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Pharmaceutical Microbiology UK

Addressing the key trends, challenges and strategies in contamination control

Copthorne Tara Hotel, London, UK

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WORKSHOPS: 23RD

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- **Olivier Chancel,** Sterility and Aseptic Process Assurance Expert, **Boehringer Ingelheim**

FEATURED SPEAKERS:

- **Alexander Stoll,** VP Competence Center Microbiology & Aseptic Technique Quality Management, **Fresenius Kabi**
- **Di Morris,** Senior Manager, Team Leader, Vaccines Quality Audit, **GSK**
- **Marine Marius,** Scientist, Analytical Research & Development Europe, **Sanofi Pasteur**
- **Philippe Dutot,** Sterility Assurance Specialist, **Novo Nordisk**
- **Renate Rosengarten,** Professor and Chair of Bacteriology and Hygiene, **University of Veterinary Medicine Vienna**
- **Thierry Bonnevay,** Microbiology Platform Head, Analytical Research and Development, **Sanofi Pasteur**
- **Tim Eaton,** Sterile Manufacturing Specialist, **AstraZeneca**

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HIGHLIGHTS IN 2019:

- **Sanofi spotlight session** on rapid micro methods and the future of endotoxin testing
- **Discuss** the challenges in developing a contamination control strategy for different product types
- **Examine** the strengths and weaknesses of VHP as a bio-contamination control agent in GMP applications
- **Explore** mold contamination challenges and how to overcome these challenges
- **Gain** insight into various real-life case studies from experiences in the cleanroom
- **Hear from experts** on the current regulations, challenges and trends in mycoplasma safety testing

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 23rd January 2019, Copthorne Tara Hotel, London, UK

A: Common Mistakes Made When Setting Up an Environmental Monitoring Programme

Workshop Leaders:
Ziva Abraham, CEO, **Microrite**
Morgan Polen, Contamination Control and Cleanroom Expert, **Microrite**
08.30 - 12.30

B: Rapid Microbial Methods & Developing a Risk-Based Cleaning and Disinfection Programme

Workshop Leaders:
Andrew Bartko, Research Leader, **Battelle Memorial Institute**
Jim Polarine, Senior Technical Service Manager, **Steris Corporation**
13.30 - 17.20

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08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Olivier Chancel, Sterility and Aseptic Process Assurance Expert, **Boehringer Ingelheim**

CONTAMINATION CONTROL CHALLENGES AND STRATEGIES

OPENING ADDRESS

09.10 **Challenges in development of a contamination control strategy for different product types**
- What is expected to be included in a contamination control strategy as a GMP requirement outlined in the revised (draft) Annex 1
- Contamination control strategy for different product types: Sterile Non-Hazardous, Aseptic Toxic, Aseptic Highly Potent (including ADC's), Aseptic Sensitising (Hormones)
- Contamination control strategy and linkage to cross contamination

Di Morris, Senior Manager, Team Leader, Vaccines Quality Audit, **GSK**

09.50 **Series of learning experiences on contaminations: poor understanding of some microbiological aspects associated with still common preventive maintenance issues:**
- Damaged gaskets in mixers
- Bad setting of travel stops
- Bad assembly of diaphragm valves
- Inappropriate inner diameter of gaskets
- Silicone sealants of panels and self-contained clean rooms
- Pressure differentials of hydrophobic filters
- How tight is hand tight?

Olivier Chancel, Sterility and Aseptic Process Assurance Expert, **Boehringer Ingelheim**

10.30 **Morning Coffee**

11.00 **Quality risk management of clean room garments and sterile packaging solutions for materials, equipment, components and ancillary items for aseptic processing**
- Assessing microbial barrier properties of porous materials
- Particulate release is a key risk factor to consider: tests for ranking of materials
- Implementing a contamination control strategy covering the entire product life cycle: from quality-by-design, through qualifications and risk assessments of implemented solutions to thorough operations management

Thierry Wagner, Regulatory Affairs Director Europe, Middle East and Africa, **DuPont**

11.40 **The strengths and weaknesses of Vaporised Hydrogen Peroxide (VHP) as a bio-contamination control agent in GMP applications**
- Application of VHP/vH202 in bio-contamination control
- Strengths considering principle attributes and qualification as a broad spectrum sporicidal agent
- Weaknesses and fragility considered in the MHRA log
- Principle scientific facts and variance in H202 vapour delivery and cycle control
- Does the attention of the regulatory agencies mean the 'Death of the VHP process' or is the 'Death of scientific ignorance' the real purpose of the Blog?

