PDA Aseptic Processing of Biopharmaceuticals 컨퍼런스 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** When pharmaceutical manufacturers decide to implement Automated Visual Inspection (AVI) for the first time, or even when they have experience and want to get a new AVI line for a new product, a lot of common mistakes are made. It is not necessarily during the execution of the project that you win or lose the project goals and milestones. Equally important is the part before: the specification and ordering of the machine. At the end of the project, a smooth handover into routine manufacturing processes can be achieved, if the project team pays attention to the right things. In this presentation, I will outline an approach we think is best followed when implementing AVI. I will illustrate each step and its possible pitfalls with real life examples from various implementation projects. Having stood at AVI machines for days and nights in a row, my team and I have probably come across a range of approaches and strategies and we now have valuable hands-on experience accumulated over the last 15 years. I will discuss some of the mistakes that are commonly made during AVI implementation projects and their potential consequences: • Poor defect definition and classification at the start of a project • Lack of focus on the mechanical design of the AVI system • Taking shortcuts at the stages of Feasibility Tests or Engineering Runs • Missing the opportunity to use Factory Acceptance Tests (FAT) as a stepstone to project success … and many others. • **Bram Keymolen MS**, Co-Founder, *eyetec*
		Integrating Risk-Based Approaches in Contamination Control Strategy: An Inspector's View Prevention of microbial, particulate, and chemical contamination is a critical focus area for health authority inspections. Contamination events or inadequate prevention controls can have dire consequences for patient safety and regulatory compliance and could lead to actions such as product recalls, inspectional observations, warning letters, import alerts and potential delays in application approvals. Each individual facility, product and manufacturing process carry unique risks for contamination that need to be thoroughly assessed and documented in a Contamination Control Strategy (CCS). The CCS is a complex document

	09:50 – 10:20	that must account for many potential sources of contamination, existing strategies to control contamination, and methods used to detect and monitor contamination if it should occur. It requires input from a multidisciplinary team on an array of topics such as incoming material control, facility and equipment design, flows of materials, personnel, and waste within the facility, process design, aseptic practices, cleaning procedures and validation, gowning practices, environmental monitoring and analytical testing. This presentation will give a former FDA investigator's perspective on the creation of an effective CCS and some common pitfalls to avoid. • **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** "My microbial environment is stable as long as my process is stable." This and similar statements are used, despite the trending requirements in the new Annex 1, as a justification to decline any questioning on the microbial status quo. That attitude is excluding the fact that microbes are highly adaptable and are more diverse, even in pharmaceutical environments, as generally expected. We compared real world global EM data with EMPQ data from our global customer database. Our findings suggest that common EM strategies do not fully uncover microbial challenges that could potentially originate from manufacturing environments. • **Christian Scheuermann** , Global Technical Services Manager, *Charles River Laboratories*
	11:40 – 12:10	**Strengthening Smoke Study Practices: A Case Study in Aseptic Manufacturing** In response to a regulatory observation citing insufficient smoke visibility during dynamic airflow visualization, Janssen Vaccines initiated a comprehensive review and remediation program to strengthen the robustness of its smoke study practices. Although the observation did not indicate a direct risk to product quality or patient safety, it underscored the importance of clear, demonstrable airflow patterns in aseptic environments. This presentation will walk through the structured response from root cause analysis to the implementation of targeted corrective and preventive actions. Enhancements included procedural revisions, equipment upgrades, improved filming techniques, and targeted training to ensure consistent execution and evaluation. A full re-execution of the smoke study under improved conditions was planned to close the loop and align with regulatory expectations. Along the way, valuable lessons learned about how subtle choices in materials and methods can lead to surprising consequences. These insights will be shared to help others avoid common pitfalls and elevate the quality of their airflow visualization programs. • **Ercan Cetin** , MSAT Manager, *Johnson & Johnson*
	12:10 – 12:40	**Contamination Control Failures: What We Learn from the Worst-Case Scenarios** When a significant contamination event occurs a site is under immense pressure to find the source, find a root cause and ensure both product and process are made safe. These investigations are among the most resource intensive and pressured environments pharmaceutical professionals can find themselves in. Time for reflection and time to consider what went wrong often comes later, once the immediate danger has passed. Across the world and more locally there are a number of contamination events occurring. What lessons can be learnt from them? How can you use this data to better strengthen your contamination control strategy? • **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** The presentation will focus on current Inspector Findings in aseptic processing of sterile pharmaceutical products and the topic of human free – Barrier Gloveless aseptic Operations. On current Inspector findings the following topics will be covered. Filling Line Set Up of indirect product contact surfaces like stopper bowl and stopper transfer. First Air Principles and what is important to consider. Glove management including visual inspection of the gloves before and after the use. Furthermore material transfers from Grade C into Grade A as for Ready to Use packed primary containers as Syringes, Vials etc. . As mentioned in the EU GMP and PIC/s Annex 1 the use of Robotics should be considered to reduce human interventions. During the presentation the design of Robotics in Grade A will be covered as well how Robotics might pose a risk to the sterile pharmaceutical materials and product. • **Richard Denk** , Senior Consultant, Aseptic Processing & Containment, *SKAN AG*
	15:00 – 15:30	**Aseptic Manufacturing for mRNA, ADCs, and Novel Biologics** In this presentation, the evolving landscape of aseptic manufacturing for advanced modalities including **mRNA therapeutics**, and **Antibody-Drug Conjugates (ADCs)** will be explored. The session will emphasize **phase-appropriate process validation strategies** tailored to the unique challenges of early-stage development. Drawing from recent regulatory guidance and practical experience, the talk will dissect the **scientific and risk-based approaches** to validation, including: • **Aseptic Process Simulation (APS)** as a cornerstone of sterility assurance • **Bracketing and matrixing strategies** for batch validation under constrained development timelines • **Validation expectations for ATMPs and investigational biologics**, referencing EMA and PIC/S Annex 13 principles Attendees will gain insights into: • How to balance **regulatory expectations** with **development agility**. • The role of **risk assessments** in defining validation scope • Strategies to ensure **robust sterility assurance** while enabling innovation in formulation and delivery technologies This session is designed for professionals involved in **quality assurance** , **regulatory affairs**, and **technical operations**, offering a pragmatic framework for navigating aseptic validation in the dynamic field of biopharmaceutical development. • **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**

