



Tuesday, 4 November

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

08:00 – 08:45	Registration
Opening Session	
08:45 – 08:50	Opening Remarks 08:45 – 08:50 Richard Denk , Senior Consultant, Aseptic Processing & Containment, SKAN AG
Session 1: Annex 1 Implementation – Progress, Updates and Practical Insights	
08:50 – 10:40	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
Session 2: Contamination Control Strategy in Aseptic Manufacturing (Part 1)	
11:10 – 12:40	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, <i>Ecolab Life Sciences</i>
Lunch Break		
12:40 – 14:10	12:40 – 12:55	Demo Session by Körber
Session 2: Contamination Control Strategy in Aseptic Manufacturing (Part 2)		
14:10 – 14:30	Q&A and Panel Discussion	
	14:10 – 14:30	• David Keen MRSB CBiol, Director Pharmaceutical Microbiology & Consulting, <i>Ecolab Life Sciences</i> • Ercan Cetin , MSAT Manager, <i>Johnson & Johnson</i> • Christian Scheuermann , Global Technical Services Manager, <i>Charles River Laboratories</i> • Richard Denk , Senior Consultant, Aseptic Processing & Containment, <i>SKAN AG</i>
Session 3: New Technologies and Modalities in Aseptic Biomanufacturing		
14:30 – 15:50	14:30 – 15:00	Regulatory Findings and Expectations in Robotics and Machine Learning • Richard Denk , Senior Consultant, Aseptic Processing & Containment, <i>SKAN AG</i>
	15:00 – 15:30	Aseptic Manufacturing for mRNA, ADCs, and Novel Biologics • Francesco Cicirello PharmD, MSc, Senior Director, Quality Compliance BioNTainer, <i>BioNTech</i>
	15:30 – 15:50	Q&A and Panel Discussion • Richard Denk , Senior Consultant, Aseptic Processing & Containment, <i>SKAN AG</i> • Francesco Cicirello PharmD, MSc, Senior Director, Quality Compliance BioNTainer, <i>BioNTech</i> • Christopher Cassidy , Operational Readiness Director, <i>Pfizer</i>
15:50 – 16:20	Coffee Break	
Session 4: Audit Reports and Compliance Issues		
16:20 – 17:40	16:20 – 16:50	Adopting USP Chapter <86>: Efficiently Transitioning to Recombinant Endotoxin Testing and Case Study • Alan Hoffmeister , Senior Global Scientific Portfolio Specialist, <i>Charles River Laboratories</i> • Shady Kamal Ph.D., Principal Scientist, Manufacturing Science & Technology, <i>Galderma</i>
	16:50 – 17:20	Building a Culture of Compliance and Continuous Improvement • Wei Xia Ang Ph.D., Senior Regulatory Compliance Lead, <i>Cytiva</i>
	17:20 – 17:40	Q&A and Panel Discussion • Emily Cheah PhD, Senior Managing Director Singapore and APAC Technical Operations Lead, <i>Charles River Laboratories</i> • Alan Hoffmeister , Senior Global Scientific Portfolio Specialist, <i>Charles River Laboratories</i> • Shady Kamal Ph.D., Principal Scientist, Manufacturing Science & Technology, <i>Galderma</i> • Wei Xia Ang Ph.D., Senior Regulatory Compliance Lead, <i>Cytiva</i>

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, <i>BioNTech</i>
	09:15 – 09:45	Audit Findings: Common Data Integrity Gaps • Michie (Mei Kuen) Ong , Executive Director, Head of Product Quality, <i>Gilead Sciences</i>
09:45 – 10:05	Q&A and Panel Discussion	
	09:45 – 10:05	• Michie (Mei Kuen) Ong , Executive Director, Head of Product Quality, <i>Gilead Sciences</i> • Francesco Cicirello PharmD, MSc, Senior Director, Quality Compliance BioNTainer, <i>BioNTech</i> • Emily Cheah PhD, Senior Managing Director Singapore and APAC Technical Operations Lead, <i>Charles River Laboratories</i>
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, <i>UPS Healthcare</i> • Andrew Lee , Associate Director, Global Quality Compliance and Audit Management, <i>Lonza</i>
	11:05 – 11:25	Q&A and Panel Discussion • Louis Indra , Sr. Quality Compliance Lead, Regulatory Compliance, <i>J&J Innovative Medicine</i> • Ching Mien Oh Ph.D., Global Logistics Account Director, Business Development, <i>UPS Healthcare</i> • Andrew Lee , Associate Director, Global Quality Compliance and Audit Management, <i>Lonza</i>
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, <i>Bausch+Ströbel GmbH + Co. KG</i>
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, <i>Cytiva</i>
	13:55 – 14:25	RTU Primary Packaging and Aseptic Transfer: An Integrated Perspective • Riccardo Marcon , Senior Vice President Sales & Marketing – DCS, <i>Stevanato Group</i> • David Kelly MEng, Manager, Global Engineering, <i>Pfizer Inc</i>

