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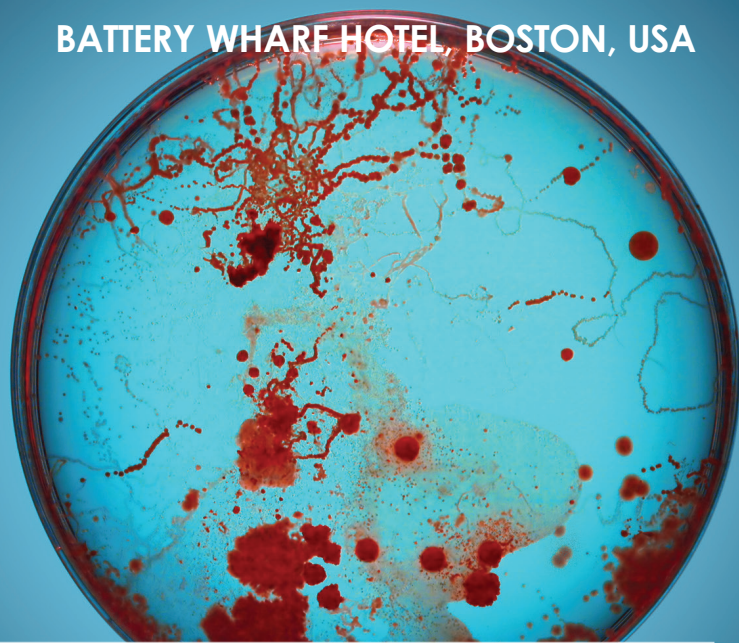
Discussing best practices and techniques to tackle
microbial control challenges

BATTERY WHARF HOTEL, BOSTON, USA

CONFERENCE: 10TH - 11TH

WORKSHOPS: 12TH

APRIL 2019



HIGHLIGHTS IN 2019:

- **Discuss** solutions for the current challenges affecting pharmaceutical microbiology industry
- **Hear** the latest in regulatory changes and evaluate strategies to ensure compliance
- **Explore** new technologies for environmental monitoring
- **Discover** more about risk management and preparing risk-based programmes
- **Gain** insight into a case study of atypical, low-level mold contamination

CHAIR:

- **James Drinkwater**, Chairman, **PHSS**, Head of Aseptic Processing Technologies & GMP Compliance, **Franz Ziel GmbH**

KEY SPEAKERS INCLUDE:

- **Cheryl Essex**, Head of Microbiological Control for Biologic Drugs, **Sanofi**
- **Frederic Ayers**, Consultant Scientist, **Eli Lilly and Company**
- **Christopher Day**, Group Leader, ASO Microbiology, **Bristol-Myers Squibb**
- **Elia Sanchez**, QC Microbiology Senior Manager, **Genentech**
- **Clyde Schultz**, Adj Professor, **University of Calgary** and Director Quality Assurance, **Celgene**
- **Andrew Bartko**, Research Leader, **Battelle Memorial Institute**



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PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS | FRIDAY 12TH APRIL 2019, BATTERY WHARF HOTEL, BOSTON, USA

A: Mold Contamination Challenges

Workshop Leader:

Ziva Abraham, CEO, **Microrite, Inc**

8.30 - 12.30

B: Microbiological control of GMP using Vapour Phase Hydrogen Peroxide bio-decontamination

Workshop Leader:

James Drinkwater, Chairman, **PHSS**, Head of Aseptic Processing Technologies & GMP Compliance, **Franz Ziel GmbH**

13.30 - 17.30



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8.30 Registration & Coffee

9.00 Chair's Opening Remarks

James Drinkwater, Chairman, **PHSS**, Head of Aseptic Processing Technologies & GMP Compliance, **Franz Ziel GmbH**

REGULATORY CONSIDERATIONS FOR CONTAMINATION CONTROL

KEYNOTE ADDRESS

9.10 Revision of Annex 1 and the impact on pharmaceutical microbiology control and monitoring



- Draft update on Annex 1
- Expected impact on pharmaceutical microbiology control and monitoring
- Microbiologist's role in building a contamination control strategy
- Ensuring compliance with new regulations

