to Contamination Control	Amanda McFarland, ValSource
1:35 p.m.–1:55 p.m.		Microbiology Quality Level (MQL): A Holistic and Proactive Approach to Product Quality	Stephen Langille, ValSource
1:55 p.m.–2:15 p.m.		Fit for Purpose Contamination Control for ATP's Based on Quality Risk Management Principles	Dieter Bachmann, Johnson & Johnson
2:15 p.m.–2:35 p.m.		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
2:35 p.m.–2:45 p.m.		Session Q&A	Session Chair: Terra Kremer, Johnson & Johnson
BREAK			
3:45 p.m.–3:50 p.m.	Sterilization Process Modalities	Session Introduction	Session Chair: Suzanne Butler, Medtronic
3:50 p.m.–4:10 p.m.		Lumen Sterilization and Gas Addition Dynamics	David Opie, Noxilizer
4:10 p.m.–4:30 p.m.		NO2 Sterilization and Medical Device Compatibility	Mohamad Al-Sheikhly, University of Maryland
4:30 p.m.–4:50 p.m.		A Case Study on Glucagon-like Peptide-1 (GLP-1) and Epidermal Growth Factor (EGF): Evaluation of Supercritical Carbon Dioxide (scCO2) -Based Sterilization for Sensitive Biologic APIs	Ankita Sarkar, NovaSterilis, Inc
4:50 p.m.–5:05 p.m.		Alternative Sterilization Modalities to Ethylene Oxide: Effects on Common Packaging Materials	Jordan Montgomery, Medtronic
5:05 p.m.–5:15 p.m.		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.	Opening Session	Session Introduction	Session Chair: Chris Anderson, Johnson & Johnson
8:40 a.m.–9:25 a.m.		Best practice with sterilization MPQ - Panel Discussion and Polling	Chris Anderson, Johnson & Johnson Jeff Martin, SQS Consulting Alexander Stoll, Fresenius Kabi Nicole McLees, Olympus
9:25 a.m.–9:30 a.m.		Session Q&A	Session Chair: Johnson & Johnson
BREAK			
10:30 a.m.–10:35 a.m.	Embracing Digital Technology	Session Introduction	Session Chair: Nupur Jain, Intuitive Surgical Inc
10:35 a.m.–10:55 a.m.		Medical Device Validation with Artificial Intelligence: A New Approach to Family Adoption	Terra Kremer, Johnson & Johnson
10:55 a.m.–11:15 a.m.		Process Analytical Technology for Inline Microbial Contamination Detection	Karin Bals, Johnson & Johnson
11:15 a.m.–11:30 a.m.		Big Data Analysis Platform to Improve Sterilizer Performance	Daniel Lasley, Baxter
11:30 a.m.–11:50 a.m.		Contemporary Three-Pronged Approach to Minimize Microbial Contamination and Maintain Product Quality for Pharmaceuticals and Medical Devices	Sarah Sambolich, Ambrx
11:50 a.m.–12:00 p.m.		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 Fred Ayers, ValSource, Inc.
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. Jim Vesper, ValSource
8:35 a.m.–9:20 a.m.		Career Development - What is the Industry Need? 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 Sopheak Srun, Quality Tech Services, LLC Chris Anderson, Johnson & Johnson Fred Ayers, ValSource, Inc. Vu Lekate, Abbott Don Singer, Ecolab Life Sciences Jami McLaren, Boston Scientific
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