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Pharmaceutical Microbiology

Pioneering new techniques for the prevention detection and management of microorganisms

20 - 21 JAN 2016

Holiday Inn Kensington Forum, London, UK

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Chairs for 2016:
- **Oliver Chancel,** Sterility and Aseptic Process Assurance Expert, **Merial Sas**
- **Francesco Boschi,** Microbiological Services Manager, **GSK Manufacturing S.p.A**
- **Salomé Gião,** Research Scientist, **Dyson Technology Ltd**

Key Speakers for 2016:
- **Thierry Bonnevay,** Microbiology Platform Head QC Development, **Sanofi Pasteur**
- **Adrianne Klijn,** Group Leader Microbiological and Molecular Analytics, **Nestle Research Center**
- **Sabina Lancaster,** Senior Manager, Sterility Assurance, Global, QA, **GSK**
- **James Drinkwater,** Chairman, **PHSS**
- **Tim Eaton,** Sterile Manufacturing Specialist, **AstraZeneca**

Benefits of attending in 2016:
- **Gain** an in-depth insight into endotoxin testing, validation and LER
- **Understand** the threats posed by VBNCs and how to detect them
- **Hear** specialist advice on contamination control and risk management to minimise costs and maximise efficiency
- **Gain** an international perspective with case studies from across the UK, EU, and USA

PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS
Tuesday 19th January 2016, Holiday Inn Kensington Forum, London, UK

WORKSHOP A
Spectrometric and Optical Technologies for Microbial Contamination Control
Leader: Andrew Bartko, Research Leader, **Battelle**
8.30 am - 12.20pm

WORKSHOP B
Endotoxin Testing: Hot Topics and New Methods in the European Pharmacopoeia
Leader: Karolina Heed, Director, Marketing and Sales, **Hyglos GmbH**
1.00 pm - 4.40pm

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Pharmaceutical Microbiology

Day One | Wednesday 20th January 2016

8.30 **Registration & Coffee**

9.00 **Chair's Opening Remarks**
Oliver Chancel, Sterility and Aseptic Process Assurance Expert, **Merial Sas**

New Mechanisms for Detection and Quality Control

9.10 **Particle deposition monitoring the missing link in contamination control**
- Product contamination
- Air and surface cleanliness
- Particle deposition
- Real time particle deposition measurement

Koos Agricola, Contamination Control Specialist, **International Confederation of Contamination Control Societies**

9.50 **Use of RMM in bacteriology lab: Application and implementation**
- Quantitative bioburden by Chemscan
- Rapid sterility testing by rapid milliflex
- Detection of mycoplasma by PCR+microarray

Thierry Bonnevay, Microbiology Platform Head QC Development, **Sanofi Pasteur**

10.30 **Morning Coffee**

11.00 **Advanced light microscopy to detect VBNC pathogens and biofilms**
- Advantages of EDIC microscopy
- Providing a rapid, real time analysis of biofilms on opaque, curved, natural or man-made surfaces
- Utilising a toolbox of physiological detection techniques to assess viability
- Visualising VBNC pathogens and biofilms in situ

Bill Keevil, Scientific Advisor to the House of Commons Select Committee on Science & Technology, Head of the Microbiology Group and Director of the Environmental Healthcare Unit. University of Southampton, UK, **University of Southampton**

11.40 **DNA-sequencing based methods: How will they shape of routine microbial testing in the future?**
- Learn about new mechanisms of bacterial detection using sequencing mechanisms
- Gain an insight into rapid microbiology sequencing methods

Adrianne Klijn, Group Leader Microbiological and Molecular Analytics, **Nestle Research Center**

12.20 **Networking Lunch**

1.50 **Operating a bioburden control facility within the vaccine industry**
- Bioburen control strategy following recent updates to vaccine regulations
- Case study of how the bioburden control strategy can be applied
- Calculating bioburden limits and understanding the risk to a bioburden control process.

Sabina Lancaster, Senior Manager, Sterility Assurance Global QA, **GSK**

Contamination and Endotoxins

2.30 **Endotoxin testing of biologics – new insights**
- Regulatory requirements, hold-time studies
- New endotoxin test procedures for in-process control and product release
- Influence of major formulation components on endotoxin detectability
- Theory of endotoxin masking (Low Endotoxin Recovery, LER) and recovering masked endotoxin - Case studies

Holger Grallert, Vice President, **Hyglos GmbH**

3.10 **Afternoon Tea**

3.40 **Endotoxin test concerns of biologics**
- Risk – historical and modern
- Emerging perspective on pyrogenicity vs. immunogenicity
- Issues
- LPS: Levels – Types – Treatments
- Dosing and Co-Administration of Non-Biologics