Cheryl Essex, Head of Biologics Microbiological Control, **Sanofi**

9.50 Debates and challenges concerning disinfectant validation and methods to circumvent them

- Effective ways to validate disinfectants, sanitizers, and sporicides
- The most common causes for coupon testing failures
- The most current industry methods for conducting coupon testing
- Developing risk assessments for choosing environmental isolates and coupon surfaces
- Current global regulatory guidance on disinfectant validation

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

10.30 Morning Coffee

11.00 Microbiological Methods: Science and Regulation

- Methods evolution
- Detection Methods
- Counting Methods
- Identification Methods
- Standards and Regulation

David Hussong, CTO, **Eagle Analytical Services**

(Former Associate Director for New Drug Microbiology, FDA)

11.40 Regulations of Endotoxin detection methods: Follow the sample through the process

- Prerequisites for in-house testing
- Qualifications
- Sampling and sample management
- Suitability testing
- Routine Testing, Trending and OOS

Veronika Wills, Associate Manager of Technical Services, **Associates of Cape Cod**



12.20 Networking Lunch

ENVIRONMENTAL MONITORING

13.20 Using an alternative gene sequence for species-level identification for closely related organisms

- An overview of closely related organisms
- The closely related organisms that are frequently recovered from environmental monitoring programs in the pharmaceutical industry
- Necessity of using alternative gene sequences for species-level identification in the pharmaceutical industry
- Evaluation of alternative gene sequence for species-level resolution in Burkholderia cepacia complex (BCC) and Bacillus cereus group (BCG)

Sunhee Hong, Senior, Staff Scientist, **Charles River** | [charles river](#) |

14.00 Environmental monitoring in barrier separation technology: Isolators and RABS

- Environmental classification, microbiological qualification and monitoring of Filling lines with barrier technology considering new GMP regulations
- Contamination control strategies, risk identification and risk assessment to define EM sampling positions and sampling frequency program
- Rapid micro methods applied to barrier technology; challenges and new novel approaches

James Drinkwater, Chairman, **PHSS**, Head of Aseptic Processing Technologies & GMP Compliance, **Franz Ziel GmbH**

14.40 Environmental monitoring and critical utility trending

- Trending expectations and best practices
- Trends below limits "The Proactive Approach"
- Cross functional team data analysis
- Understanding impact to environment, utility and process

Steven A. Wiczorek, Associate Director, Quality Control Microbiology, **Sanofi**

15.20 Afternoon Tea

15.50 Signal intensity - an integrated approach to EM data trending

- The challenges of interpreting and trending environmental monitoring (EM) data
- Overcoming the limitations of microbiological data generated via traditional culturing methodologies
- Holistic analysis and trending of EM data utilizing a novel integrated approach

Austin Kuo, Principal Research Scientist, Sterility Assurance, **Eli Lilly**

16.30 What should a biotechnology company know about microbiology?



- Emerging biopharmaceutical companies responsible for a high percentage of biopharmaceutical product launches
- Challenges for emerging biotechnology companies in taking products through discovery to the market place
- Lack of microbiological expertise and dependence on CRO's to provide these essential services
- Overview of the areas of microbiology that are critical in the development of product dependent on recombinant DNA technologies, cell and gene therapies, RNA interference and human microbiome modification
- Emphasis on clinical trial phase-appropriate solutions

Tony Cundell, Principal Consultant, **Microbiological Consulting, LLC**

17.10 Chairman's Closing Remarks and Close of Day One

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8.30 Registration & Coffee

9.00 Chair's Opening Remarks

James Drinkwater, Chairman, **PHSS**, Head of Aseptic Processing Technologies & GMP Compliance, **Franz Ziel GmbH**

