PharmaED RESOURCES, Inc.

Aseptic Processing Summit 2025

Best Practice Technologies for Aseptic Processing and Contamination Control

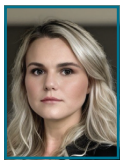
October 8-9, 2025, Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Jürgen Metzger
Bausch+Stroebel

Liz Brockson
Takeda

Dan Klein
STERIS



Alexis Stachowski
Regeneron

Donald Singer
New Beginnings Microbiology

Derek Duncan
Lighthouse Instruments

Klaus Ullherr
Syntegon GmbH

Amanda Curtis
ValSource

Jim Polarine
STERIS

Richard Denk
SKAN AG

Josh Russell
AST Inc

Marsha Steed
Steed Microbio

Elizabeth Massoth
CURIS

Sebastian Scheler
Innerspace

Mitch Garber
MG Aseptic & QA Consulting

With Comprehensive Coverage On:

- **Annex 1 Feedback After Three Years in Force—Lessons Learned**
- **Global Guidance for a Risk-Based Contamination Control Strategy—A Case Study**
- **Root Cause Analysis of Contamination Events: Case Study and Lessons Learned**
- **Developing a CCS (Contamination Control Strategy) for ATMP Cleanrooms**
- **Case Study on the Global Implementation of a Practical and Compliant CCS**
- **Critical Issues—Reducing Risk in Cleanroom Material Transfer**
- **Innovations Shaping Bio-decontamination In Transfer Environments**
- **Understanding Human-Centric Contamination Risks: Gowning, Movement, and Training Deficiencies**
- **Reducing Glove Interventions in Aseptic Manufacturing: Challenges and Benefits**
- **Advancing Fill-Finish with Digital Twin Technology**
- **Flexible Fill/Finish Solutions for Ready-to-Use Containers**
- **Testing and Control Strategies for Container Closure Integrity**
- **How to Use Environmental Monitoring Data as an Indicator of Aseptic Process Quality**
- **Hot Topics in Aseptic Behaviors**

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Wednesday, October 8, 2025

7:45 *Registration Check-in & Complimentary Breakfast*

8:40 *Chairperson's Welcome & Opening Remarks*

Critical Issues—Implementation of Annex 1

8:45 **Annex 1 Feedback After Three Years in Force!**

Richard Denk, Senior Consultant, Aseptic Processing & Containment, SKAN AG

During the last three years the presenter did a global journey on Annex 1 training sessions, conferences and workshops, meeting around 16,000 people on this journey on all continents including intensive inspector trainings. The presentation will cover the main challenges implementing Annex 1 in the different regions. Topics covered include:

- What are the main challenges implementing Annex 1:
- Where is more guidance needed to be compliance with Annex 1
- Material Transfers and CCS Contamination Control Strategy

9:30 **Case Study on Global Guidance for a Risk-Based Contamination Control Strategy**

Liz Brockson, Aseptic Processing and Sterility Assurance Lead, Takeda

Recent revisions to EU Annex 1 emphasize the importance of a Quality Risk Management (QRM) approach to contamination control, and the requirements and guidance are numerous and cover many topics. This presentation will describe the basic principles, regulatory requirements, and industry best practices for the use of QRM in a contamination control strategy (CCS). Additionally, this presentation will provide an overview of one company's approach for interpreting and implementing the Annex 1 QRM CCS requirements, including updating existing CCS global guidance and implementing tools such as a template for sites to create local CCS and global contamination risk assessment with recommended risk questions, appropriate risk assessment tools/methods for each risk question, and guidance on how to group risk assessments for efficient management.

