

PharmaED RESOURCES, Inc.

Aseptic Processing Summit 2026

Best Practice Technologies for Aseptic Processing and Contamination Control

December 2-3, 2026, Sheraton La Jolla, CA

Featuring Lessons Learned & Case Studies from Industry Experts:



Jürgen Metzger
PharmaTech Consulting



Amanda (Curtis) Kimlicka
ValSource



Stephen Yang
Merck



James Hathcock
Cytiva



Birte Scharf
Franz Ziel GmbH



Jim Polarine
STERIS



Derek Duncan
LIGHTHOUSE Instruments



Meg Provenzano
Veolia



Tim Cser
MilliporeSigma



Elizabeth Massoth
CURIS



Allison Scott
BWT Pharma & Biotech, Inc.



Mark Hallworth
Particle Measuring Systems



Josh Russell
AST Inc.



Jeff Woodson
CURIS



Sebastian Scheler
Innerspace



Mitch Garber
MG Aseptic & QA Consulting



Noël Long
Cytiva

With Comprehensive Coverage On:

- **FDA Warning Letters: Root Cause Analysis and Technology Enablers in Aseptic Manufacturing**
- **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**
- **Using Environmental Monitoring Data as an Indicator of Aseptic Process Quality**
- **Advances in Rapid EM and Continuous Monitoring in Cleanrooms and Controlled Environments**
- **Techniques for Monitoring Robotic Filling Machines**
- **Testing and Control Strategies for Container Closure Integrity**
- **Ensuring First Air Integrity in Aseptic Manufacturing**
- **Applying New Industry Guidance on Designing a Robust Disinfectant Field Trial**
- **Annex 1 CCS—Lessons Learned**
- **Innovations Shaping Bio-decontamination in Material Transfer Environments**
- **Case Study in Applying the ANSI-03 Quality Risk Management Standard**
- **Transforming Quality Risk Management for Faster Commercialization**
- **And More!**

With Representation From:

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Wednesday, December 2, 2026

7:30 *Registration Check-in & Complimentary Breakfast*

8:25 *Chairperson Jürgen Metzger's Welcome & Opening Remarks*



Jürgen M. Metzger, CEO, Pharma-Technology-Consulting, LLC

Spotlight on Environmental Monitoring

8:30

How to Use Environmental Monitoring Data as an Indicator of Aseptic Process Quality



Amanda (Curtis) Kimlicka, 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 stakeholders, and how such insights can inform product impact assessments and next steps.

9:10

What's New in Rapid EM and Continuous Monitoring in Cleanrooms and Controlled Environments



Tim Cser, Senior Technology Specialist, MilliporeSigma

The world of active, viable sampling has evolved quickly over the last few years with the implementation of EU Annex 1 and the introduction of new technologies. With newer technologies such as biofluorescent viable and non-viable counting, "continuous monitoring" and a revised data integrity focus, firms have more variables than ever in designing and testing their clean spaces. This presentation will explain the latest advancements and expectations in the active, viable monitoring world.

Regulatory Spotlight—What FDA Warning Letters Reveal in Aseptic Manufacturing

9:50

FDA Warning Letters: Root Cause Analysis and Technology Enablers in Aseptic Manufacturing



Jürgen M. Metzger, CEO, Pharma-Technology-Consulting, LLC

Human interventions remain one of the most persistent sources of contamination risk and operational variability in aseptic manufacturing. Despite widespread adoption of isolator technology, glove interventions continue to contribute significantly to deviations, with industry data indicating that up to 50% of quality events are linked to human error.

This presentation examines the residual risks associated with glove-based interventions from a microbiological, engineering, and regulatory perspective, including their impact on first air principles, airflow disruption, and contamination pathways. Current expectations from EU GMP Annex 1 and FDA guidance are discussed, emphasizing the increasing regulatory focus on minimizing or eliminating human interaction.

Real-world case studies from Lonza and Biogen illustrate how Human Performance (HuP) programs can significantly reduce deviations by shifting focus from individual error to system design. Building on this, the presentation introduces gloveless aseptic processing platforms as a next-generation solution, integrating robotics, sensors, and vision systems to eliminate manual interventions entirely.

Attendees will gain insight into how advanced technologies, combined with system-centric design principles, can enhance sterility assurance, improve operational resilience, and support evolving manufacturing demands such as ATMPs and personalized therapies.

10:30 *Mid-morning Coffee & Networking Break*

11:00

Merck Presentation



Stephen Yang, Director in Global Quality—Microbial Control and Sterility Assurance, Merck & Co.

