PharmaED RESOURCES, Inc.

Aseptic Processing Summit 2023

Best Practice Technologies for Aseptic Processing and Contamination Control

October 11-12, 2023 Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Les Edwards
Skan US

Julian Petersen
Groninger & Co. GmbH

Ashlan Ziegelmeier
Syntegon

Dan Klein
STERIS

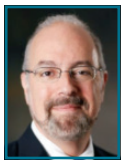
Ilona Endisch
Novatek Int'l

Sebastian Scheler
Innerspace

Donald Singer
Ecolab Life Sciences

Mark Hallworth
Particle Measuring Systems

Derek Duncan
Lighthouse Instruments



Norman Goldschmidt
Genesis AEC

Beth McQuade
CURIS

Richard Denk
Skan AG

Jim Polarine
STERIS

Evan Lamb
Skan US

Michael Eakins
Eakins & Assoc.

Tom Haney
Benchmark Products

With Comprehensive Coverage On:

- The Current Regulatory Landscape for Aseptic Processing
- What is New in the Annex 1
- End-to-End Contamination Control in Aseptic Manufacturing Through Advanced Risk Profiling
- Contamination Control as per Annex 1 and Digitalization of the Environmental Monitoring Process
- Annex 1 and Airflow Visualization—Evolving Expectations, Procedures and Pitfalls
- Robotics: How Robots Can Make Aseptic Fill/Finish Safer, More Effective and Convenient
- Isolator Integration with Cell and Gene Therapy Processes
- Innovations in Continuous Microbiological Environment Monitoring
- Problematic Microorganisms and their Prevention in Aseptic Processing
- Quality Risk Management—Application of Principles and Tools
- Case Study: A Disinfectant Field Trial that Meets Annex I Guidance
- And More!

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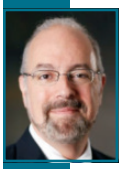
Wednesday, October 11, 2023

7:15 *Registration Check-in & Complimentary Breakfast*

8:15 *Chairperson Michael Eakins' Welcome & Opening Remarks*

8:20

Annex 1 and Airflow Visualization—Evolving Expectations, Procedures and Pitfalls



Norman Goldschmidt, President, Genesis AEC

If the increasing number of inspection citations (483s and warning letters) wasn't enough to convince us, the latest version of Annex 1 leaves no doubt that Airflow Visualization ("Smoke Studies") are viewed by inspectors as an important compliance evaluation.

In this session we will discuss the expectations of both Annex 1 and FDA guidance, common mistakes, observations and the best practices to help you avoid these pitfalls. Whether your company performs their own visualization studies or outsources to a third party, this session will give you actionable insights to improve your studies and enhance compliance.

9:00

Quality Risk Management—Application of Principles and Tools

Michael Eakins, Principal Consultant, Eakins & Associates

Quality Risk Management (QRM) may be defined as a systematic process for the assessment, control, communication and review of risks to product quality and the safety of drug products across the product life cycle. The final version of Annex 1 stated that the principles of QRM should be used in the design and control of facilities, equipment, systems and procedures used for the manufacture of all sterile products to ensure that microbial, particulate and endotoxin/pyrogen contamination is prevented in the final product. However, Annex 1 does not provide guidance as to how QRM principles can be utilized.

In January 2023 ICH published Q9(R1) Guideline Quality Risk Management and this was followed by an FDA Guidance for Industry Q9(R1) Quality Risk Management published in May 2023. These documents provide a comprehensive review of the principles involved in, and examples that can be applied to, different aspects of pharmaceutical quality. The presentation will provide an overview of the management of QRM based on these guidances.