James Drinkwater, Chairman, **Pharmaceutical and Healthcare Sciences Society**

12.20 **Networking Lunch**

13.30 **Session Reserved for Biomerieux**

14.10 **Case study on using contamination recovery rates to measure performance and improve contamination control**
- Use of contamination recovery rates as an effective tool for cleanroom monitoring
- How to use these metrics to improve your contamination control
- Case study showing step change in the metrics, and thus showing improvement in contamination control

Alexander Stoll, Vice President, Head of Competence Center Microbiology and Aseptic Techniques, **Fresenius Kabi**

KEYNOTE ADDRESS

14.50 **Case study: Use of applied methodology for the transfer of moist heat sterilised parts from an autoclave to RABS aseptic processing line with Grade A continuity**
- Principles of Grade A continuity and how to implement solutions in process operations
- Definition, classification and qualification of localised uni-directional airflow used as aerodynamic protection of autoclave unload and loading of transfer carts and unload of transfer carts into RABS aseptic process line
- Transfer cart case study: maintaining sterile integrity of sterilised parts in transfers

Tim Eaton, Sterile Manufacturing Specialist, **AstraZeneca**

15.30 **Afternoon Tea**

16.00 **Smoke studies: Misconceptions and regulatory implications**
- Regulatory expectations and recommendations
- Myths and facts about AFV where mistakes are made
- Discussion of FDA 483s related to smoke studies

Morgan Polen, Contamination Control and Cleanroom Expert, **Microrite, Inc.**

MOLD CONTAMINATION CHALLENGES

16.40 **Case studies in deinococcus and fungal and bacterial spores in cleanrooms**
- The complexities of CAPA excursion investigations
- Ways to proactively limit bacterial and mold spore contamination from incoming items into cleanrooms
- Current industry regulations in the US and Europe with relation to sporicides and disinfectants
- Recent case studies on new antimicrobial chemistries and their performance against fungal and bacterial spores in cleanrooms

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

17.20 **Mold contamination challenges**
- Understanding mold
- Understanding disinfection and disinfectant qualification as it relates to mold
- Investigating mold contaminations
- Clinical relevance of objectionable mold

Ziva Abraham, Founder and CEO, **Microrite**

18.00 **Chairman's Closing Remarks and Close of Day One**

18.30 - 20.00 **Networking Drinks Reception Sponsored by** DuPont Tyvek IsoClean

08.30 Registration & Coffee

09.00 **Chairman's Opening Remarks**
James Drinkwater, Chairman, **Pharmaceutical and Healthcare Sciences Society**

REGULATIONS, CHALLENGES AND TRENDS FOR PLASMA-DERIVED MATERIALS

OPENING ADDRESS

09.10 **Mycoplasma safety testing of biopharmaceuticals and ATMPs by rapid NAT-based detections methods - Current regulations, challenges and trends**

- Why do mycoplasmas pose such a challenge in implementing safety concepts for biopharmaceuticals and ATMPs
- Haemoplasmas as potential contaminants of ATMPs
- A risk-based approach for the validation and implementation of rapid NAT-based mycoplasma safety testing
- How to tailor a product-specific mycoplasma NAT method validation study to meet the regulatory requirement

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

09.50 **Risk mitigation strategies for animal-derived raw materials**

- Risk mitigation in sourcing
- Does geography matter?
- Where did that serum come from?
- Robust viral clearance steps
- Overview of options
- Review of what works and why

Rosemary Versteegen, CEO, **International Serum Industry Association**

10.30 Morning Coffee

11.00 **Innovative sampling strategies to retrieve the invisible**

- What swab to use for surface monitoring of environmental microbial contamination?
- The hidden technology of COPAN FLOQSwabs®
- Innovative approaches for sampling

Sonia Allibardi, Market Access Manager, **Copan**

11.40 **Current and novel viral safety strategies applied to the manufacture of plasma-derived medicinal products (PDMPs)**

- Current challenges and methods of adventitious agent clearance
- Novel strategies for safeguarding patients
- Quality by Design (DoE approach)
- Next Generation Sequencing

Steve Simoneau, Biological Safety Project Manager, **The LFB Group**

12.20 Networking Lunch

ENVIRONMENTAL MONITORING

13.30 **Real time microbial detection - Process control and implementation of online microbial monitoring for pharmaceutical waters**

- Review of Pharmacopeia and Regulatory positions on adoption of alternative microbial methods
- Current state of real time microbial detection technology
- Case study of implementation of online microbial monitoring in a Global Pharmaceutical facility
- Guidance for evaluation and establishment of new microbial limits

