

Aseptic Processing Virtual Summit 2020

September 21 – 22, 2020
Online, Eastern Daylight Time

Featuring Lessons Learned and Case Studies from Industry Experts:



Michael Eakins
Eakins & Associates
(Event Chairperson)



Les Edwards
Skan US



Laura Moody
Syntegon



Chuck Raye
Millipore Sigma



Dawn Watson
Merck



Jessica Frantz
Sartorius Stedim



William Peterson
Merck



Sheba Zaman
Novatek
International



Pallavi Badkar
MedisourceRX



Andre Zduncyk
Bausch + Stroebel



Jim Polarine
Steris



Carol Julich
TSI Inc.



Chris Fee
IMA Life N.A.



Joe Brower
Aseptic Process
Solutions



Travis J Imhof
Fluid
Management
Technologies

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:

- A Risk Based Approach to an Environmental Monitoring Assessment
- Using Scientific Data to assess the Risk of Sterilizing Filter Flaw Masking and the Need for Pre-use, Post-Sterilization Integrity Testing
- Designing a Risk Based Cleaning and Disinfection Program
- Continuous Microbiological Environmental Monitoring for Aseptic Manufacturing
- Innovations in Aseptic Processing- Opportunities & Challenges for Implementation
- Single Use Manufacturing Systems – Practical Considerations
- Aseptic Compounding in 503b Industry: Challenges and Mitigation
- Terminal Sterilization or Bioburden Reduction Processes using Ionizing Radiation
- Isolators for Cell and Gene Therapy: Closing the Process for ATMPs
- NextGen Now-The Future of Advanced Therapy Medicinal Products (ATMP) Facilities
- New Developments in Lyophilization and Automatic Vial Loading/Unloading
- Single-Use Technologies Used for Aseptic Processing and Final Filling Applications
- Media Fills/Aseptic Process Simulation and Validation
- Clinical and Small-Scale Aseptic Manufacturing, a Modular Filling System Approach
- And More!

With Representation From:



**Monday, September 21,
Eastern Daylight Time**

8:20 *Chairperson Michael Eakins' Welcome & Opening Remarks*

8:35 **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. The presentation will discuss some of the proposed changes to Annex 1.

Since 2010, there have been numerous additions to the microbiology chapters in the USP which are relevant to aseptic processing. Also the USP Packaging Expert Committee has product four drafts of their Single-Use Systems General Chapters <665> and <1665> with the latest draft scheduled for publication in the Pharmacopeial Forum on September 1, 2020. The relevant microbiology chapters and the latest draft of the two SUS chapters will be reviewed.

Spotlight on Single-Use Systems & Technologies

9:15 **Single-Use Technologies Used for Aseptic Processing and Final Filing Applications**



Jessica Frantz, Technology Expert — Aseptic Transfer, Sartorius Stedim North America, and Travis J. Imhof, Field Application Specialist, Fluid Management Technologies



Single-Use systems are being implemented by many end-users in the Biopharmaceutical manufacturing community. From bags for storage & mixing to aseptic connections & disconnections, these items are being used from media & buffer prep all the way to final filling applications. This presentation will go over the single-use technologies available today for use in aseptic manufacturing. In addition, the presentation will cover single-use systems used for the aseptic transfer of components and final drug product into the Grade A manufacturing space. Single-Use filling systems will also be discussed, showing the details needed for system design to ensure sterility and maintain dosing accuracy.

9:55 **Single-use Technologies in Aseptic Filling Applications**



Chuck Raye, Single Use Final Fill Manager, MilliporeSigma

This presentation will provide an overview of how SU systems are used in final sterilization filtration and aseptic filling processes to enable a more flexible drug product manufacturing process. Advancements in SU technologies such as SU filter designs to enable PUPSIT, packaging of SU filling needles for isolator/RABS filling machines and SU rotary piston pumps will be presented.

10:35 **Morning Break & Sponsor Presentations**



10:50 **Single Use Manufacturing Systems — Practical Considerations**



Joseph Brower, President, Aseptic Process Solutions, LLC

Single use manufacturing systems are widely used in bio-pharmaceutical manufacturing due to their safety, convenience, and design flexibility. They offer many advantages over re-usable systems but care must be taken when choosing single use systems. There are disadvantages as well including chemical compatibility issues, sterility assurance questions, supply interruptions, and questions regarding environmental impact. Careful consideration of the pros and cons will help determine where single use systems are preferred, and when they may be the wrong choice.