9:40 *Mid-morning Coffee & Networking Break*

Complimentary WIFI brought to you by LIGHTHOUSE The Science of Pharmaceutical Manufacturing

SPOTLIGHT ON CONTAMINATION CONTROL STRATEGIES

10:10

End-to-End CCS in Aseptic Manufacturing Through Advanced Risk Profiling

Sebastian Scheler, Co-founder, Managing Director and Chief Methodologist, Innerspace

The quality of the CCS is highly dependent on the resolution of the available risk data - the more accurate this risk data is, the more targeted and effective these control mechanisms can be. The presentation introduces the Frame-by-Frame Risk Profiling approach for generating end-to-end CCS. Frame-by-Frame Risk Profiling identifies trends and recurrent patterns that indicate potential risks to the process. Process-frames have resulted from contextual and operational aspect assessment of the task and the context in which the process occurs. Accumulation of these process-frames have led to data-based frame library that provides a centralized repository of information that can benefit to inform the assessment process consistently and objectively. Every process-frames incorporate high-resolution risk data which can be used to generate end-to-end CCS. By linking to the Process Frame Library, an end-to-end CCS can incorporate targeted risk mitigation strategies for MBR, work instructions, QA monitoring guidelines, and training, and keep all information consistent across processes and manufacturing sites. Furthermore, end-to-end CCS incorporates Pharma 4.0 technologies such as Virtual Reality in order to train and assess operator behavior. The presentation will also share insights from implementation of Frame-by-Frame Risk Profiling Pilot at Johnson & Johnson CAR-T.

10.50

A Contamination Control Strategy Approach for Contamination in ATMP Cleanrooms

Jim Polarine, Senior Technical Service Manager, STERIS Corporation

This presentation will cover a contamination control strategy approach to pass thru decon of critical items into cleanrooms, air locks, pass throughs, biological safety cabinets (BSCs), Isolators, and RABS. There will be a focus on how to proactively prevent contamination from fungal spores and other microorganisms including viruses, bacteria, and spore forming bacteria. A recent fungal spore case study from the past few months in cell and gene therapy cleanroom facility will be discussed in relation to incubators and pass thru decon. Published data will also be highlighted to convey effective methods in controlling bioburden into the cleanrooms, RABS, Isolators, and BSCs. This presentation will be a complete holistic approach to controlling bioburden from entering cleanrooms and BSCs.

11:30 **Time & Cost Efficiencies To Consider in Critical Production Environments**

Thomas Haney, Northeast Regional Manager, Benchmark Products

This presentation will examine production activities that support the manufacturing process, which might be better handled as a third party service, or with demonstrated new technologies.

11:50 *Complimentary Lunch, Sponsored by*

BENCHMARK Bioprocessing Solutions

1:00 **Achieving Both: Contamination Control as per Annex 1 and Digitalization of the Environmental Monitoring Process**

Ilona Endisch, Associate Director of Product Innovations, Novatek International

The arrival of the updated Annex 1 is an obvious concern for most. Many companies in Europe are scrambling to update their processes to meet Annex 1 before the deadline. North American companies that sell to Europe or that have subsidiaries in Europe must also consider this aspect before making a decision to automate—this is a new learning curve for some. At the same time, digitalization is a trending term in the industry that many are looking to understand and incorporate into their infrastructure. Several new titles with this word included have popped up in the industry over the span of just a couple of years. We have never before seen so much interest to automate the EM process over the laboratory chemistry and quality process. Clearly it has become priority number one for many.

In this presentation, we will focus on the environmental monitoring process and define what digitalization can mean in this respect. We will also cover several points from Annex 1 and demonstrate how best to meet this regulation using examples of a process-based software. Throughout it all, we will discuss a few lessons learned from the industry, companies that are already ahead of the curve in this regard.

Technology Spotlight—Robotics & Manufacturing

1:40 **Robotics in Pharma: How Robots Can Make Aseptic Fill/Finish Safer, More Effective and Convenient**

Julian Petersen, Director of Business Development and Product Management, Groninger & Co. GmbH

The recently released EU GMP Annex 1 mentions, within the second section, the use of robotics to "increase the protection of the product from extraneous sources." This section, and others within the Annex 1, are demanding the reduction or elimination of human intervention within the ISO 5 environment. The goal is to drastically increase product and, ultimately, patient safety. This session will take a closer look at how we currently apply robotics in the pharmaceutical environment based on executed applications within aseptic environments. We will review benefits and limitations. Furthermore, we will go into detail about how to completely remove an operator from the aseptic environment with a gloveless isolator filling line.