James Cannon, Head of OEM and Markets, **Mettler-Toledo**

14.10 **Influence of temperature of incubation on results of microbiological environmental monitoring**

- Regulatory perspective
- Bibliography review focused on "in situ" studies
- Results of a one-year comparison study between two incubation regimens (30-35°C for 3 days vs 20-25°C for 5 days) for the monitoring of a pharmaceutical production classified area

Philippe Dutot, Sterility Assurance Specialist, **Novo Nordisk**

RAPID MICROBIAL METHODS & ENDOTOXIN AND VBNC BACTERIA TESTING

14.50 **Rapid microbial-detection methods**

- The benefits, applications, pitfalls and challenges involved
- Time to result benefits to manufacturing economics
- Enhanced quality control impact on manufacturing risk
- Overcoming the hurdles of new technology validation

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

15.30 Afternoon Tea

SANOFI SPOTLIGHT SESSION

16.00 **Return of experience on implementation of mycoplasma alternative method to release vaccines**

- Implementation of a Rapid Microbial Method for mycoplasma testing
- Journey of an investigational vaccine
- Journey of a legacy product
- Return of experience

Marine Marius, Scientist, Analytical Research and Development Europe, **Sanofi Pasteur**

16.40 **Future of endotoxin testing in pharmaceutical industries**

- Trends in endotoxin testing
- Evaluation and implementation of new methods
- Results of an internal evaluation
- What's next?

Thierry Bonnevay, Microbiology Platform Head Analytical Research & Development, **Sanofi Pasteur**

17.20 **How dead is dead? The problem of VBNC bacteria**

- Defining what VBNC bacteria are
- Tools to identify VBNC bacteria and biofilms
- When disinfectants or sanitizers mislead
- Animal models to confirm VBNC infectivity

Bill Keevil, Head of Microbiology Group and Director of the Environmental Healthcare Unit, **University of Southampton**

18.00 **Chairman's Closing Remarks and Close of Day Two**

HALF-DAY POST-CONFERENCE WORKSHOP A
Wednesday 23rd January 2019, Copthorne Tara Hotel, London, UK
08.30 - 12.30

Workshop Leaders:
Ziva Abraham, CEO, **Microrite**
Morgan Polen, Contamination Control and Cleanroom Expert, **Microrite**

Common Mistakes Made When Setting Up an Environmental Monitoring Programme

Workshop Overview:
Learn about the common mistakes when setting up an environmental monitoring programme that can lead to missing product contamination risk or excessive excursions. Learn how to apply appropriate standards, guidance and science to ensure that the programme meets regulatory requirements and is effective in assessing risk to product. Additionally, learn about barrier system issues, misdiagnosed airflows, inadequate choice of monitoring equipment (specification etc.), media management gaps, and perceived vs actual risk assessment that can affect contamination detection.

Why You Should Attend this Workshop:
The purpose of an environmental monitoring programme is to detect particulate and microbial contamination risk to product. This cannot be accomplished if the cleanroom and barrier system flaws are not known, collection efficacy of monitoring devices is not understood, quality of microbiological media is not comprehended and the sites that pose real risk to product are not realized. Multiple case studies will be utilized as examples related to deficient Environmental Monitoring Programmes which have led to 483 observations, warning letters and data integrity issues.

About the Workshop Leaders:

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.

Morgan Polen has been involved with cleanrooms and contamination control since 1984. He has worked in over 40 countries involved with projects ranging from cleanroom design, construction, validation, AFV, monitoring programme development, particle counter design and product management for cleanroom related products and systems. He has addressed monitoring and control solutions in a wide variety of clean industries such as pharmaceutical, medical device, semiconductor, data storage, aerospace, defense, automotive, optical and others. Morgan is a member of IEST's US Technical Advisory Group to ISO/TC 209 Cleanrooms and Associated Controlled Environments, participating in the process of adapting the latest cleanroom standards.

About the Organisation:

microrite,inc.

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

08.30 **Registration and Coffee**

09.00 **Chairman's Opening Remarks**

09.10 **Understanding barrier system flaws**
- Barrier system design and integration flaws that led to environmental monitoring excursions and data integrity issues leading to a warning letter and export ban
- How not understanding cleanroom standards led to excessive monitoring of an OSD facility, leading to consistent failures and generation of fraudulent data
- Improperly performed smoke studies leading to false sense of control; EM excursions showed otherwise
- Inadequate Air Flow Visualization Studies leading to incorrect monitoring locations

09.40 **Evaluation of environmental monitoring devices**
- Learn from current FDA observations related to particle loss in particle monitoring devices
- Points to consider when choosing particle & active air samplers; understand technologies and risks