10:15 *Mid-morning Coffee & Networking Break*

Contamination Events—Identifying Root Causes

10:45 **Root Cause Analysis of Contamination Events: Case Study and Lessons Learned**

Alexis Stachowski, Associate Director of Quality Assurance Microbiology for Biologics, Regeneron Pharmaceuticals

Despite robust aseptic design and procedural controls, contamination events in sterile manufacturing persist—and often recur—due to ineffective or incomplete root cause analysis (RCA). This presentation delves into the complexities of identifying true root causes of contamination in aseptic environments, where events may result from subtle, interdependent factors such as human behavior, process gaps, or facility design flaws.

Using anonymized real-world case studies, we will examine how different contamination events were investigated, where investigations succeeded or failed, and what lessons were ultimately learned. Emphasis will be placed on the critical difference between identifying a proximate cause and uncovering a systemic root cause. The session will highlight the value of cross-functional investigation teams, incorporation of smoke study data, behavioral observations, and trend analysis.

Spotlight on Environmental Monitoring

11:30 **How to Use Environmental Monitoring Data as an Indicator of Aseptic Process Quality**

Amanda Curtis, Microbiology Consultant, ValSource

As the understanding of aseptic manufacturing continues to evolve, it's increasingly clear that assessing the quality of aseptically manufactured products requires the integration of data from multiple sources. In-process bioburden testing, finished product sterility testing, process validation (including media fills), and environmental monitoring (EM) are each limited on their own; when considered together, they provide critical insight into the holistic state of control of both the process and facility, as well as overall product quality.

One key area of this challenge lies in effectively leveraging the vast amount of EM data generated during production. How can this data be efficiently interpreted and translated into action? What are its strengths and limitations? And what do excursions (or the dreaded "adverse trend") truly indicate about the state of control or the product batch in question?

This presentation will explore these questions and offer practical guidance on how both the EM/Microbiology and Aseptic Processing teams can use EM data to gain a clearer understanding of process performance and product quality. A case study will illustrate how an adverse trend can be communicated effectively to stakehold-

ers,and how such insights can inform product impact assessments and next steps.

12:15 *Complimentary Lunch*

Spotlight on Innovations in Cleanroom Material Transfer

1:30 **Improving Materials Movement into Cleanrooms - Reducing Risk**

Don Singer, Senior Global Microbiology Consultant, and Mitch Garber, President, MG Aseptic and Quality Assurance Consulting

Controls in the cleanroom environment for sterile and aseptically processed medicines must be suitable to reduce microbiological risk to the patient. Material transfer can be a complex process dependent on material packaging, design of pass-through chamber, and method of bio-decontamination. Evaluating this risk holistically, from warehouse to Grade A is the key to ensuring microbiological control is robust. With both manual and automated bio-decontamination options available, each presents critical concerns that incorporate close assessment of operator behavior and equipment capability. This presentation will build on fundamental knowledge with case studies for reducing risks with material transfers.

2:15 **From Efficiency to Efficacy: Innovations Shaping Bio-decontamination in Transfer Environments**

Elizabeth Massoth, Biocontainment Specialist, CURIS System

As use of automated biodecontamination continues to expand, pharmaceutical manufacturers' concerns about challenges associated with traditional methods, such as material degradation, prolonged aeration times, and staff safety have grown, as well. This presentation covers the latest breakthroughs in integrated biodecontamination systems for material transfer environments in pharmaceutical and research facilities. Drawing from studies conducted at pharmaceutical manufacturing locations across the US, we will explore the implementation of novel systems in both upstream and downstream transfer spaces, with a focus on their ability to maintain efficacy without compromising staff safety or compatibility with sensitive equipment or materials.

The discussion will include:

- A review of microbial decontamination challenges in different use cases for pharmaceutical and research facilities.
- Results from the automated system's operation, including cycle times, microbial efficacy, and material impact.
- Best practices for implementing an integrated biodecontamination system for transfer spaces.

The studies highlight the potential for integrated systems to streamline operations, minimize contamination risks, and provide a consistent, reliable solution for biodecontamination. By presenting real-world data, this session aims to provide facility managers, quality engineers, process engineers, and operational leaders with practical insights into optimizing biodecontamination strategies in aseptic environments.