RAPID MICROBIAL METHODS & ENDOTOXIN CONTROL

9.10 Rapid microbial methods — a case study of implementation

- The implementation of rapid methods in practice, how best to adopt these new methods and keep up with developments
- Validating the methods and conforming to regulatory requirements
- The issues surrounding the implementation of rapid methods and how to overcome them
- How to best tailor your implementation proposal in terms of validation of your rapid method

Andrew Bartko, Research Leader, **Battelle Memorial Institute**

9.50 Industry perspective on automated endotoxin testing and process automation

- Streamlining QC testing through automated endotoxin testing
- Advantages and disadvantages of automation
- New technologies for automated endotoxin testing and process automation
- Ensuring compliance with regulatory requirements

Clyde Schultz, Adj Professor, **University of Calgary** and Director Quality Assurance, **Celgene**

10.30 Morning Coffee

11.00 Rapid Microbiology Methods — An Overview

- Overview
- Regulatory Expectations
- Stumbling Blocks
- Looking forward

Christopher Day, Group Leader, **Bristol Myers Squibb**

STERILITY ASSURANCE

11.40 Sterility Assurance Risk Management

Sterility is one of the most critical quality attributes that all parenteral products must possess; yet, it is one of the most difficult to consistently and convincingly demonstrate to regulators. This presentation discusses:

- Demonstrating sterility towards regulators
- Integrated, cross-functional strategy implemented at Eli Lilly and Company's parenteral manufacturing facility in Indianapolis
- Evaluate and mitigate risk associated with the manufacturing process and environment

Frederic Ayers, Consultant Scientist, Sterility Assurance, **Eli Lilly**

12.20 Networking Lunch

DEEP DIVE - CASE STUDY

13.20 Case study of environmental mold isolation in a controlled manufacturing facility

- Area awareness and detection of atypical, low level recovery in a controlled environment
- Response to atypical, low level recovery in a controlled environment
- Manufacturing during atypical recovery in a controlled environment

Leslie Falco, Microbial Control Strategist, **Pfizer**

14.00 Combining Genetics with Traditional Methods for Microbial ID

- Summary of the Genetic Analysis Technology
 - Bacterial ID vs Fungi ID
 - Exceptions to the rules
- Traditional methods (Back to the basics case studies)

Elia Sanchez, QC Microbiology Sr. Manager, **Genentech**

14.40 Progress and challenges in the design and clinical development of microbial therapies

- The power of poop: Fecal microbiota transplantation for treatment of Clostridium difficile infection
- Leaky Gut Syndrome in autoimmune diseases – a potential target for therapy
- Success in a probiotic trial in Irritable Bowel Syndrome – a new therapeutic perspective targeting the dysbiosis and beyond
- Designing multi-targeted bacterial therapy – what tools do we need?

Shahram Lavasani, CEO, **ImmuneBiotech AB**

15.20 Afternoon Tea

RISK MITIGATION FOR MYCOPLASMAS AND ANIMAL SERA

15.50 Mycoplasmas in biopharmaceutical and biotechnological processes: assessment of potential mycoplasma entry and growth as basis for mycoplasma contamination control and risk mitigation

- Features of mycoplasmas with respect to their contamination potential
- Evaluation of potential mycoplasma entry into cell culture and manufacturing processes and subsequent growth
- Risk mitigation by mycoplasma testing: choosing a suitable detection method and an appropriate validation design based on risk assessments
- Lot release mycoplasma testing: avoiding false-positive and false-negative results

Renate Rosengarten, Professor and Chair of Bacteriology and Hygiene, **University of Veterinary Medicine Vienna**

16.30 Management of risk in the use of animal sera

- Certification of processes
 - Testing for geographic testing
 - Everything you need to know about Gamma Irradiation
- Rosemary Versteegen**, CEO, **International Serum Industry Association**

17.10 Chairman's Closing Remarks and Close of Day Two

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HALF-DAY POST-CONFERENCE WORKSHOP A FRIDAY 12TH APRIL 2019 | 08.30 - 12.30 BATTERY WHARF HOTEL, BOSTON, USA

Workshop Leader:
Ziva Abraham, CEO, Microrite, Inc

MOLD CONTAMINATION CHALLENGES

microrite, inc.