10.10 **Morning Coffee**

10.30 **Media quality and management**
- False positive and false negative results directly related to media quality and management
- FDA 483s related to media quality and inadequate use

11.00 **Real risk vs perceived risk when choosing environmental monitoring sites**
- 483 observations related to risk based sampling site selection
- How to utilize airflow visualization to identify sampling sites which pose a real risk to product

11.30 **Group Exercise: Group discussion on various risk assessment strategies used for EM site selection; what worked and what did not**

12.30 **Closing Remarks and End of Workshop**

HALF-DAY POST-CONFERENCE WORKSHOP B
Wednesday 23rd JANUARY 2019, Copthorne Tara Hotel, London, UK
13.30 - 17.20

Workshop Leaders:
Andrew Bartko, Research Leader, **Battelle Memorial Institute**
Jim Polarine, Senior Technical Service Manager, **Steris Corporation**

Rapid Microbial Methods & Developing a Risk-Based Cleaning and Disinfection Programme

Workshop Overview:
The workshop will begin with a survey of rapid microbial methods, including spectrometric and optical methods that are used for sensing contaminants. Operating principles will be discussed and related to microbial attributes being interrogated. The Pros and Cons of the methods will be analyzed with respect to traditional microbial quality control methods. Finally, the practical aspects of implementation, validation, and regulatory considerations will be discussed. The workshop will also cover a risk-based cleaning and disinfection programme and the current best practices in the industry to control bioburden in cleanroom operations. Participants will gain insight into the latest cleaning methods and frequencies. Disinfectant rotation and rinsing and residue removal in cleanrooms will also be covered from a risk -based approach. Finally, the current industry best practices on disinfectant validation will be covered along with the best methods to overcome disinfectant validation challenges.

Why You Should Attend this Workshop:
The workshop will include a synopsis of Rapid Microbial Methods options to the industry as well as a technical description of sensing of contaminants in production. Participants will also gain a deeper understanding of the advantages and limitations of contamination sensing and barriers to implementation. They will also gain insight into how Rapid Microbial Methods compares with traditional methods. The second half of the workshop will provide current industry insight and case studies on developing a risk-based cleaning and disinfection programme. This workshop should be attended by quality managers, validation managers, production managers, operations managers, regulatory managers, and consultants in the pharmaceutical, biotech, hospital compounding, and medical device industries.

About the Workshop Leaders:

Dr. Andrew P. Bartko received a B.S. from the University of Pittsburgh in 1997 and a Ph.D. in physical chemistry in 2002. His graduate work consisted of deciphering spatially heterogeneous relaxation dynamics of glass forming systems using novel rotational single molecule microscopy techniques. In 2002, Dr. Bartko joined the Softmatter Nanotechnology and Advanced Spectroscopy Team at Los Alamos National Laboratory where he studied the ultrafast photophysics of semiconducting quantum dots. Dr. Bartko is a senior scientist in Battelle's Technology Development Group where he contributes to several applied spectroscopy efforts that focus on biological and chemical sensing. He now leads Battelle's Rapid, Enumerated, Bioidentification System development programme.

Jim Polarine is a senior technical service manager at STERIS Corporation. He has been with STERIS Corporation for seventeen years. His current technical focus is microbial control in cleanrooms and other critical environments. He has lectured in North America, Europe, Middle East, Asia, and Latin America on issues related to cleaning and disinfection in cleanrooms. Mr. Polarine is a frequent industry speaker and published several PDA book chapters and articles related to cleaning and disinfection and contamination control. He is active as co-chair on the PDA's microbial investigations task force. Mr. Polarine graduated from the University of Illinois with a Master of Arts in Biology. He previously worked as a clinical research coordinator with the Department of Veterans Affairs in St. Louis, MO and as a biology and microbiology instructor at the University of Illinois. His main hobby is storm chasing and is very active in tornado research and tornado safety.

About the Organisations:

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Programme

13.30 **Registration and Coffee**

14.00 **Opening Remarks and Introductions**

14.10 **Commercially off-the-shelf options and technical aspects of sensing**
- Microbial contamination detection and identification
- Fidelity of results
- Actionable limits
- Time to result / action

14.40 **Implementation of strategies**
- Comparability to standard methods
- Return on investment
- Risk reduction advantages

15.10 **Afternoon Tea**

15.40 **Validation pitfalls to avoid**
- Viable but not culturable
- Approaches to regulatory approval
- Case studies

16.20 **A risk based cleaning and disinfection programme**

16.50 **Validating disinfectants used in cleanroom operations**

17.20 **Closing Remarks and End of Workshop**

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