Abstract Coming Soon

11:40 **Advancing Sterility Assurance Through Biofluorescent Particle Counting in Closed, Gloveless Robotic Aseptic Filling Platforms**



James Hathcock, Principal Director of Regulatory and Validation Strategy, Cytiva

Aseptic filling in pharmaceutical manufacturing can be challenging, with contamination risks and scalability constraints risking time to market for delivering life-changing therapeutics. Standardized and scalable platform approaches employing state-of-the-art gloveless, robotic filling technologies coupled with real-time environmental monitoring can improve process understanding, strengthen sterility assurance, eliminate interventions, and accelerate time to market. This presentation will share lessons learned from computational fluid dynamics (CFD) modeling and airflow visualization studies using neutrally buoyant smoke to optimize airflow design and environmental monitoring (EM) sampling locations within standardized aseptic filling platforms. In addition, a practical roadmap for implementing biofluorescent particle counting (BFPC) for Grade A environmental monitoring will be presented, including experiences with baseline establishment, interference assessments, and approaches for demonstrating that the manufacturing process remains in a validated state of control. This standardized modular approach strengthens process understanding and control, while minimizing additional validation for end-users, thereby accelerating time to GMP inspection approval and time to market.

12:20 *Complimentary Lunch*

1:30 **Protective Airflow in Aseptic Manufacturing - Ensuring First Air Integrity**



Dr. Birte Scharf, Senior Scientist GMP Compliance, Franz Ziel GmbH

Maintaining unidirectional airflow and protecting first air over critical process surfaces remain key aspects to Annex 1 compliant aseptic operations. In practice, this can be difficult whenever operator interventions or equipment design disrupt airflow patterns. Smoke studies are still the primary tool to demonstrate airflow performance, yet their usefulness depends greatly on how realistically they are designed, executed and interpreted. Therefore, Computational Fluid Dynamic Studies (CFDs) can be a very supportive tool to predict critical airflow patterns and mitigate risks already during design phase of Barrier Systems.

One recurring challenge is the need to manipulate Rapid Transfer Ports (RTPs) from inside the barrier system, which can impair First Air Protection above indirect product contact parts. Such situations underline how essential careful glove management strategies are and at the same time expose the inherent limitations of gloved operations for contamination control.

To address these risks, several approaches are gaining importance, such as reducing glove use and moving towards equipment designs that avoid glove reach above critical surfaces, including gloveless technologies. These developments show how airflow design, human factors, and equipment innovation must be considered together in order to achieve contamination control that align with Annex 1 expectations.

Technology Spotlight—Digital Twin & Robotics Applications

2:10 **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.

2:50 *Afternoon Snack & Networking Break*

3:20 **Monitoring of Robot Filling Machines**



Mark Hallworth, Life Sciences GMP Advisor, Particle Measuring Systems

With the advancement of small batches and ATMP/CGT the use of glove-free isolators is becoming prevalent and robotics are used for the majority of material handling within the isolator. As glove ports were historically used for routine environmental monitoring, the absence of these gloves and operator interactions, require that the robot performs these functions. This ses-

sion will look at the mechanisms being used in industry today, along with advancements in performing remote, traditional, microbiological sampling meeting the needs of regulatory guidance and providing speciation without additional constraints on the environment.

4:00 **Transforming QRM for Faster Commercialization**



Sebastian Scheler, Managing Director, Innerspace

Abstract Coming Soon

4:45 *End of Day One*

5:00 *Happy Hour Mixer*

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

Thursday, December 3, 2026

7:30 *Complimentary Breakfast*

Spotlight on Container Closure Integrity

8:30 **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.

Controlling Bioburden Through a Robust CCS

9:10 **Case Study: New Industry Guidance on Designing a Robust Disinfectant Field Trial**



Jim Polarine, Jr., MA, Principal Consultant, STERIS Corporation

This case study utilized a ready to use quaternary ammonium disinfectant and a hydrogen peroxide/peracetic acid sporicide to control bioburden in a new cleanroom operation post construction. Material flow, engineering controls, utility supplies, and operational procedures will be discussed. This presentation will cover new details such as witnessing activities during a disinfectant field trial from the new PDA Technical Report #70. In depth, field trial environmental monitoring data will be covered. This CCS case study has recently been published in Cleanroom Technology Europe.

