PDA Aseptic Processing of Biopharmaceuticals Conference 2025

Agenda

Tuesday, 4 November

South Korea Standard Time Standard Time (UTC +9:00)

08:00 – 08:45	**Registration**	
08:45 – 08:50	**Opening Session**	
	08:45 – 08:50	**Opening Remarks** • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG*
08:50 – 10:40	**Session 1: Annex 1 Implementation – Progress, Updates and Practical Insights**	
	08:50 – 09:20	**Annex 1 Implementation in Practice: Lessons from Pfizer Australia's Journey Toward Contamination Control Excellence** • **Christopher Cassidy** , Operational Readiness Director, *Pfizer*
	09:20 – 09:50	**Implementation of Automated Visual Inspection: Getting It Right From The Start** • **Bram Keymolen MS**, Co-Founder, *eyetec*
	09:50 – 10:20	**Integrating Risk-Based Approaches in Contamination Control Strategy: An Inspector's View** • **Steven Bowen Ph.D.**, Principal Consultant, *Eliquent Life Sciences*
	10:20 – 10:40	**Q&A and Panel Discussion** • **Christopher Cassidy** , Operational Readiness Director, *Pfizer* • **Bram Keymolen MS**, Co-Founder, *eyetec* • **Steven Bowen Ph.D.**, Principal Consultant, *Eliquent Life Sciences* • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG*
10:40 – 11:10	**Coffee Break**	
11:10 – 12:40	**Session 2: Contamination Control Strategy in Aseptic Manufacturing (Part 1)**	
	11:10 – 11:40	**Environmental Monitoring (Performance Qualification) Approaches vs. Real World Cases: Insights Uncover Myths** • **Christian Scheuermann** , Global Technical Services Manager, *Charles River Laboratories*
	11:40 – 12:10	**Strengthening Smoke Study Practices: A Case Study in Aseptic Manufacturing** • **Ercan Cetin** , MSAT Manager, *Johnson & Johnson*
		Contamination Control Failures: What We Learn from the Worst-Case Scenarios

	12:10 – 12:40	• **David Keen MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*
12:40 – 14:10	**Lunch Break**	
	12:40 – 12:55	**Demo Session by Körber**
14:10 – 14:30	**Session 2: Contamination Control Strategy in Aseptic Manufacturing (Part 2)**	
	14:10 – 14:30	**Q&A and Panel Discussion** • **David Keen MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences* • **Ercan Cetin** , MSAT Manager, *Johnson & Johnson* • **Christian Scheuermann** , Global Technical Services Manager, *Charles River Laboratories* • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG*
14:30 – 15:50	**Session 3: New Technologies and Modalities in Aseptic Biomanufacturing**	
	14:30 – 15:00	**Regulatory Findings and Expectations in Robotics and Machine Learning** • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG*
	15:00 – 15:30	**Aseptic Manufacturing for mRNA, ADCs, and Novel Biologics** • **Francesco Cicirello PharmD, MSc**, Senior Director, Quality Compliance BioNTainer, *BioNTech*
	15:30 – 15:50	**Q&A and Panel Discussion** • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG* • **Francesco Cicirello PharmD, MSc**, Senior Director, Quality Compliance BioNTainer, *BioNTech* • **Christopher Cassidy** , Operational Readiness Director, *Pfizer*
15:50 – 16:20	**Coffee Break**	
16:20 – 17:40	**Session 4: Audit Reports and Compliance Issues**	
	16:20 – 16:50	**Adopting USP Chapter <86>: Efficiently Transitioning to Recombinant Endotoxin Testing and Case Study** • **Alan Hoffmeister** , Senior Global Scientific Portfolio Specialist, *Charles River Laboratories* • **Shady Kamal Ph.D.**, Principal Scientist, Manufacturing Science & Technology, *Galderma*
	16:50 – 17:20	**Building a Culture of Compliance and Continuous Improvement** • **Wei Xia Ang Ph.D.**, Senior Regulatory Compliance Lead, *Cytiva*
	17:20 – 17:40	**Q&A and Panel Discussion** • **Emily Cheah PhD**, Senior Managing Director Singapore and APAC Technical Operations Lead, *Charles River Laboratories* • **Alan Hoffmeister** , Senior Global Scientific Portfolio Specialist, *Charles River Laboratories* • **Shady Kamal Ph.D.**, Principal Scientist, Manufacturing Science & Technology, *Galderma* • **Wei Xia Ang Ph.D.**, Senior Regulatory Compliance Lead, *Cytiva*

