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!
Monday, September 21

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

8:45  Single-Use Technologies Used for Aseptic Processing and Final Filing Applications

Jessica Frantz, Technology Expert – Aseptic Transfer, Sartorius Stedim North America

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.

9:25  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.

10:05  Coffee & Networking Break

10:30  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.

11:10  Single Use Technologies Panel Discussion

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

Discussants: The Audience

11:40  Complimentary Networking Lunch

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

5:05 Challenges from Design through Implementation

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

10:45 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

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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.

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.

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 cleanrooms 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.

Coffee and Networking Break

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

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.

Close of Program
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