PharmaED RESOURCES, Inc.

Aseptic Processing Summit 2024

Best Practice Technologies for Aseptic Processing and Contamination Control

October 23-24, 2024 La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Juergen Metzger
Bausch+Strobel

Laura Moody
Syntegon

Dan Klein
STERIS

Sebastian Scheler
Innerspace

Donald Singer
Ecolab

Merritt Postma
SKAN US

Derek Duncan
Lighthouse Instruments

Mike Dingle
TSI

Amanda Curtis
ValSource

Jim Polarine
STERIS

Tony Perry
Schott Pharma

Maria Luisa Bernuzzi
Mesa Labs

Michael Eakins
Eakins & Assoc.

Beth Massoth
Curis System

Marsha Steed
JYA

Josh Russell
AST Inc

Mark Hallworth
Particle Measuring Systems

Richard Denk
SKAN AG

With Comprehensive Coverage On:

- First Inspector Findings and Requirements Based on the Annex 1
- A Roadmap to a Successful Cleaning and Disinfection Program that Meets Annex I Guidance
- Environmental Data Collection, Reporting and Analysis; Current Requirements and Trends for the Future
- Biofluorescent Particle Counting: a Solution for Meeting Annex 1 Viable Air Testing Requirements
- Qualifying a Risk-based, Next-gen Cleaning and Disinfection Program: The Crossroads of Efficiency and Compliance in Today's Cleanroom
- Using Advanced Robotics to Remove Operators from Aseptic Fill/ Finish Processing
- The Future is Patient-Centered: Advancements in ATMP Fill-Finish
- Optimizing CCS for Barrier Technologies and Cleanrooms: Insights from Biodecontamination Studies
- How to Design a Risk-Based EM Performance Qualification
- Contemporary Small Batch Fill Finish Solutions and the Next Generation in Pharma Machinery
- Bioburden and Biofilm Remediation
- Controlling Contamination During Material Transfer for Aseptic Processing
- Container Closure Integrity Assurance: A Modern Holistic Approach to Container Closure

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Wednesday, October 23, 2024

7:30 *Registration Check-in & Complimentary Breakfast*

8:30 *Chairperson Michael Eakins' Welcome & Opening Remarks*

Critical Issues—Contamination Control Strategies

8:35

Contamination Control Strategy—a Holistic Approach

Tony Perry, Customer Support Director, SCHOTT Pharma NA

In August 2023, the EU GMP Annex 1 for the manufacture of sterile medicinal products came into effect. According to Annex 1 and various summaries (such as the PDA letter from November 2022), Quality Risk Management is crucial. Contamination Control Strategy is a significant area that requires a holistic approach to enhance the quality of the product and ensure patient safety.

In this section, we will discuss strategies for controlling particle contamination. The incorporation of isolator technology and robotic systems in the fill and finish area has played a substantial role in reducing particle generation in recent years. Many of these lines are flexible filling lines that work with ready-to-use packaging to eliminate glass-to-glass contact throughout the process, which is a considerable benefit. Additionally, suppliers of primary packaging in a ready-to-use configuration can also significantly reduce particle contamination by reducing the risk already at the introduction into the isolator. SCHOTT Pharma has identified multiple crucial areas to support pharma companies to comply with Annex 1, including quality by design in regards to the ready-to-use packaging and others.

9:15

A Roadmap to a Successful Cleaning and Disinfection Program that Meets Annex I Guidance

Jim Polarine, Senior Technical Services Manager, STERIS Corporation

This presentation will cover a Contamination Control Strategy that utilizes a risk-based approach to cleaning and disinfection of cleanrooms. The seminar will focus on cleaning and biodecontamination of cleanrooms, BSCs, RABS, and Isolators. There will be a focus on how to control hard to kill fungal spores such as Aspergillus as well as bacterial spores and viruses. Biodecontamination and cleaning of BSCs, RABS, and Isolators will be covered in detail. The topics of cleaning frequency, disinfectant rotation, and rising frequencies will be discussed. Recent case studies from cleanroom facilities will be discussed in relation to materials transfer. Published data will also be mentioned to convey effective methods in control bioburden into the aseptic processing area. This presentation will be a holistic approach to controlling bioburden from entering cleanrooms and controlled environments.