Wednesday, 5 November

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08:45 – 10:05	**Session 5: Data Integrity and Digital Compliance**	
	08:45 – 09:15	**Common Data Integrity Pitfalls Observed During Inspections: Intentional, Unintentional and Systemic Vulnerabilities** • **Francesco Cicirello PharmD, MSc**, Senior Director, Quality Compliance BioNTainer, *BioNTech*
	09:15 – 09:45	**Audit Findings: Common Data Integrity Gaps** • **Michie (Mei Kuen) Ong** , Executive Director, Head of Product Quality, *Gilead Sciences*
	09:45 – 10:05	**Q&A and Panel Discussion** • **Michie (Mei Kuen) Ong** , Executive Director, Head of Product Quality, *Gilead Sciences* • **Francesco Cicirello PharmD, MSc**, Senior Director, Quality Compliance BioNTainer, *BioNTech* • **Emily Cheah PhD**, Senior Managing Director Singapore and APAC Technical Operations Lead, *Charles River Laboratories*
10:05 – 10:35	**Coffee Break**	
10:35 – 11:25	**Session 6: Supply Chain Resilience and Cold Chain Logistics**	
	10:35 – 11:05	**Cold Chain Management for Biologics and Cell Therapies** • **Ching Mien Oh Ph.D.**, Global Logistics Account Director, Business Development, *UPS Healthcare* • **Andrew Lee** , Associate Director, Global Quality Compliance and Audit Management, *Lonza*
	11:05 – 11:25	**Q&A and Panel Discussion** • **Louis Indra** , Sr. Quality Compliance Lead, Regulatory Compliance, *J&J Innovative Medicine* • **Ching Mien Oh Ph.D.**, Global Logistics Account Director, Business Development, *UPS Healthcare* • **Andrew Lee** , Associate Director, Global Quality Compliance and Audit Management, *Lonza*
11:25 – 11:55	**Session 7: Packaging Innovations for Parenteral Biopharmaceuticals (Part 1)**	
	11:25 – 11:55	**Primary Packaging Compatibility, Sterility and The Use For High Potent Products** • **Michael Hessenthaler** , Vice President, Sales, *Bausch+Ströbel GmbH + Co. KG*
11:55 – 13:25	**Lunch Break**	
13:25 – 14:45	**Session 7: Packaging Innovations for Parenteral Biopharmaceuticals (Part 2)**	
	13:25 – 13:55	**USP <382> takes effect in December: Are you ready?** • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	13:55 – 14:25	**RTU Primary Packaging and Aseptic Transfer: An Integrated Perspective** • **Riccardo Marcon** , Senior Vice President Sales & Marketing – DCS, *Stevanato Group* • **David Kelly MEng**, Manager, Global Engineering, *Pfizer Inc*

	14:25 – 14:45	**Q&A and Panel Discussion** • **Michael Hessenthaler** , Vice President, Sales, *Bausch+Ströbel GmbH + Co. KG* • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva* • **Riccardo Marcon** , Senior Vice President Sales & Marketing – DCS, *Stevanato Group* • **David Kelly MEng**, Manager, Global Engineering, *Pfizer Inc* • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
14:45 – 15:15	**Coffee Break**	
15:15 – 17:05	**Session 8: Cell and Gene Therapy – Aseptic Manufacturing Challenges**	
	15:15 – 15:45	**Aseptic Processing for ATMPs: Facility and Process Design** • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
	15:45 – 16:15	**Aseptic Manufacturing in Cell & Gene Therapy, Challenges and Opportunities in Implementing Annex 1: A Korea Perspective** • **Jaeseung Lim, Ph.D.** , CEO & CSO, *Cellatoz Therapeutics, Inc*
	16:15 – 16:45	**Regulatory and Quality Considerations for Regenerative Medicine Product Manufacturing: A Japan Perspective** • **Takumi Miura Ph.D.**, Chief, Section of Somatic Cell Therapy Products, Division of Cell-Based Therapeutic Products, *National Institute of Health Sciences*
	16:45 – 17:05	**Q&A and Panel Discussion** • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)* • **Jaeseung Lim, Ph.D.** , CEO & CSO, *Cellatoz Therapeutics, Inc* • **Takumi Miura Ph.D.**, Chief, Section of Somatic Cell Therapy Products, Division of Cell-Based Therapeutic Products, *National Institute of Health Sciences* • **Michie (Mei Kuen) Ong** , Executive Director, Head of Product Quality, *Gilead Sciences*