Overview:

In recent years Mold Contaminations and Recalls have been a focus of attention for the FDA. The wave of mold related inspections and recalls are in response to a deadly fungal meningitis outbreak linked to contaminated steroids from a now infamous compounding pharmacy and a wave of high profile recalls. A risk-based approach to mold is required in order to prevent a catastrophic outcome. There is no one solution for preventing, controlling and remediating mold contaminations. The same mold may be detrimental in one product but may have no clinical implication in another. Mold proliferation, prevention and control are not understood because there is a gap in mycological expertise within the pharmaceutical industry. SMI invites you to attend this never before offered intensive workshop.

Why you should attend:

- All current cleanroom standards and GMP guidance's recommend or require a risk based monitoring approach. Additionally, there is an increase in regulatory observations related to lack of risk based environmental monitoring. This workshop will address the requirements and provide guidance on how to establish a risk based Environmental Monitoring Program.
- Multiple Case Studies will be utilized as examples related to deficient Environmental Monitoring Programs which have led to 483 observations, warning letters and data integrity issues.

Who should attend:

Senior Microbiologist, Lead Scientist, Laboratory Manager, QA Specialist Drug Substance External Manufacturer, Business Development Manager - Testing, Pharmaceutical Microbiology Consultant, Analytical Standards Specialist

About the Workshop leader:

Ziva Abraham is the President and Founder of Microrite, Inc., a California based consulting firm providing consulting and training services to pharmaceuticals, biotechnology, medical devices and in vitro diagnostics in the areas of quality assurance, quality control, microbiology, and validation. Ziva has over 25 years of academic, research, clinical and industrial experience in microbiology and quality assurance. Ziva has received her Master's Degree in Microbiology with a focus on Mycology and has conducted research on developing microbial insecticides using entomogenous bacteria and fungi for her PhD degree. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Her experience in clinical laboratories has provided her with the framework to understand the effects of microbial contamination in products from a patient safety perspective.

About the Company:

Microrite is a San Jose, CA based consulting company helping pharmaceuticals, biotechnology, medical devices, In-Vitro Diagnostics and Combination products in the areas of Quality Assurance, Contamination control, Microbiology, Process Development, Process validation, Facility, Utility and Equipment Validation

Programme:

- 8.30 Registration & coffee**
9.00 Workshop leader introduction
9.10 Understanding mold (hands-on exercise)
Understand mold classes, sporulation patterns and how easy to kill mold can switch its proliferation method where the spores are impossible to eradicate.
 - This will be a hands on exercise using fungal reference texts and images
 - This exercise will allow attendees to understand that no matter what method you use, you may not always have the correct identification
 - Learn about the sources and proliferation methods of various cleanroom mold isolates and develop a prevention plan**9.50 Mold myths and facts**
 - Myths about disinfection and disinfectant qualification related to mold removal
 - Understanding the fungicidal activity of various disinfectants used in the industry, how fungicidal label claims are established and why they could be misleading
 - Cleaning practices that actually encourage mold growth**10.30 Morning coffee**
11.00 Investigating mold contaminations
Often the risk of mold contamination is not addressed until contamination has happened!
 - Understand why investigating and managing mold contamination can be difficult without proper knowledge of mold and controlled environments
 - Points to consider when investigating mold contamination
 - Why excessive cleaning and disinfection or fogging is not the solution when it comes to cleanroom contamination by mold**11.40 Clinical relevance of objectionable mold**
Learn about what mold is objectionable via which mode of administration
 - Guidelines on how to assess risk of mold in your product
 - Understanding the level of risk and making changes to remediate the situation**12.20 Closing remarks**
12.30 End of workshop

HALF-DAY POST-CONFERENCE WORKSHOP B FRIDAY 12TH APRIL 2019 | 13.30 - 17.30 BATTERY WHARF HOTEL, BOSTON, USA

Workshop Leader:
James Drinkwater, Chairman, PHSS,
Head of Aseptic Processing Technologies & GMP Compliance,
Franz Ziel GmbH

