PharmaED RESOURCES, Inc.

Aseptic Processing Summit 2022

October 25–26, 2022, San Diego, CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Les Edwards
Skan US

Laura Moody
Syntegon

Tristen Stewart
Genentech

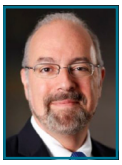
Sheba Zaman
Novatek Int'l

Pallavi Badkar
MedisourceRX

Joe Brower
Aseptic Process Solutions

Evan Lamb
SKAN US

Jeremiah Genest
Amylyx Pharmaceuticals



Norman Goldschmitt
Genesis AEC

Michael Eakins
Eakins & Assoc.

Josh Russell
AES Clean Tech.

Jim Polarine
Steris

Jim Polarine
Steris

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:

STERIS® · SYNTEGON PROCESSING & PACKAGING · Genentech A Member of the Roche Group · AMYLYX · NOVATEK INTERNATIONAL · SKAN

Medisource Rx · GENESIS ARCHITECTS • ENGINEERS • CONSTRUCTORS · TS® · aes Clean Technology · Aseptic Process Solutions, LLC

Contact: Kim Hubbard
khubbard@pharmaedresources.com or call (217) 721-5774

Tuesday, October 25, 2022

8:30 *Registration & Complimentary Breakfast*

9:10

Chairperson Michael Eakins' Welcome & Opening Remarks

9:15 **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*

1:30 **Considerations & Strategies for ATMP Facility Design to Deliver Flexibility, Expandability & Quality**

Josh Russell, Vice President, Sales and Marketing, 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

2:15 **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**
- **Josh Russell, AES Clean Technology**
- **Evan Lamb, SKAN US**

Participants:

The Audience

3:00 ***Afternoon Coffee & Networking Break***

Critical Issues—Aseptic Compounding in the 503B Industry

3:30 **Contemporary & Critical Issues Surrounding Aseptic Compounding in the 503B Industry**

Tristen Stewart, Aseptic GMP Observation Consultant, Genentech

This session will focus on the contemporary and critical issues surrounding Aseptic Compounding within the 503B Industry. That includes cleaning of cleanrooms and materials, personnel challenges inside the ISO environment, and product management during production and post-production. The key concern is maintaining microbial control of the environment in sterile compounding processes. This is because personnel, even those who use good aseptic techniques, shed enormous numbers of particles from themselves and their clothing and these particles are laden with microorganisms. This highlights the critical need for education, evaluation of aseptic technique, and compounding of sterile products. All the issues and remediation described above are to maintain compliance with USP-NF Chapter <797>, cGMP Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503b of the FD&C Act, and regulatory expectations for the pharmaceutical industry.

4:15 **Aseptic Compounding in the 503B Industry: Challenges and Mitigations**

Pallavi Devurkar-Badkar, Director of Operations-503b, MedisourceRx

The NECC tragedy in the compounding industry prompted Congress to sign the Drug Quality and Security Act (DQSA) with the goal of preventing future tragedies. The 503B Outsourcing Facility designation originated from the DQSA. This type of facility is a primary and preferred manufacturing source of drugs on shortage. They also may manufacture sterile injectables from non-sterile APIs from the FDA approved bulk list. The challenge for this entity is that 503B's must follow cGMP but payers request small batch sizes of several types of drugs packaged in various containers. While it is most ideal to employ automatic filling machines to ensure sterility assurance of aseptic processing of drugs, these technologies are cost prohibitive, inefficient in changeover, and often not flexible in container choice. Therefore, manual aseptic processing (MAP) is often employed in this industry as well as in traditional compounding pharmacies. While MAP allows for an increased flexibility of the containers used and drug formulations produced, there is a high risk of contamination from human interventions.

The goal of this presentation is to discuss various approaches to mitigate the challenges of semi-automatic aseptic processing using best practice aseptic techniques to ensure sterility during critical human interventions. Select small batch filling and finishing equipment, closed ready-to-fill systems, and single-use aseptic processing supplies will also be discussed as aids in achieving sterility with MAP. Finally, the importance of sourcing injectable-grade APIs as a manufacturer's responsibility in preventing adverse drug events will also be discussed.

5:00 ***End of Day One***

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**

Jim Polarine, 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 well 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.

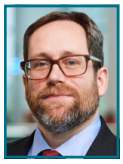
12:00 *Complimentary Lunch*

Panel Discussion—Ask the Experts

1:20 **Contamination Control, Risk and Quality Management**

Moderator: Michael Eakins, Eakins & Associates, Inc.



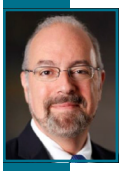
Panelists:

- **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^3 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 **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.

4:35 ***Close of Program***

Pharma Ed's Aseptic Process Summit is Sponsored by

SYNTEGON PROCESSING & PACKAGING

NOVATEK INTERNATIONAL

element

ON drugDELIVERY

PharmaED RESOURCES, Inc.

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

About your conference destination:

Located in Mission Valley, the Marriott San Diego Mission Valley is the ideal gateway to experience the best of San Diego. Enjoy easy access to San Diego State University, SDCCU Stadium (formerly Qualcomm), Old Town, or hop on the Rio Vista Trolley and explore Mission Bay, SeaWorld, and Downtown San Diego including PETCO and Gaslamp District. See our refreshed meeting spaces including our all-new event lawn ideal for memorable outdoor gatherings. Enjoy a host of amenities and services, from views and casual dining at DEN to our fully equipped fitness center and outdoor pool with a waterfall. Well-appointed guest rooms and spacious suites offer 55" SMART TV's, high-speed Internet and balconies and are perfect for groups visiting San Diego. You will appreciate our Mission Valley hotel's unmatched charm and sophistication.

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com **Phone:** (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____
LAST NAME: _____
TITLE: _____
COMPANY: _____
ADDRESS: _____
ADDRESS: _____
CITY: _____ **STATE:** _____
ZIP: _____ **COUNTRY CODE:** _____
OFFICE PHONE: _____
MOBILE PHONE: _____
FAX: _____
E-MAIL: _____

VENUE INFORMATION:

Dates:	October 25–26, 2022
Venue:	Marriott San Diego Mission Valley
Venue Address:	8757 Rio San Diego Drive San Diego, CA 92108
Venue Phone:	(619) 692-3800

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	

PAYMENT METHOD

CREDIT CARD REGISTRATION:
☐ CREDIT CARD ☐ VISA ☐ MASTERCARD ☐ AMEX
NAME: _____
CARD #: _____
EXPIRATION: ____ / ____
SIGNATURE: _____
BILLING ADDRESS: _____

CHECK REGISTRATION:
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.
PURCHASE ORDER #:

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.