Q&A: Ask the Experts

11:30 **Single Use Technologies Panel Discussion**

Moderator: Michael Eakins, Eakins & Associates

Panel:

- Chuck Raye, MilliporeSigma
- Joseph Brower, Aseptic Process Solutions
- Jessica Frantz, Sartorius Stedim
- Travis Imhof, Fluid Management Technologies

Discussants: The Audience

12:00 **Lunch Hour. Visit the Networking Chatroom.**

**Industry Working Group Update —
The Sterile Filtration Quality Risk
Management Consortium**

1:00

**Using Scientific Data to Assess the Risk of
Sterilizing Filter Flaw Masking and the Need for
Pre-use, Post-Sterilization Integrity Testing**



**William Peterson, Associate Director
of Engineering: Sterile Product
Manufacturing, Merck**

This talk summarizes the efforts of the Sterile Filtration Quality Risk Management consortium ("SFQRM"), a joint project by the Parenteral Drug Association and the BioPhorum. Using objective methodologies, the team has generated new data shedding light on the risk of filter flaw masking. The publication of a manual of best practices for pre-use, post-sterilization filter integrity testing will be announced, compiled by filtration experts across the industry and designed to minimize the risks to sterile products when performing this complex operation. Recommendations will be made for the use of scientific data in process-specific risk assessments on filter integrity testing.

**Critical Issues — Risk-Based Approaches
to Environmental Monitoring**

1:40

**A Risk Based Approach to an Environmental
Monitoring Assessment**



**Dawn Watson, Director, Sterile Technology
& Commercialization, Merck**

An industry collaboration comprising of 20 companies worked on the development of an easy to use standardized risk-based EM approach which improves the level of objectivity when identifying environmental monitoring locations in cleanrooms, conventional aseptic filling lines, RABS, and isolators. The approach will be described and recommendations will be provided for how the industry could adopt this approach to ensure that high standards for the design of a risk-based EM program are followed in a consistent manner.

2:20

**Continuous Microbiological Environmental
Monitoring for Aseptic Manufacturing**



**Carol Julich, Contamination Specialist,
TSI Inc.**

Biofluorescent particle counters (BFPC) offer an alternative method for viable air testing that not only monitors continuously, but provides real-time results with improved detection. This provides better understanding of the aseptic manufacturing process to make more informed quality decisions. In addition, they remove the contamination risk from the environmental monitoring process because no interventions are required. This presentation will review the technology used by these instruments and how to use them to improve your process and reduce risk.

3:00

Afternoon Break & Sponsor Presentations



Q&A: Ask the Experts

3:15

**Environmental Monitoring & Sterile Product
Manufacturing Panel Discussion**

Moderator: Michael Eakins, Eakins & Associates

Panel:

- William Peterson, Merck
- Dawn Watson, Merck
- Carol Julich, TSI, Inc.

Discussants: The Audience

3:55

**Terminal Sterilization or Bioburden Reduction
Processes Using Ionizing Radiation**

**Betty Howard, Senior Radiation Sterilization
Manager, Applied Sterilization Technologies,
STERIS Corporation**

This presentation will review Ionizing radiation processes (Gamma, Electron Beam and X Ray). What they are, how they work, their similarities and differences, their Pros and Cons vs. other sterilization modalities, key considerations in using them and applications in Pharmaceutical products and processes.

4:35

End of Day One

**Tuesday, September 22,
Eastern Daylight Time**

8:20

Pharma Ed welcome and opening remarks

8:35

**Designing a Risk Based Cleaning and
Disinfection Program**



**Jim Polarine, Jr., Senior Technical Service
Manager, STERIS Corporation**

This presentation will cover the current industry trends and best practices in disinfectant global regulations, rotation, disinfectant application methods, application frequencies, residue removal and rinsing strategies, and a case study will be covered that examines CAPA investigations with fungal and bacterial spores in cleanroom operations. Annex I (Draft 2019), Warning Letters, 483s, and PDA Technical Report No. 70 sections will be covered which relate to the topics mentioned.

The presentation will focus on industry trends and industry best practices based on 20 years of global industry experiences.

Key Topics Covered:

- Industry Regulations
- Technologies (Chemistries)
- How to Select the Best Chemistry
- Application Methods
- Frequencies of Sanitizers, Disinfectants, and Sporicides
- Rotation and Rinsing Strategies

Technology Spotlight — The Present & Future of Aseptic Fill-Finish Operations

9:15

How the Future of Final Fill Demands Future-focused Solutions: A Case Study



Laura Moody, Ph.D., Product Manager – Primary Packaging, Pharma Liquid Packaging, North America, Syntegon Pharma Technology, Inc.