3:00 *Afternoon Networking Break*

Going Gloveless

3:30 **Reducing Glove Interventions in Aseptic Manufacturing: Challenges and Benefits**

Jürgen Metzger, Director of Turnkey Projects & New Technologies, Bausch + Stroebel Machine Company, Inc.

Minimizing glove interventions in aseptic processing environments is critical to enhancing product sterility, operator safety, and regulatory compliance. While isolator and RABS technologies have significantly reduced human interaction, glove ports remain a residual risk for contamination and ergonomic strain. This session explores the key challenges associated with manual interventions—ranging from operator dependence and contamination risk to process complexity—and highlights the benefits of intervention reduction through advanced automation, robotics, and intelligent system design. Participants will gain insights into enabling technologies, best practices, and risk-based strategies aligned with Annex 1 and FDA expectations, ultimately supporting a more robust and efficient aseptic operation.

4:15 **Flexible Fill/Finish Solutions for Ready-to-Use Containers – From Classic to Gloveless**

Klaus Ullherr Senior Product Manager SPM-PHL, Syntegon Technology GmbH

The presentation will show the journey from flexible nest filling with statistical and 100% IPC to completely gloveless systems. Key topics to be covered include:

- Case study: The seamless integration of a state-of-the-art fill finish solution within an existing production environment
- Packstyle flexibility, enabling rapid adaptation to changing market requirements
- No-touch-transfer system ensuring sterility and contamination control
- 100% in-process checkweighing (IPC) enhancing product quality and compliance
- Peristaltic pump with single-use filling systems
- Integration of in-air isolator
- Implementation of Annex 1 requirements in practice

- CFD and smoke studies

- Use of different robotics solutions

- Gloveless working cell for small batches

- Fully aseptic set-up of the machine

And finally, a sneak peek into the future: A breakthrough in next-generation aseptic fill/finish production.

5:00 *Happy Hour Mixer*

Join us in the hotel lounge for informal networking. Complimentary appetizers provided.

Thursday, October 9, 2025

7:45 *Complimentary Breakfast*

Spotlight on Container Closure Integrity

8:45 **Testing and Control Strategies for Container Closure Integrity**

Derek Duncan, Director Product Lines, LIGHTHOUSE Instruments

In response to the implementation of the revised EU GMP Annex 1 and the announced revision of the USP<1207> Package Integrity Evaluation—Sterile Products chapter, best practices for assuring container closure integrity have and will continue to evolve. In addition, the continued development of novel therapies (cell & gene therapies) as well as the increased use of complex delivery systems (autoinjectors, for example) have required new approaches for container closure integrity (CCI) testing. This presentation uses current case study examples of how companies are evolving best practices and defining approaches to comply with new container closure requirements. The case studies illustrate various topics and approaches including the validation of container closure integrity test methods for novel therapies and containers, generating CCI data in a product life cycle approach, and the choice to perform 100% leak detection vs. sampling in commercial manufacturing.

9:30 **Human-Centric Contamination Risks: Gowning, Movement, and Training Deficiencies**

Alexis Stachowski, Associate Director of Quality Assurance Microbiology for Biologics, Regeneron Pharmaceuticals

In aseptic processing, the human operator remains the most significant and unpredictable source of contamination. Despite advanced facility design and engineering controls, improper gowning practices, unintentional movement patterns, and inadequate training continue to contribute to microbial and particulate contamination risks. This presentation focuses on identifying, evaluating, and mitigating human-centric contamination vectors in cleanroom environments.

We will explore common failure modes in aseptic gowning, including unnoticeable breaches and behavioral habits that compromise integrity. Best practices will be presented to illustrate how simple operator movements can disrupt first air, dislodge particulates, or bypass critical zones. Through real-world examples and regulatory observations, we will highlight how even well-trained personnel may exhibit unconscious behavior that increases risk.