Session 4: Audit Reports and Compliance Issues

16:20 – 16:50	**Adopting USP Chapter <86>: Efficiently Transitioning to Recombinant Endotoxin Testing and Case Study** The official publication of USP *Chapter <86> Bacterial Endotoxins Test Using Recombinant Reagents*, marks a significant milestone in bacterial endotoxin testing, incorporating recombinant reagents as an accepted method. This change prompts critical questions for laboratories: What updates are necessary to existing procedures? Can current legacy systems continue, or is an overhaul required? How can this be done efficiently and align with global regulations. For labs planning to adopt these recombinant methods, understanding the pathway for a seamless transition is vital. Including a real-world case study with supporting data, from Galderma, detailing a potential validation process and feasibility study, this presentation will tackle these critical questions head-on and offer practical guidance for incorporating recombinant BET methods with minimal operational disruption. This session will cover: • The implications of Chapter <86> on your lab's current practices. • A comparative analysis of USP <86> and international regulations to align global compliance strategies. • Step-by-step recommendations for adopting recombinant methods, with a case study. Attendees will leave equipped with actionable insights to adapt to regulatory changes efficiently, ensuring compliance while safeguarding patient safety and maintaining cost-effective operations. • **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** The manufacturing of cell and gene therapies (CGT) presents unique challenges driven by product complexity, patient-specific workflows, and extreme sensitivity to process and material variation. Ensuring Good Manufacturing Practice (GMP) compliance for CGT products therefore requires a phase-appropriate, lifecycle approach to quality that extends and adapts traditional biologics expectations. Early clinical work often uses scientifically justified, simplified controls to protect participant safety, but as programs advance, drug developers must progressively implement full CGMP controls (facility and environmental controls, validated aseptic processing, and rigorous documentation) to support later-stage evidence and licensure. In this session, we will explore phase-appropriate GMP requirements for cell and gene therapy products and review case studies that highlight regulatory perspectives. • **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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Session 5: Data Integrity and Digital Compliance

	Common Data Integrity Pitfalls Observed During Inspections: Intentional, Unintentional and Systemic Vulnerabilities

