

# Aseptic Processing Summit 2022

October 25–26, 2022, La Jolla, CA

*Featuring Lessons Learned and Case Studies from Industry Experts:*



**Les Edwards**  
Skan US



**Laura Moody**  
Syntegon



**Sheba Zaman**  
Novatek Int'l



**Joe Brower**  
Aseptic Process  
Solutions



**Evan Lamb**  
SKAN US



**Jeremiah Genest**  
Amylyx  
Pharmaceuticals



**Norman Goldschmidt**  
Genesis AEC



**Michael Eakins**  
Eakins & Assoc.



**Royce Tourtillott**  
AES Clean Tech.



**Dan Klein**  
STERIS



**Mike Dingle**  
TSI

Regulators in North America and Europe are requiring stricter standards for environmental monitoring systems, facility cleaning and disinfectant qualification, aseptic cleanroom operations, filtration, sterilization, and aseptic process simulation (or media fill). This two-day summit features expert insight into the robust aseptic processing requirements facing the industry. Pharma Ed's Aseptic Processing Summit features comprehensive coverage on the implementation and management of the latest knowledge in aseptic, barrier, containment, and aseptic best practice technologies.

## *With Comprehensive Coverage On:*

- The Current Regulatory Landscape for Aseptic Processing
- How ATMPs Have Changed the Fill/Finish Industry Forever
- Considerations & Strategies for ATMP Facility Design to Deliver Flexibility, Expandability & Quality
- The Present & Future of Aseptic Fill-Finish Operations
- Contemporary & Critical Issues Surrounding Aseptic Compounding in the 503B Industry
- Risk-based Approaches to Contamination Control
- A Risk Assessment Approach to Address Fungal Spore Contamination in a Cell and Gene Therapy Cleanroom
- Future Trends in Total Contamination Control Strategies
- Critical Environments in an Age of Transformation
- Viable Air Testing and the Myth of 1 CFU
- A Common-Sense Approach to Lyophilizer Cleaning Validation
- And More!

## *With Representation From:*



Aseptic Process Solutions, LLC

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## Tuesday, October 25, 2022

8:30 Registration & Complimentary Breakfast

8:55 Chairperson Michael Eakins' Welcome & Opening Remarks



9:05 The Current Regulatory Landscape for Aseptic Processing

**Michael Eakins, Principal Consultant, Eakins & Associates**



While the FDA's Guidance *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* has remained unchanged since 2004, the European Union's GMP guidance Annex 1, *Manufacture of Sterile Medicinal Products* issued in 1971 has undergone a series of minor revisions in 2005 to 2010 and a complete rewrite issued as a draft for comment in December 2017. Following a large number of substantial comments, Annex 1 was reissued February 2020 for comment. This second revision of the Annex 1 generated over 2,000 comments and there are reported plans to issue the final version by mid 2022. The presentation will discuss some of the major proposed changes to Annex 1.

Since 2015, there have been numerous additions to the microbiology chapters in the USP which are relevant to aseptic processing. The recent changes to the <1229> series of chapters on sterilization methods for compendial articles will be reviewed in addition to other recent USP updates and new chapters on microbiology.

### Spotlight on Advanced Therapy Medicinal Products (ATMPs)

10:05 How ATMPs Have Changed the Fill/Finish Industry Forever

**Laura Moody, Product Manager, Syntegon Pharma Technology, Inc.**



The advent of cellular and molecular biotechnology has prompted an evolution in the pharmaceutical manufacturing industry. Where high-speed, high-throughput fill/finish was once the gold standard, an increasing number of pharmaceutical manufacturers are investing in the development and commercialization of high value drug products that have very different fill/finish needs (i.e., isolators, 100% IPC, ready to use components, minimization of rejects, single-use fluid paths, etc). This presentation will highlight the changing requirements for downstream processing of small batch drugs, along with how machine manufactures are adapting to the evolving needs of the industry.

10:50 Midmorning Coffee and Networking Break

11:20 Advanced Aseptic Processing for ATMPs

**Les Edwards, Vice President, Technology and Business Development, SKAN US, & Evan Lamb, Applications Specialist, Cell and Gene Therapy, SKAN US**



In the manufacturing of advanced therapy medicinal products (ATMP), the need of technologies transfer from traditional lab bench work to therapies' production and commercialization phases became a bigger challenge. Due to the process requirements of ATMP manipulation, a high sterility assurance is required all the way through the workflow process; from the sample collection to the cell handling and gene editing up to final fill and finish formulation. Isolators technology become a natural next step to increase cell and gene therapies production and their quality control. Recently developed isolators allow for upstream, downstream and aseptic filling steps to be performed in a closed system with a validated aseptic control environment avoiding cross-contamination.