10:15 *Midmorning Coffee & Networking Break*

Critical Issues—Contamination Control Strategies

10:45 **Developing a Contamination Control Strategy (CCS) for ATMP Cleanrooms**

Jim Polarine, Principal Consultant, Technical Services, STERIS Corporation, & Dan Klein, Director of Technical Service, STERIS Corporation

This presentation will cover a contamination control strategy approach to materials transfer of critical items into barrier systems, cleanrooms, air locks, RABS, and Isolators.

Critical discussion points how to decontaminate process parts which cannot be cleaned and sterilized out of place. There will be a focus on how to control hard to proactively prevent contamination from viruses, spores (fungal and bacterial) and vegetative bacteria. Recent case studies from ATMP cleanroom facilities will be discussed and how to control bioburden from entering aseptic areas will be discussed in relation to incubators and pass thru decon. Published data will also be covered to convey effective methods in control bioburden into ATMP cleanrooms and BSCs. This presentation well be a holistic approach to controlling bioburden from entering cleanrooms and BSCs.

11:30 **Case Study on the Global Implementation of a Practical and Compliant Contamination Control Strategy**

Liz Brockson, Aseptic Processing and Sterility Assurance Lead, Takeda

EU Annex 1 emphasizes the need for a holistic Contamination Control Strategy (CCS) to ensure the safety of pharmaceutical products. This presentation will describe the basic principles and applicability of contamination control, as well as regulatory requirements and industry best practices for CCS. Additionally, this presentation will provide an overview of one company's novel approach for interpreting and implementing the Annex 1 CCS requirements to create a practical and compliant six-step approach to define and evaluate contamination controls, including a pragmatic approach to

leveraging existing contamination controls. Furthermore, this presentation will describe a simple lifecycle management approach to ensure the CCS is maintained in an accurate state.

12:15 *Complimentary Lunch*

Technology Spotlight—Digital Twin Applications for Fill-Finish Operations

1:30 **Advancing Fill-Finish with Digital Twin Technology**

Josh Russell, Vice President of Technical Sales, AST

As pharmaceutical manufacturers are looking to navigate and excel in Pharma 4.0, a key aspect of the digitization breakthrough is the advent and exploration of digital twin technology. Digital twin is a dynamic, predictive virtual model that synthesizes real-time data, physical operations, and virtual environments in an exact digital replica of a machine, system, or complete manufacturing operation. A natural part of progress within any industry is the transition from one technological paradigm to the next, and, with the advent of solutions like digital twin, a host of opportunities and questions face drug product manufacturers. The innovative integration of the physical, digital, and data spaces offered by digital twin provides exciting possibilities for the production of liquid pharmaceuticals at every stage of drug development to commercial manufacturing. This presentation will provide an overview of the evolution of digital manufacturing solutions and Pharma 4.0, a primer on digital twin technology, and what the industry can anticipate going into the future. Highlights include:

- Definitions and principles of digital twin technology
- Three real-world use cases of digital twin for fill-finish
- An exploration of potential applications and benefits for drug product manufacturing, including time to market, process formulation, quality control, risk assessments, and predictive analytics

2:15 **Hot Topics in Aseptic Behaviors**

Marsha Steed, Founder and CEO, Steed MicroBio LLC

This presentation will highlight the critical importance of effective aseptic practices and training, address challenges like employee turnover, and explore cutting-edge techniques in BSC (Biological Safety Cabinets), RABS (Restricted Access Barrier Systems), and Isolators. Additionally, Marsha will present crucial regulatory observations related to breaches in good aseptic behaviors from the FDA and European regulators. The importance of good aseptic behaviors and training on good aseptic behaviors will be covered.

3:00 **TBA**

Sebastian Scheler, Co-founder, Managing Director, Chief Methodologist, and Frame-by-Frame Risk Profiling Supervisor, Innerspace

Abstract Coming Soon

3:45 *Close of Program*

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