2:20 **Enhancing Manufacturing Processes to Match Increased Demand for Single-Use Systems**

Ashlan Ziegelmeier, Technical Product Sales Specialist, Syntegon Pharma Technology, LLC

Over the past several years, the demand for single-use systems have significantly increased. This increase in demand has resulted in single-use suppliers struggling to maintain the availability of their products. Due to the shortage of single-use technologies, the average lead times for single-use orders have also significantly increased. Single-use technology suppliers, like Syntegon, consistently review manufacturing processes to determine the bottlenecks, identify how to improve the process and ultimately reduce lead times. A manufacturing process might seem stable and not require a change, however, strategic modifications that do not disrupt quality can significantly increase the throughput to ensure availability and a reliable supply. In this presentation, Syntegon's approach to enhance the manufacturing process for single-use filling needles will be discussed, with an emphasis on how throughput was increased by 90% and how validation testing was completed to ensure quality targets were met.

3:00 *Afternoon Coffee & Networking Break*

3:30 **Complying to the New EU Annex 1 Container Closure Requirements: A Holistic Science-based Approach**

Derek Duncan, Director Product Line, LIGHTHOUSE Instruments

The new EU Annex 1 contains some significant new language with respect to requirements for container closure integrity testing. While some requirements are specific, other requirements clearly motivate generating container closure data in a product life cycle approach. This presentation describes a holistic science-based approach to container closure integrity assurance that enables compliance to the new EU Annex 1 requirements.

4:10 **Risk-based Approach to an Environmental Monitoring Assessment**

Mark Hallworth, Life Sciences Strategic Senior GMP Scientist, Particle Measuring Systems

The environmental monitoring program is required to be structured on a formal risk assessment. Particle Measuring Systems have been performing EMRA's for several years against a robust methodology. The initial identification of process or room risks, these are then evaluated qualitatively to identify Critical Control Points. These CCP's can then be weighed against several factors to determine a quantitative score, which aids in establishing a location. Adding frequency and method, supported by documentation, gives an output to base the monitoring qualification around.

4:50 ***Happy Hour Mixer***

Join your colleagues in the hotel lounge for informal networking. Complimentary beverage and appetizers provided.

Thursday, October 12, 2023

7:30 ***Complimentary Breakfast***

8:30 **What is New in the Annex 1**

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

Since the first draft publication of the Annex 1 in 2017 the topics of QRM Quality Risk Management, CCS Contamination Control Strategies and Barrier were in global discussion. Especially the wording "In case not to use Barriers you should justify this in your CCS. Considering Barriers like RABS or Isolators and reading the Annex 1 in detail the trend goes to closed RABS or Isolators to fulfill the requirements. The presentation does focus on the Barrier Requirements, difference between RABS and Isolators, Glove Management, Surface Decontamination, Robotics and Cleaning for Aseptic Filling in Isolators.

Spotlight On Isolators in Cell & Gene Therapy Manufacturing Processes

9:10 **The Battle of the Biosafety Cabinet: Isolator Integration with Cell and Gene Therapy Processes**

Les Edwards, Technology and Business Development, and Evan Lamb, Applications Specialist, Cell and Gene Therapy, SKAN US

Biosafety cabinets in a Grade B background have previously been the standard for pre-clinical and clinical stage cell and gene therapy manufacturing processes. As processes mature and regulations evolve (like Annex 1 and Annex 2A), some processes require and other process steps can benefit from a closed-isolator system. Once some baseline procedures are established and operators are properly trained, the increased sterility assurance as well as safety benefits of utilizing isolators earlier in the lifecycle of the cell and gene product become more attractive. Also, new evolutions in transfer technologies and system flexibility have made isolator an attractive alternative. This presentation will highlight some common processes from mesenchymal stem cell and CAR-T process case studies using isolators. A discussion of the challenges and advantages of early implementation of isolator systems will also be covered.

9:50 ***Midmorning Coffee & Networking Break***

Critical Issues—Approaches to zBio-decontamination

10:20 **Best Practices for Bio-decontamination of Aseptic Processing Areas for Improved Efficiency, Outcomes, and Compliance to Annex 1**

Donald Singer, Senior Microbiology Technical Consultant, Ecolab Life Sciences

Implementing a scientific and pragmatic approach to contamination control requires a strategy that is current, effective and reduces variability. To develop improved sterility assurance, aseptic processing operations must integrate controls to reduce the contamination risk associated with human intervention while seeking efficiencies and GMP compliance. Microbiological contamination can be reduced using a pragmatic approach that incorporates automation. Automating the bio-decontamination process for equipment such as isolators, RABS, material transfer chambers, or a cleanroom suite can reduce microbiological contaminants, reduce chemical residue from manually applied sporicide, eliminate the human error associated with manual disinfection, leading to improved sterility assurance while increasing operational efficiencies.