12:05 Complimentary Lunch

1:25 Eurofins Biopharma Product Testing Presentation  
**Speaker to be determined.**

Abstract coming soon

1:45 Considerations & Strategies for ATMP Facility Design to Deliver Flexibility, Expandability & Quality

**Royce Tourtillott, Sales Manager, Western Region, AES Clean Technology**



Advanced Therapy Medicinal Products (ATMPs) stretch current and historic paradigms within the industry. The proven technologies and facility designs for bulk biologic aseptic manufacturing are challenged to meet the needs of low volume, high mix these patient centered products require. Translating lab based manual production practices to clinical and commercial scales have unique impacts on facility and equipment design that have to be considered to safe guard product quality and safety. As a consequence, new approaches to facility design, personnel/material flows, containment, and equipment are being implemented. The presentation will discuss cleanroom design, equipment integration and HVAC considerations and best practices for a variety of ATMP applications for autologous and allogeneic applications, and facility design approaches for rapid scaling of production processes without disruption of existing operations.

## Panel Discussion: Ask the Experts

2:30

### The Present & Future of Aseptic Fill-Finish Operations

Moderator: Michael Eakins, Eakins & Associates, Inc.



#### Panelists:

- Laura Moody, Syntegon Pharma Technology, Inc.
- Les Edwards and Evan Lamb, SKAN US
- Royce Tourtillott, AES Clean Technology
- Evan Lamb, SKAN US

#### Participants:

The Audience

3:10

*Afternoon Coffee & Networking Break*

### Critical Issues—Aseptic Compounding in the 503B Industry

3:40

#### A Common-Sense Approach to Lyophilizer Cleaning Validation



**Joe Brower, President, Aseptic Process Solutions**

Lyophilizers are huge consumers of Water for Injection during Clean in Place processes. This consumption is driven in part, by the conflation of lyophilizers with other process vessels. In fact, for most lyo processes, product contamination of the interior surfaces of the lyophilizer is minimal. This discussion puts forth a risk-based approach to cleaning evaluation and validation that results in limited sampling during qualification activities, shorter cycles, and reduced WFI usage overall.

4:25

*End of Day One*

4:45

*Happy Hour Mixer*

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

## Wednesday, October 26, 2022

8:30

*Complimentary Breakfast*

### Critical Issues—Risk-based Approaches to Contamination Control

9:15

#### Contamination Control, Risk, and the Quality Management System



**Jeremiah Genest, Head of Quality Management Systems, Amylyx Pharmaceuticals**

Contamination Control is a fairly wide term used to mean "getting microbiologists out of the lab" and involved in risk management and the quality management system. This presentation will evaluate best practices in building a contamination control strategy and ensuring its use throughout the quality system. Leveraging a House of Quality approach, participants will learn how to: create targeted/ risk based measures of contamination avoidance; implement key performance indicators to assess status of contamination control; and ensure a defined strategy for deviation management (investigations), CAPA and change management.

10:00

#### A Risk Assessment Approach to Address Fungal Spore Contamination in a Cell and Gene Therapy Cleanroom



**Dan Klein, Senior Technical Service Manager, STERIS Corporation**

This presentation will cover a risk-based approach to pass thru decon of critical items into cleanrooms and RABS. There will be a focus on how to control hard to kill fungal spores such as Aspergillus and Chaetomium as well as bacterial spores and viruses. Recent case studies from the past few months in cell and gene therapy and compounding pharmacies will be discussed in relation to pass thru decon. Published data will also be mentioned to convey effective methods in control bioburden into the APA. This presentation will be a holistic approach to controlling bioburden from entering cleanrooms and controlled rooms.

10:45

*Midmorning Coffee and Networking Break*



11:15

## Future Trends in Total Contamination Control Strategies



**Sheba Zaman, Head of Product Specialists and Training Services, Novatek International**

The recent revision of Annex 1 encourages companies to develop a total contamination control strategy (CCS). A comprehensive strategy includes data from cleaning, environmental monitoring (EM), cleanroom qualification, media fills, and utility monitoring (UM). This enables expediting product development, improving quality, and reducing costs. Companies automating their trending often automate the elements of contamination control in hybrid systems, in isolation, or in data silos and this approach does not effectively facilitate root cause analysis or a comprehensive strategy for contamination control. As such, by the time the data from the various systems are correlated, and a trend is discovered, the underlying condition is likely to have changed.