08:45 – 10:05	08:45 – 09:15	In this presentation, Francesco Cicirello will delve into the critical topic of data integrity within aseptic manufacturing environments. His presentation titled “Common Data Integrity Pitfalls Observed During Inspections: Intentional, Unintentional and Systemic Vulnerabilities” will highlight the spectrum of vulnerabilities—both deliberate and accidental—as well as systemic challenges that manufacturers face during regulatory inspections. Drawing from recent inspection trends and practical industry experience, the session will demystify common myths versus facts about data integrity, including: • Intentional versus unintentional data integrity failures and how to recognize their warning signs • Systemic vulnerabilities that can erode compliance, even in well-established processes • Practical strategies to proactively address and remediate data integrity issues before they impact regulatory perceptions Attendees will gain actionable insights into: • How to identify and avoid the most frequent unintentional data integrity pitfalls in aseptic manufacturing • Approaches for fostering a compliance-driven culture that supports robust data management practices • Tools and frameworks for balancing operational efficiency with the rigorous demands of regulatory authorities This session is tailored for professionals working in quality assurance, regulatory affairs, and technical operations, providing a pragmatic roadmap for strengthening data integrity and safeguarding your organization’s reputation in the global biopharmaceutical landscape. • **Francesco Cicirello PharmD, MSc**, Senior Director, Quality Compliance BioNTainer, *BioNTech*
	09:15 – 09:45	**Audit Findings: Common Data Integrity Gaps** Data integrity remains a critical focus for global health authorities as recent inspections continue to reveal deficiencies impacting product quality and patient safety. This presentation will explore current regulatory requirements and examine common findings. We will discuss root causes, compliance risks, and best practices for prevention. • **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** Cold chain management of biologics and cell therapies is critical to ensure their safety, efficacy, and quality. These temperature-sensitive products require strict temperature control throughout the entire supply chain to prevent product compromised by temperature fluctuations or excursions. An effective cold chain management requires a combination of validated cold storage facilities, shipper box, cryogenic storage vessel temperature-controlled transport vehicles. Temperature data loggers and tracking systems are also important to ensure the required temperatures are maintained throughout the distribution. Proper sampling of temperature-sensitive product upon arrival is essential to ensure sampling and thawing process does not compromise the product quality. • **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** The presentation “Primary packaging compatibility, sterility and the use for high potent products” explores the critical intersection of regulatory compliance, advanced engineering, and patient safety in the aseptic processing of highly potent pharmaceuticals—specifically Antibody-Drug Conjugates (ADCs). As ADCs continue to revolutionize targeted cancer therapies, their complex and sensitive nature demands filling solutions that meet the highest standards of sterility, containment, and operator protection. This session will highlight how Annex 1-compliant machine designs ensure aseptic integrity throughout the filling process, aligning with the latest EU GMP guidelines. It will further examine specialized high-potent equipment configurations tailored to the unique challenges of ADCs, including precise dosing, minimal product loss, and robust cleaning protocols. Central to the discussion is the role of advanced containment strategies with isolators - which safeguard both product and personnel without compromising efficiency or flexibility. By integrating regulatory foresight with technological innovation, these filling solutions not only meet compliance requirements but also accelerate the safe delivery of transformative therapies to patients worldwide. • **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?** Next month, USP Chapter <382> becomes effective, joining USP <381> and shifting the focus from testing individual elastomeric closures to evaluating how they perform within their final assembled packaging configurations. Notably, this change places responsibility on drug manufacturers to test their container closure systems in real-world conditions. This session will unpack the reasons behind the update, what it means for compliance, and the technical hurdles ahead. You will learn how USP <382> strengthens patient safety by requiring packaging systems to prove their performance where it matters most. • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	13:55 – 14:25	**RTU Primary Packaging and Aseptic Transfer: An Integrated Perspective** The integration of *ready-to-use* (RTU) containers — vials, syringes, and cartridges — and their packaging systems (tubs, trays) into high-speed aseptic filling lines still faces multiple challenges. It is crucial to balance efficiency, sustainability, and logistical impact while ensuring full compliance with sterility requirements. This presentation addresses logistics, handling, and management of RTU packaging, focusing on the transfer process from non-classified warehouse areas to aseptic filling. Advanced solutions for cleanroom entry will be discussed, highlighting the role of sanitization and bio-decontamination in reducing bioburden. Within Grade A environments such as isolators or RABS, handling approaches may include multilayer secondary packaging (NTT – No-Touch Transfer) or single-layer solutions combined with decontamination technologies, with the E-Beam tunnel remaining the most widely adopted worldwide. • **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** This presentation will share TBMC's experience in aseptic processing for advanced therapy medicinal products (ATMPs). We will provide an overview of our GMP operation design at the Zhubei facility, covering manufacturing, QC, warehouse, and utilities. The talk will highlight facility and process design concepts with deep dives into our CT suites for CAR-T and MSC, mRNA vaccine suites for LNP-formulated mRNA, and conceptual design for gene therapy production based on suspension AAV/LVV. We will also present our qualification efforts to ensure compliance and operational excellence. • **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** Cell therapy products (CTPs) should be made under aseptic conditions since they are administered via injection. However, traditional sterile protocols (heating & radiation) are often unsuitable for CTPs because their active ingredients are live cells designed to remain active in the body for an extended period, secreting essential cytokines and hormones. Like bone marrow transplantation, the primary focus for making CTPs is on prevention of infection through specialized training (under GLP), rather than adherence to typical aseptic processes. However, as medicinal products manufactured under GMP and delivered to hospitals for infusion by medical doctors, CTPs must be produced under very strict sterile conditions, and our aseptic process protocols should be thoroughly validated. I will share our concerns regarding the sterility of cell therapy products and look forward to discussing the challenges we are currently facing. • **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** This presentation will provide an overview of the regulatory framework for regenerative medicine in Japan, highlighting key requirements for the development of cell therapy products (CTPs). It will address challenges related to the heterogeneity and comparability of CTPs, incorporating insights from our recent research on identifying functional cell subpopulations and biomarkers to enhance the efficiency of mesenchymal stem cell (MSC)-based product manufacturing. In addition, findings from studies on the tumorigenicity associated with pluripotent stem cell-derived products will be briefly discussed. The talk will also touch on Japanese guidelines for aseptic manufacturing of CTPs. • **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*