	Q&A and Panel Discussion • Michael Hessenthaler , Vice President, Sales, <i>Bausch+Ströbel GmbH + Co. KG</i> • Brent N. Lieffers , Senior Director, Innovation Advocacy, <i>Cytiva</i> • Riccardo Marcon , Senior Vice President Sales & Marketing – DCS, <i>Stevanato Group</i> • David Kelly MEng, Manager, Global Engineering, <i>Pfizer Inc</i> • David Y.H. Chang, Ph.D. , CEO, <i>Taiwan Bio-Manufacturing Corporation (TBMC)</i>								
14:45 – 15:15	Coffee Break								
15:15 – 17:05	Session 8: Cell and Gene Therapy – Aseptic Manufacturing Challenges <table> <tr> <td data-bbox="236 504 405 640">15:15 – 15:45</td><td data-bbox="405 504 1557 640"> Aseptic Processing for ATMPs: Facility and Process Design • David Y.H. Chang, Ph.D. , CEO, <i>Taiwan Bio-Manufacturing Corporation (TBMC)</i> </td></tr> <tr> <td data-bbox="236 640 405 813">15:45 – 16:15</td><td data-bbox="405 640 1557 813"> Aseptic Manufacturing in Cell & Gene Therapy, Challenges and Opportunities in Implementing Annex 1: A Korea Perspective • Jaeseung Lim, Ph.D. , CEO & CSO, <i>Cellatoz Therapeutics, Inc</i> </td></tr> <tr> <td data-bbox="236 813 405 1010">16:15 – 16:45</td><td data-bbox="405 813 1557 1010"> 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, <i>National Institute of Health Sciences</i> </td></tr> <tr> <td data-bbox="236 1010 405 1361">16:45 – 17:05</td><td data-bbox="405 1010 1557 1361"> Q&A and Panel Discussion • David Y.H. Chang, Ph.D. , CEO, <i>Taiwan Bio-Manufacturing Corporation (TBMC)</i> • Jaeseung Lim, Ph.D. , CEO & CSO, <i>Cellatoz Therapeutics, Inc</i> • Takumi Miura Ph.D., Chief, Section of Somatic Cell Therapy Products, Division of Cell-Based Therapeutic Products, <i>National Institute of Health Sciences</i> • Michie (Mei Kuen) Ong , Executive Director, Head of Product Quality, <i>Gilead Sciences</i> </td></tr> </table>	15:15 – 15:45	Aseptic Processing for ATMPs: Facility and Process Design • David Y.H. Chang, Ph.D. , CEO, <i>Taiwan Bio-Manufacturing Corporation (TBMC)</i>	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, <i>Cellatoz Therapeutics, Inc</i>	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, <i>National Institute of Health Sciences</i>	16:45 – 17:05	Q&A and Panel Discussion • David Y.H. Chang, Ph.D. , CEO, <i>Taiwan Bio-Manufacturing Corporation (TBMC)</i> • Jaeseung Lim, Ph.D. , CEO & CSO, <i>Cellatoz Therapeutics, Inc</i> • Takumi Miura Ph.D., Chief, Section of Somatic Cell Therapy Products, Division of Cell-Based Therapeutic Products, <i>National Institute of Health Sciences</i> • Michie (Mei Kuen) Ong , Executive Director, Head of Product Quality, <i>Gilead Sciences</i>
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