9:55 *Mid-morning Coffee & Networking Break*

Case Study on Annex 1

10:30

First Inspector Findings and Requirements Based on the Annex 1

Richard Denk, Senior Consultant, Aseptic Processing & Containment, SKAN AG

CCS protecting the critical area like the transfer from the primary packaging and the sterile product. Where are the critical areas and how to protect them with first air, automated and validated transfers of the primary packaging, the right handling of indirect product contact surfaces, cleaning of non and indirect product contact surfaces and the future outlook of the use of robotics.

Spotlight on ATMPs

11:10

The Future is Patient-Centered: Advancements in ATMP Fill-Finish

Josh Russell, Vice President, Sales & Marketing, AST Inc.

ATMPs have become a center of focus and innovation within the pharmaceutical manufacturing industry. As applications in patient-centered medicine continue to grow and reach more people, manufacturers and regulatory bodies alike continue to adjust and strategize on the best path forward. Prevailing manufacturing and regulatory frameworks are being reassessed as there's growing interest in agile concepts like distributive manufacturing and streamlined approval processes. The market is being primed for growth, and the question becomes how best parenteral drug manufacturers can meet the ever-growing requirements for speed and flexibility in ATMP production. This presentation will cover both the latest breakthroughs in the production of highly targeted liquid pharmaceuticals, and survey real-time operational solutions implemented through robotics and automation while maintaining cGMP compliance (including Annex 1) and data integrity. Presentation includes:

- Current regulatory and manufacturing trends for ATMP production
- Best practices for implementing an automated fill-finish line
- Utilizing flexible technology to meet operational requirements

- Leveraging cohesive vision and sensor checks for quality control
- Bolstering Grade A air and product integrity
- Fill-finish breakthroughs: highlighting some of the latest automated aseptic processing innovations

11:50 *Complimentary Lunch, Sponsored by*

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1:05 **Qualifying a Risk-based Next-gen Cleaning and Disinfection Program: The Crossroads of Efficiency and Compliance in Today's Cleanroom**

Donald Singer, Senior Microbiology Technical Consultant, Ecolab

Microbiological contamination is a primary reason for contamination control strategy. Our industry continues to strive to change from legacy approaches for cleaning and disinfection to modern technologies with the values gained from incorporating automation and closed systems. Supported by new Annex 1 revisions, along with expectations of risk-based thinking, regulatory investigators globally are seeking better control and understanding for cleaning and disinfection programs and a crucial fit into contamination control strategy. This presentation will offer expertise to biopharmaceutical, cell and gene therapy, and pharmaceutical scientists with a roadmap of solutions to qualify your cleaning and disinfection program pragmatically and scientifically.

1:50 **Autogenerated Risk Profiles to Accelerate Process Design**

Sebastian Scheler, Co-founder, Managing Director, Chief Methodologist, and Frame-by-Frame Risk Profiling Supervisor, Innerspace

To accelerate commercialization, the necessary production processes must be developed quickly without compromising safety and risk management. However, due to their inherent complexity, the risks in the processes are often manifold and can only be identified with a considerable amount of time and resources. This delays the market launch of important drugs and is often associated with major corrections, as some process weaknesses remain unidentified, jeopardizing the entire commercialization process. The main reason for the high-effort and error-prone nature of process design and risk assessment is that they have to be created largely manually. The presentation will introduce a novel process simulation approach that utilizes a generic database around so called "process-frames" (process-microsteps) to develop data-driven recommendations for process design and autogenerated risk management insights with unprecedented accuracy. By linking the "process frames" with numerous production data, a self-learning software has been created that also identifies potential risks for new process ideas and helps to achieve robust process design and CCS more efficiently. The presentation presents case studies and shows how "Frame-by-Frame Risk Profiling" has significantly accelerated process design and risk management - both prerequisites for faster plant and operational readiness.

