Aseptic Processing Summit 2020
April 15–16, 2020
Philadelphia, PA

Featuring Lessons Learned and Case Studies from Industry Experts:

- 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 Comprehensive Coverage On:

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.
### Wednesday, April 15

**8:00**
*Registration & Complimentary Breakfast & Chairperson’s Welcome*

**8:45**
*S spotlight on Single-Use Systems & Technologies*

**9:25**
*S single-use Technologies in Aseptic Filling Applications*

**10:05**
*Coffee & Networking Break*

**10:30**
*S single Use Manufacturing Systems — Practical Considerations*

**11:00**
*Q&A: Ask the Experts*

**11:40**
*Complimentary Networking Lunch*

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**11:10**
**Single Use Technologies Panel Discussion**

Panel:
- Chuck Raye, MilliporeSigma
- Joseph Brower, Aseptic Process Solutions
- Jessica Frantz, Sartorius Stedim North America

Discussants: The Audience

**11:40**
**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.

**1:45**
**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.

**2:30**
**Coffee & Networking Break**
3:00 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.

Q&A: Ask the Experts

3:35 Environmental Monitoring & Sterile Product Manufacturing Panel Discussion

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

Discussants: The Audience

4:05 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.

4:50 Networking Happy Hour

Thursday, April 16

8:00 Complimentary Breakfast

8:45 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

9:30 Advanced Sterile Facilities: Opportunities and Challenges from Design through Implementation

Hite Baker, Principal Process Engineer, O’Neal, Inc.

The journey from design-to-licensure of new sterile facilities was revolutionized during the 2000’s by technical advancements: modular/ flexible fillers, barrier systems for product protection and containment, advancing automation, smart robotics, single-use and ready-to-use components. As the benefits of Advanced Aseptic Technology multiplied, so also did the challenges during project delivery multiply. Owners must not only choose optimum aseptic technology, but also program the facility to create efficient/compliant layouts for good flow and cGMP cleanliness. Owners must also construct the building, commission it, qualify it, validate and license it. In 2020, it’s more important than ever not only get the technical scope right, but also to create an accurate cost estimate, a controllable budget and a manageable schedule. Lessons learned and lively case studies will show the opportunities and pitfalls during design, construction and start-up, and how to avoid the big mistakes.

Coffee and Networking Break

10:15 Research Spotlight — Overcoming Small Batch Aseptic Manufacturing Challenges

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 APIs as a manufacturer’s responsibility in preventing adverse drug events will also be discussed.

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.

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.
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