Based on Annex 1, a total contamination control strategy is achievable through both automation tools and a centralized program. It starts with proper cleaning, proper determination of Maximum Safe Carryover (MSC), a routine cleaning program, EM, UM, and personnel monitoring, which completes the contamination control cycle. For this presentation, we discuss elements of a sound CCS, routine trends and data analysis that support a total CCS, and trending for investigational purposes including root cause determination. Furthermore, how to correlate or centralize trending of disinfectant qualification, effectiveness of cleaning, EM, UM, and personnel qualification.

12:00

*Complimentary Lunch*

## Panel Discussion—Ask the Experts

1:20

## Contamination Control, Risk and Quality Management

Moderator: Michael Eakins, Eakins & Associates, Inc.



Panelists:

- Sheba Zaman, Novatek
- Jim Polarine, STERIS Corporation
- Jeremiah Genest, Amylyx Pharmaceuticals

Participants:

The Audience

2:00

## Critical Environments in an Age of Transformation



**Norm Goldschmidt, President, Genesis**

Designing, building and managing the critical environments required to assure the quality and safety of pharmaceutical products was never easy. Don't believe me? Read the literally hundreds of 483 warning letters and other citations issued by regulators for failures in this area. Many of these issues are associated with the products and processes we have been doing for nearly 50 years. How then, do we handle the new challenges presented by an industry that is in the grip of massive transformation?

- Transformation of Modalities
- Transformation of Technologies
- Transformation of Expectations
- Transformation of Understanding

Transformation yields uncertainty, but it also brings opportunity! In this talk, we will discuss navigating the above transformations in the design, construction and management of critical environments. We will address a number of challenges and the tools to make the most of these changes to drive efficiency and cost-effective operation.

- ATMPs
- Single-use technology
- Closed processing
- Robotics
- Changing Regulations
- Cleanroom Classification and Monitoring Changes
- Elimination of Air Change Rates from Standards

2:45

*Afternoon Break*

3:05

## Viable Air Testing and the Myth of 1 CFU



**Mike Dingle, Product Specialist, TSI**

Annex 1 currently states the recommended limit of < 1 CFU/m<sup>3</sup> for air sampling in Grade A areas. This has led many to create a requirement for new air sampling equipment of being able to detect down to 1 CFU, whether it is an active air sampler or an instrument using an alternative microbiological method. This requirement is not complete and is insufficient to specify what is needed to be suitable for use. In order to determine what their true requirement should be, users need to understand what a CFU is and how it is detected; this is especially important if evaluating an alternative method that detects something other than CFUs. This presentation will discuss these topics and what should be considered in a detection requirement for air sampling equipment.

3:50

*Close of Program*



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La Jolla, California, has enchanted generations of travelers. Follow in their footsteps and embark on an adventure like no other with a stay at Sheraton La Jolla Hotel. Famous attractions like Torrey Pines Golf Course, the San Diego Zoo, Balboa Park, LEGOLAND and the USS Midway are all nearby. Visit celebrated academic institutions such as Birch Aquarium and the University of California San Diego. Our La Jolla hotel also places you near local restaurants, breweries, distilleries and shops. If you prefer to relax at our hotel, we offer an oasis filled with palm trees, manicured gardens, cascading waterfalls and tranquil koi ponds. Stay fit in our hotel gym and heated outdoor pool. At night, savor tasty cuisine, inventive cocktails and live entertainment at our two on-site restaurants before you retire to your peaceful accommodations. See why La Jolla is called the "Jewel of San Diego."



## **Registration Information**

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### **VENUE INFORMATION:**

Dates: **October 25–26, 2022**  
Venue: **Sheraton La Jolla Hotel**  
Venue Address: **3299 Holiday Court**  
**La Jolla, CA 92037**  
Venue Phone: **1 (858)-453-5500**

Please register me for:

### **Aseptic Processing Summit, 2022**

Early Bird (by Aug. 1)	\$1,395
Standard Registration	\$1,595
Call for government, academic, or non-profit rate	

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To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

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### **PLEASE NOTE:**

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