2:30 *Afternoon Coffee & Networking Break*

3:00 **Biofluorescent Particle Counting—A Solution for Meeting Annex 1 Viable Air Testing Requirements**

Mike Dingle, Senior Product Specialist, Controlled Environments, TSI

Annex 1 of the European Good Manufacturing Practices is the most widely followed guidance in the world for the monitoring of pharmaceutical cleanrooms. After numerous drafts and pandemic related delays, an update was released in 2022. A push for modernization is a theme throughout the document. This is viewed as a way to not only avoid shortages through increased production, but to also improve quality. Biofluorescent Particle Counting (BFPC) is a modern method for viable air monitoring in Grade A environments that is fully automated and provides results in real-time. Implementing use in place of traditional microbiological methods increases process understanding and eliminates interventions that interrupt production and introduce risk.

CRITICAL ISSUES—ENVIRONMENTAL MONITORING

3:40 **How to Design a Risk-Based EM Performance Qualification**

Amanda Curtis, Microbiology Consultant, ValSource

A risk-based approach to creating an environmental monitoring (EM) program demonstrates that the program is properly set up to detect potential contamination. This approach is also a regulatory expectation, as evidenced by multiple recent 483 observations for missing scientific justification of EM sampling decisions. PDA Technical Report 13 was revised in 2022 to include enhanced guidance for performing an EM Performance Qualification (EMPQ) and the revisions in Annex 1 (2022) include requirements for how and when to perform an EMPQ. This presentation introduces the EMPQ and demonstrates how the concepts of quality risk management can be applied when designing an EMPQ and routine EM program.

4:20

Bio-Decontamination with Hydrogen Peroxide: In a World of Uncertainty, How to Use Biological Indicators to Provide a Sure Result

Maria Luisa Bernuzzi, Product & Application Engineer, Mesa Labs

Biological Indicators were always used as "sensors" for the effectiveness of the process.

Positive and unpredictable results in decontamination validation or revalidation have caused difficulties, delays, costs and rogue BIs were often considered the real cause of a failure. The user blamed them as responsible for the unexpected results.

An overview of the biological indicators for the process, their "instructions for use" for decontaminating an isolator and the "Rogues" topic.

5:00 ***Happy Hour Mixer, sponsored by***

STERIS Life Sciences

Join us in the hotel lounge for informal networking. Complimentary beverage and appetizers provided by STERIS.

Thursday, October 24, 2024

7:45 ***Complimentary Breakfast***

8:45

Environmental Data Collection, Reporting and Analysis; Current Requirements and Trends for the Future

Mark Hallworth, Life Sciences GMP Advisor, Particle Measuring Systems

The revision to Annex 1 has placed more emphasis on how to treat environmental data, it is now not only the value that is important but that piece of data's place in the monitoring program. This session will look at how to collect meaningful data, how to interpret that data, and how to report the environmental conditions in a format that is aligned with current requirements and a site CCS program.

9:25

Contemporary Small Batch Fill Finish Solutions and the Next Generation in Pharma Machinery

Juergen Metzger, Director of Turnkey Projects & New Technologies at Bausch + Stroebel Machine Company

This presentation highlights the success story over the last 10 years of the flexible filling platforms for vial, syringe and cartridge processing.

Looking forward, we will highlight the advancements shaping the next generation of pharmaceutical manufacturing. The pharmaceutical industry is constantly evolving, driven by technological innovations aimed at enhancing efficiency, quality, and adaptability in drug manufacturing processes. Central to the advancements in pharmaceutical machinery is the introduction of the linear motor container transport system, which offers unparalleled precision, speed, and flexibility compared to traditional drive systems.

We will provide an overview of the innovations driving the next generation of pharma machinery, including robotics, artificial intelligence, virtual reality, predictive maintenance, integrity testing, (Environmental) Monitoring, single-use technology, ready-to-use principle, Annex 1 compliance, and specialized equipment for emerging applications such as cell and gene therapy and antibody-drug conjugates (ADCs).

These technological advancements are propelling the pharmaceutical industry forward with transformative potential optimizing the drug manufacturing processes, ensuring product quality, and meeting the evolving demands of the healthcare landscape.