MICROBIOLOGICAL CONTROL OF GMP USING VAPOUR PHASE HYDROGEN PEROXIDE BIO-DECONTAMINATION



Overview:

VHP/ vH2O2 has been used in the pharmaceutical industry for many years initially in Isolator barrier technology but now in cleanrooms but the science and process have not always been fully understood or applied correctly. This lack of knowledge has led to increasing regulatory observations and a blog from the MHRA considering the Fragility of VHP that has challenged the pharma industry. This workshop closes the knowledge gap in science and requirements for CGMP compliance and explains current developments to meet process challenges for aseptic processing of biological products where H2O2 residuals may impact at low levels.

Why you should attend:

This workshop would benefit;

- Biological product development specialists who need to consider H2O2 residuals that apply in environmental control of processing areas hence may impact product
- Microbiologists involved in environmental control of CGMP classified/ controlled areas
- Validation/ qualification specialists involved in VHP cycle development and qualification
- Process engineers that need to consider the technical integration of VHP bio-decontamination
- Production operations that need to consider how to achieve short robust VHP cycles for effective operations

About the Workshop leader:

James Drinkwater is a pharmaceutical process engineer with additional education in pharmaceutical microbiology. Having spent 10 years in the pharma industry (Amersham-GE Healthcare) James had director roles at barrier technology and hydrogen peroxide vapor generator companies achieving subject matter expert status. Current roles include Head of GMP compliance and Aseptic process support for F Ziel GmbH, the largest Isolator and RABS manufacturer in Germany working on major filling line projects and independently an elected role as Chairman of the PHSS: Pharmaceutical & Healthcare Sciences Society and leader of the PHSS Aseptic processing, Aseptic-Containment and Annex 1 focus groups.

About the Company:

At F Ziel the role includes process integration of environmental control barrier systems with sterile product aseptic processing and support for GMP compliance including environmental control and monitoring risk assessments. The PHSS is a Not for Profit educational platform for GMP providing supportive guidance in the form of technical monographs, impact statements and Clarity on GMP guidance notes. PHSS provide workshop and training courses in the UK having a strong connection with the UK MHRA.

Programme:

- 13.30 Registration & Coffee**
14.00 Opening remarks and introductions
14.10 Key points on Science of VHP bio-decontamination
 - Vaporisation of H2O2, control of condensable vapor and impact on cycle time
 - Hydrogen bonding characteristics and impact on gas distribution
 - Scientific comparison of VHP and Dry Fog for applications in Isolators and Cleanrooms
 - Applied science to optimise overall cycle time and efficacy**14.50 Addressing regulatory concerns in 'Fragility of VHP'**
 - Limitations of VHP penetration through protective layers/ spore clumps and impact on cycle Fragility
 - MHRA Blog on Fragility of VHP – key considerations and discussion
 - PHSS Clarity on GMP Guidance note: Assurance of Sterility for surfaces that contact product contacts parts
 - Managing limitations of VHP and using the strengths for a robust CGMP compliant process**15.30 Afternoon Tea**
16.00 Application of VHP bio-decontamination in Filling line barriers
 - Process integration of a VHP bio-decontamination process
 - Biological indicator pre-use qualification to reduce risks of unexpected BI positive growth
 - VHP cycle development – improved practice to make the process efficient and with reduced risks of issues at site qualifications
 - VHP bio-decontamination of material loads in support to Filling lines**16.40 Session 4 H2O2 residual biocompatibility with biological products**
 - Oxidizing potential of H2O2 and possible impact on biological products
 - DoE: Design of Experiment studies to assess VHP/ H2O2 residual impact on biological products
 - Analytical methods applied in H2O2 residual transfer studies
 - Examples from VHP/H2O2 residual studies and product impact**17.20 Closing remarks**
17.30 End of Workshop

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