Spotlight on Annex 1

9:50 **Modernizing Endotoxin Testing within the EU GMP Annex 1 Contamination Control Strategy**



Meg Provenzano, Global Product Manager for Endotoxin, Veolia

With the formal finalization of EU GMP Annex 1, pharmaceutical manufacturers are mandated to design and implement a holistic, lifecycle-based Contamination Control Strategy (CCS). A central pillar of any sterile manufacturing CCS is the rigorous control and monitoring of bacterial endotoxins across critical utilities (such as Water for Injection), raw materials, in-process steps, and finished parenteral products. Furthermore, Annex 1 explicitly encourages the adoption of scientifically sound, modern, and innovative technologies to streamline processes, minimize human error, and enhance sterility assurance.

Traditionally, Bacterial Endotoxins Testing (BET) has relied on manual, operator-dependent methods that are highly susceptible to analyst technique variations, accounting for the vast majority of out-of-specification (OOS) deviations and high invalid retest rates (historically 5% to 10%). Moreover, legacy LAL assays consume large volumes of natural horseshoe crab resources, posing supply chain and ecological vulnerabilities.

This presentation outlines a modern, fully compliant framework for integrating automated centripetal microfluidics and recombinant Cascade Reagents (rCR) into a site's CCS. By transitioning to a microfluidic platform , laboratories can automate the fluidic measuring, splitting, and mixing of samples and reagent.

This session will detail:

- **Alignment with Annex 1 & Quality Risk Management (QRM): Establishing endotoxin control points across the product lifecycle.**

- **Microfluidic Compliance: Ensuring data integrity (ALCOA+) and pharmacopeial compliance by executing a live 3- to 5-point standard curve in triplicate contemporaneous with every single assay, maintaining a <2% invalid rate.**

- **Validation and Recombinant Migration Pathways: Streamlining the transition from traditional LAL to rCR via direct comparison studies and 3-lot alternative method validations.**

By combining microfluidic automation with recombinant biochemistry, not only is the core regulatory intent of Annex 1 met, but attendees will see how an historically volatile manual assay is transformed into an automated, highly robust, and ecologically sustainable control point.

Key Learning Objectives for Attendees:

- **Understand the regulatory mandates of EU GMP Annex 1 regarding holistic Contamination Control Strategies (CCS)**

- **Learn how the implementation of modern, rapid microbiological methods achieve Annex 1 compliance.**

- **Evaluate the biochemical differences and recovery equivalencies between traditional LAL, single-protein recombinant Factor C (rFC), and full-cascade recombinant Cascade Reagents (rCR).**

- **Quantify the operational, financial, and data integrity advantages of microfluidic automation**

- **Formulate a structured validation roadmap for transitioning water loops and product matrices from manual gel-clot or kinetic assays to microfluidic-based rCR under USP <86> guideline.**

10:30 *Midmorning Coffee & Networking Break*

11:00

Innovation in Continuous Monitoring—Online Water Bioburden Analyzer Technologies and Implementation Case Study



Allison Scott, Principal Scientist, BWT Pharma & Biotech, Inc.

Multiple Online Water Bioburden Analyzers are now available that support the online monitoring of bioburden in pharmaceutical water systems. Pharmaceutical water bioburden monitoring has historically relied on point of use sampling and culture-based testing—methods that are labor-intensive and provide retrospective results. Today, advanced online water bioburden analyzers support real or near-real-time monitoring of bioburden within pharmaceutical water systems through the detection of intrinsic or extrinsic fluorescence instead of growth. These systems provide a rich dataset for trending due to more frequent sampling and support proactive process monitoring and in-process control applications. Key objectives include providing an overview of available online water bioburden analyzer technologies and an implementation case study including establishing alert and action levels and trending rules.

11:40

Improving Materials Movement into Cleanrooms—Reducing Risk



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.

12:20 *Complimentary Lunch*

Critical Issues—Material Transfer

1:35

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





Beth Massoth, Biocontainment Specialist CURIS & Jeff Woodson, VP of Revenue Operations, CURIS

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.

2:15 **Applying the ANSI-03 Quality Risk Management Standard—A Case Study**



Noël Long, Senior Sterility Assurance Adviser, Cytiva

This talk walks through a real-life example of how the ANSI-03 standard can improve aseptic filling and low bioburden processing where contamination is a concern. Using the Swiss cheese analogy from the QRM standard, a team of microbiologists and engineers evaluated the layers of protection designed into a gloveless robotic isolator – from changeover and set-up through unloading of filled and closed vials. By providing a real-life example, the audience will gain familiarity with the standard and learn how the team adapted the method to evaluate and understand continuous improvement that is prioritized based on risk. The case study will show how ANSI-03 standardizes risk-based decision-making, enables team discussions, and provides a structured framework that supports proactive identification, assessment, and control of contamination risks. Attendees will leave with insights into the standard's core principles and how it aligns with global regulatory expectations.

2:55 *Close of Program*



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