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

TECHNOLOGY SPOTLIGHT—ROBOTICS IN FILL/FINISH

10:35

Using Advanced Robotics to Remove Operators from Aseptic Fill/Finish Processing

Laura Moody Ph.D., Director of Product Management Pharma, North America, Syntegon

During aseptic pharmaceutical manufacturing, contamination is the enemy. Where does most of the contamination originate? Humans. By eliminating humans from the production process, product safety skyrockets. This can be accomplished using advanced robotics. Fully robotic aseptic working cells within gloveless isolators are popping up within the primary packaging industry and adoption of this new manufacturing process is rapidly growing. Making the switch to advanced robotic processing is not an easy decision for pharmaceutical manufacturers. This presentation will cover the current state of robotic fill/finish and what drug producers should consider regarding regulatory compliance, process efficiency, flexibility, and product safety.

Spotlight on Biofilm Remediation

11:15 **Bioburden and Biofilm Remediation**

Dan Klein, Senior Technical Services Manager, STERIS Corporation

There is no universal method to determine the presence of biofilm within a cleanroom environment. Standard disinfecting approaches often will not solve this challenging issue which can cause multiple problems for product manufacturing and worsen over time. This presentation will outline general bioburden strategies and the testing and claims associated with disinfecting biofilm. Successful approaches will be presented showing how to identify, remediate and prevent recolonization of biofilm in a controlled environment. This presentation will also address complicating factors such as mixed-species biofilm, biofilm containing bacterial spores and biofilm on rouged or damaged surfaces. Case studies will be presented.

11:55 *Complimentary Lunch*

1:05 **Controlling Contamination During Material Transfer for Aseptic Processing**

Marsha Steed, Founder & CEO at Steed MicroBio/Expert Microbiology Consultant at JYA, and Merritt Postma, Executive Director, SKAN USA

Transferring materials into a Grade A manufacturing environment is a high-risk activity for the introduction of contamination into the critical processing area. The revision of Annex 1 has placed a strong emphasis on the importance of proper contamination controls during material transfer to prevent microbial contamination. This presentation will review proper cleaning, disinfection, decontamination and/or sterilization requirements for material transfer into various Grade A environments (e.g., biological safety cabinets (BSCs), RABS and isolators). A review of the Annex 1 requirements will be presented and challenges to the requirements will be reviewed.

A review of material transfer risks for manual material transfer into BSCs for pharmaceutical, biologics and/or ATMP manufacturing will be performed and solutions for improved material transfer, including use of isolator technology, will be presented. Advanced options in material transfer into isolators using e-beam sterilization will also be presented.

1:45 **Optimizing CCS for Barrier Technologies and Cleanrooms: Insights from Biodecontamination Studies**

Beth Massoth, Biocontainment Specialist, CURIS System

Optimizing contamination control while maintaining rapid throughput requires a delicate dance between efficacy and cycle time of your decontamination process. As regulators enforce stricter standards by requiring barrier technologies to provide the protection of a Grade A environment, as well as leveling up the disinfection requirements for surrounding cleanroom spaces (Annex 1), it is important to identify easier-to-implement, yet efficacious, processes for contamination control in both environments. This presentation will offer insights into potential process improvements in achieving reliable, repeatable sterility assurance levels in aseptic environments. We will explore studies on fill-finish cycles using various hydrogen peroxide technologies with total cycle times ranging from hours to minutes. Differences in delivery methods, cycle times, concentrations, and outcomes will be considered. Understanding the need to decontaminate outside the barrier environment as well as the inside of isolators, RABs, or BSCs in a timely manner, we will also review data applying these same principles, benefits, and applications to effective decontamination of cleanrooms. This presentation will provide an overview of best practices for ensuring optimal contamination control strategies (CCS) in all areas of your facility while expediting the decontamination process.

2:25 *Afternoon Break*

Spotlight On Container Closure Integrity

2:40 **Container Closure Integrity Assurance: A Modern Holistic Approach to Container Closure**

Derek Duncan, Director, Product Line, LIGHTHOUSE Instruments

Driven by recent regulatory guidance, best practices in container closure integrity (CCI) testing are evolving. This presentation describes case study examples of how companies are complying to new container closure requirements by taking a holistic approach. This approach includes appropriate validation of container closure integrity (CCI) test methods, generating container closure integrity data in a product life cycle approach, and the identification of risk to CCI (for example, in the ultracold chain) followed by the implementation of control strategies.

3:20 *Close of Program*

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