Necessity is the mother of invention. When a major biopharmaceutical manufacturer's R&D facility needed a new fill-finish line to support preclinical and clinical development of their advanced therapies pipeline, the equipment industry landscape was not well suited to their requirements. After striking an innovative partnership with Bosch Packaging Technology (now Syntegon Pharma Technology), a new machine concept was born. This presentation will discuss the journey from design to delivery, highlighting both technological advances in the field (i.e. barrier systems, automation, robotics, flexibility in dosage form, etc.) as well as challenges overcome along the way.

9:55

Morning Break & Sponsor Presentations



STERILE TECHNOLOGY

Research Spotlight — Overcoming Small Batch Aseptic Manufacturing Challenges

10:10

Aseptic Compounding in the 503B Industry: Challenges and Mitigations



Pallavi Badkar, MS, RPH, BCSCP, Manufacturing Manager, 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 API's 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 manual 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 API's as a manufacturer's responsibility in preventing adverse drug events will also be discussed.

10:50

Clinical and Small-Scale Aseptic Manufacturing, a Modular Filling System Approach



Andre Zdunczyk, Sales Manager, Bausch + Stroebel

The trend in Bio-Pharmaceutical processing is towards smaller and personalized batches of medicines. Brining a diverse mix of therapies packaged in different delivery methods to the market is one of the main challenges in the pharmaceutical industry. This presentation will cover the transition of components into a filling Isolator, robotic TUB and nest handling, the utilization of a single use product path with the flexibility to change containers and filling methods using a single modular aseptic packaging system.

11:30

Learn How to Trend & Analyze EM Data



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

This presentation will cover two areas critical to the Aseptic Processing space.

Part 1: EM Trending Requirements

- Overview on requirements and guidelines on EM data analysis
- Considerations for EM data analysis using computerized system versus manual systems including speed of analysis, accuracy, volume of data
- Routine Environmental Monitoring Reporting for State of Control including Recovery Rate Reports, Control Charts, Continuous Monitoring Trends, Microorganism Trends and Linear Regression by sampling sites
 - Review of method for trending
 - Frequency of trending
 - Data parameters used
 - Filtering and grouping data
- Understanding the meaning of EM data trends including risk identification, pattern recognition, actions required, and conclusions.

Part 2: Trending for Root Cause Analysis

- **Non-Routine data analysis for assisting in investigations including**
 - Assessing root cause and assessment of impact to product including comparison of personnel, equipment, product sampling sites, media, microorganisms, occupant count, proximity to process/product.
 - Setting appropriate alert measures required for maintaining a state of control based on data including pattern recognition (rolling specifications), adverse trends, and non-conformances.
- Using EM data analysis as part of a continuous improvement to EM program improvements

12:15 *Lunch Hour. Visit the Networking Chatroom.*

1:15 **Isolators for Cell and Gene Therapy: Closing the Process for ATMPs**



Les Edwards, Vice President, Technology & Business Development, SKAN US, Inc.

It is well acknowledged that aseptic fill-finish operations, even for small batch processing, is preferred to be performed within an isolator. Many upstream, cell expansion and downstream operations also benefit from a more secure aseptic environment to improve quality, environmental control, and reduce the chance of product contamination. The challenge is to implement isolators in operations that are traditionally performed in clean-

rooms and biosafety cabinets. The facility and operational savings can also be significant. The right technologies need to be deployed to allow for easy, validatable and rapid transfers for temperature sensitive items, and integration of incubation and centrifugation equipment in addition to traditional lab instrumentation.

1:55

New Developments in Lyophilization and Automatic Vial Loading/Unloading



Chris Fee, Product and Sales Manager, IMA Life North America, Inc.

There are numerous advanced technologies being developed for and incorporated into freeze drying processes (a.k.a. lyophilization) to improve product homogeneity, increase efficiency, and reduce cGMP risk. In this presentation we will explore various tools and techniques, and discuss what the future will bring.

Q & A — Ask the Experts

2:35

Closing Panel Discussion — The Present & Future of Aseptic Fill-Finish Operations

Panelists:

- Laura Moody, Syntegon Pharma Technology, Inc.
- Les Edwards, SKAN US
- Chris Fee, IMA Life N.A.

3:00

Close of Program

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In the Age of COVID, the Show Must Go Online

In response to overwhelming audience and speaker feedback, and in view of the current health and safety concerns involving the novel coronavirus COVID-19, we're taking our events online (at least for the foreseeable future; we do hope to see you again soon in person when all this is over!) **Aseptic Processing Virtual Summit 2020** is an entirely online event, complete with insightful presentations from leading researchers, 1:1 networking opportunities, live question & answer sessions, and sponsored informational presentations that highlight how vendors are tackling some of the key issues facing this market. Just sit back and enjoy this online learning experience from the safety and comfort of your home or office. Missed a session or two? No worries—the full program will be archived and available for post-conference viewing and download.



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