Kevin Williams, Senior Scientist, **Lonza QC Testing Solutions**

4.20 **Cleanrooms to clinic – managing microbiology of stem cell manufacture**
- Background to the stem cell manufacture process (case study)
- Microbial test considerations during the manufacture of stem cell therapeutics
- Managing the risk of out of specification results

Thomas Caws, QC Associate, **ReNeuron Group plc**

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

Register online at: **www.pharma-microbiology.com** • Alternatively f

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Hyglos is dedicated to innovation in Endotoxin Detection & Endotoxin Removal. Based on recombinant reagents, our methods are entirely animal-free without using Horseshoe crabs. The results generated with EndoLISA®, EndoZyme® and Endo-RS® convince customers from biopharmaceutical research and industry, overcoming limitations of currently used methods, including Low Endotoxin Recovery (LER). **www.hyglos.com**

Lonza QC Testing Solutions: Lonza supports the critical needs of your QC laboratory by supplying endotoxin detection reagents, equipment, consumables, in addition to the WinKQCL™ Endotoxin Detection and Analysis Software. Complementary to the endotoxin detection portfolio, Lonza offers MODA™, a robust informatics platform enabling paperless QC processes for environmental monitoring, product testing, and trending. **www.lonza.com/lal**

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Case Studies in Pharmaceutical Microbiology

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Francesco Boschi, Microbiological Services Manager, **GSK Manufacturing S.p.A.**

9.10 **Sterility case studies and management perspectives**
- Learn about case studies provided on specific sites
- Sharing experience on personal site visits and remarks on issues
- How to prevent contamination events
- The importance of correct training and management


Olivier Chancel, Sterility and Aseptic Process Assurance Expert, **Merial Sas**

9.50 **Risked-based contamination control and environmental monitoring in sterile product manufacturing**
- Control strategies for sterile product manufacturing; expected new requirement for EU GMP Annex 1
- Best practice in contamination control for Aseptic processing of different product types
- Risk based environmental monitoring of manufacturing environments


James Drinkwater, Chairman of PHSS Pharmaceutical & Healthcare Sciences Society, **PHSS**

10.30 **Morning Coffee**

11.00 **Assessment methods for accurate determination of microbial contamination during clean room manufacture**
- Microbial contamination in the cleanroom
- Quantification of risk by airborne deposition
- Quantification of risk by surface contact and liquids


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

11.40 **Current practices in disinfectant validation and starting up a cleanroom after a worst case event**
- Best practice for cleaning and disinfection of cleanroom operations
- Elements of disinfectant validation will be covered including coupon studies
- Starting up a new cleanroom operation and how to address cleanroom excursions will be covered


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

12.20 **Networking Lunch**

1.40 **Afternoon Chair Opening Remarks**
Salome Giao, Reseach Scientist, **Dyson Technology Ltd**

Sterility VBNCs and Biofilms

1.50 **Bioburden test of bulk solutions before sterilising filtration: Current practices and expectations**
- Scope and limitations of bioburden test on bulk solutions before sterilisation
- Regulatory Documents and Guidelines on bioburden
- Bioburden test by "conventional" microbiological methods: key issues to obtain reliable and significant
- Microbial identifications from bioburden test samples and evaluation of the recovered flora
- Bioburden test by Rapid Microbiological Methods


Francesco Boschi, Microbiological Services Manager, **GSK Manufacturing S.p.A.**

2.30 **Risk analysis and mitigation of the analysis process of sterility testing in an isolator environment**
- False positive" sterility tests are a major concern for business continuity
- A non-zero percentage Sterility test failure rate is a Regulatory Auditor topic which can be avoided
- How to use FMEA as a tool to reduce risk of "false positives"implmentation of risk mitigation and it's influence on sterility test failure rate


Hans Noordergraaf, Microbiologist, **Abbott Biologicals B.V.**

3.10 **Afternoon Tea**

3.40 **Controlling and monitoring contamination in water for pharmaceutical use (WPU)**
- Reflecting on how to avoid any contamination of your installation by a bio burden
- Explaining the regulatory framework exists and is increasingly demanding as WPU can come into direct or indirect contact with the drug administered to the patient
- Water contamination case studies and monitoring

Robert Neri, Water for Pharmaceutical Use Referent, **Sanofi Pharma**

4.20 **The viable but non-cultivable (VBNC) state of pathogens: A myth or reality?**
- VBNC as a controversial and ignored state
- Why do cells undergo VBNC?
- Are VBNC virulent?
- New methods to detect VBNC cells: an urgent need


Salome Giao, Reseach scientist, **Dyson Technology Ltd**

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

HALF-DAY PRE-CONFERENCE WORKSHOP A
Tuesday 19th January 2016
~~9.15am~~ - 12.20 pm
Holiday Inn Kensington Forum, Central London, UK

Spectrometric and Optical Technologies for Microbial Contamination Control

Leader:
Andrew Bartko, Research Leader, **Battelle**

Overview of workshop:
The workshop will begin with a review the scientific foundation of spectrometric and optical methods that are used for sensing microbes. Fundamental principles will be discussed and related to microbial attributes being interrogated. The Pros and Cons of the methods will be discussed with respect to traditional microbial quality control methods. Finally, the practical aspects of implementation, validation, and regulatory considerations will be discussed.