11:00 **A Risk-Based Approach to Successful Hydrogen Peroxide Bio-decontamination**

Beth McQuade, Biocontainment Specialist, CURIS

Efficacy and material compatibility of your decontamination process is critical to aseptic processing. Unwanted outcomes can greatly increase costs associated with equipment replacement, revalidation, and downtime. This presentation will take a risk-based approach investigating the effects of vaporous hydrogen peroxide (H2O2) on isolator and cleanroom surfaces to examine variations in efficacy and material effects. Studies will be examined to understand consequences of hydrogen peroxide concentrations on sporicidal results, residue accumulation and equipment failure to

help determine suitable approaches that safeguard efficient processes in the GMP environment and help support new Annex 1 regulations. This presentation will aid industry professionals in making informed decisions in selecting appropriate decontamination methods that strike the right balance of efficient processes and superior outcomes.

11:40 *Complimentary Lunch*

12:40 **Problematic Microorganisms and their Prevention in Aseptic Processing**

Dan Klein, Senior Technical Service Manager, STERIS Corporation

This session will focus on problematic and difficult to eradicate microorganisms found in cleanrooms that can significantly affect aseptic processing. Included will be a data review and discussion about species of bacteria, fungi, spores and even biofilm that can wreak havoc on a cleanroom's operations and persist for a long time in the environment. There will be a review of available technologies and resources to eradicate each and considerations for the use of liquid disinfectants and sporicides as well as vaporized hydrogen peroxide. In addition to a general discussion around microorganisms' susceptibility to disinfection, familiar species such as Bacillus cereus, Pseudomonas aeruginosa, and Chaetomium globosum will be reviewed relative to their potential sources and what it takes to eradicate them and ensure appropriate measures are incorporated into a Contamination Control Strategy (CCS).

1:20 **Innovations in Continuous Microbiological Environment Monitoring**

Mark Hallworth, Life Sciences Strategic Senior GMP Scientist, Particle Measuring Systems

With Annex 1 now requiring the cleanroom first be qualified as a fixed exercise and followed up with planned monitoring, respective to risk, a new approach is required to meet the continuous monitoring in Grade A zones. There are essentially two paths forward, one is the enhancement of traditional methodologies and the other is the application of rapid microbial methods using autofluorescence. This presentation will look at the advantages of each method verses the current Annex 1 requirements for frequent monitoring using traditional only, and how best to interpret the information from such systems, to better support risk assessment requirements.

2:00 *Afternoon Break*

2:15 **Case Study: A Disinfectant Field Trial that Meets Annex I Guidance**

Jim Polarine, Senior Technical Service Manager, STERIS Corporation

CASE STUDY

This presentation will cover key components of CCS (Contamination Control Strategy) in a recent biopharma disinfectant field trial. The case study utilized a ready to use quaternary ammonium disinfectant and a hydrogen peroxide/peracetic acid sporicide to control bioburden in a new cleanroom operation post construction. Material flow, engineering controls, utility supplies, and operational procedures will be discussed. In depth field trial environmental monitoring data will be covered. This CCS case study has recently been published in a peer reviewed industry journal.

2:55 *Close of Program*

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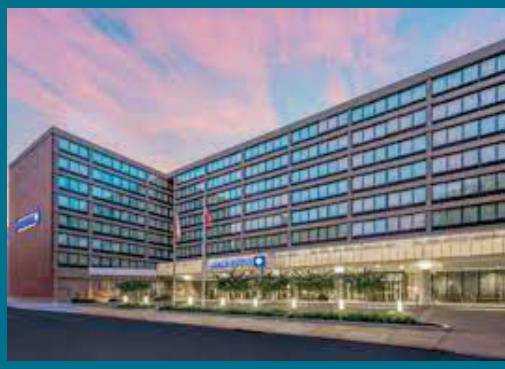

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Venue:	Wyndham Philadelphia Historic District
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