Why should delegates attend this workshop:
- Synopsis of Rapid Microbial Methods options to the industry
- Technical description of optical sensing of biological materials
- Advantages and limitations of contamination sensing
- Barriers to implementation
- Comparison to traditional methods

8.30 **Registration and coffee**

9.00 **Opening remarks and introductions**

9.15 **Session 1 - Sensing Fundamentals**
- Optical and mass spectrometry
- Fluorescence, Vibrational, Absorption and Raman Spectroscopy
- Mass spectrometry

10.00 **Coffee**

10.15 **Session 2 - Utilization of Spectrometric Methods in Pharmaceutical Production**
- Advantages and Limitations of New Methods
- Comparisons to Traditional Microbial Quality Control

11.00 **Coffee**

11.15 **Session 3 - Implementation**
- Pitfalls when Implementing Rapid Methods
- Regulatory Considerations

12.20 **End of Workshop**

About workshop leader:
Dr. Andrew 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. Dr. Bartko is the manager and technical leader of an interdisciplinary team that is developing Battelle's Resource Effective Bioidentification System (REBS). Rapid microbial sensing capabilities of REBS have been shown to have practical and strategic importance where rapid, accurate and precise microbial contamination control is required. Dr. Bartko has developed several rapid microbial control applications for industries such as defense, security and industrial market sectors.

About the organisation:
Every day, around the world, the people of **Battelle** work at the forefront of scientific innovation to solve what matters most for our government and commercial clients.

We create new products, new processes, new technologies - even new industries. We take breakthrough research from theory to market-ready products and services that save lives, meet growing energy demands, protect the environment, and create competitive advantage. We reach into the future for discoveries that improve the quality of life for millions here and now.

Battelle is making the world healthier by solving critical challenges in public health, improving the performance of medical devices and helping pharmaceutical companies get new therapies to market quickly and safely. We work with government and commercial clients to condense development timelines and to accelerate innovation in health and life sciences.

HALF-DAY PRE-CONFERENCE WORKSHOP B
Tuesday 19th January 2016
1.00pm - 4.40pm
Holiday Inn Kensington Forum, Central London, UK

Endotoxin Testing: Hot Topics and New Methods in the European Pharmacopoeia

Leaders:
Karolina Hedd, Director Marketing & Sales, **Hyglos GmbH**
Holger Grallert, Head of R&D, **Hyglos GmbH**

Overview of workshop:

This workshop will provide the fundamental knowledge on the latest technological and regulatory developments regarding the analysis of endotoxin in pharmaceutical products and pharma production environments. Furthermore the underlying mechanisms of Endotoxin Masking (Low Endotoxin Recovery, LER) in pharmaceutical formulations will be explained as well as the newly developed sample preparation methods.

Why should delegates attend this workshop:

- Quality Control and Production professionals from pharmaceutical and biotech industries
- R&D pharma and biotech, especially new drug formulation development
- Research Institutes and Universities

Programme

1.00 **Registration and Refreshments**

1.30 **Session 1**
The recombinant factor C (rFC) test – new method in the European pharmacopoeia
- Introduction BET and Pyrogen Test Methods
- New Ph. Eur. chapter 5.1.10

2.10 **Session 2**
Implementation of the rFC test in a routine service laboratory
- Endotoxin testing under GMP
- Bioanalytical Method Validation of the rFC test

2.50 **Afternoon Tea**

3.20 **Session 3**
Endotoxin Detection of Biologics I – What are Masking Effects?
- Endotoxin structure and activity
- Impact on detection systems
- Masking of endotoxin (LER)

4.00 **Session 4**
Endotoxin Detection of Biologics II – Demasking Endotoxin with dedicated sample preparation
- Demasking protocol development
- Implementation of demasking method - case studies
- Regulatory requirements

4.40 **Closing Remarks**

About the workshop leader:

Karolina Heed studied chemistry and economics in Gothenburg Sweden and Florence Italy. Prior to heading the marketing & sales of Hyglos GmbH, Ms. Heed worked almost 10 years in the biotech industry in different roles.

About the organisation:

Hyglos GmbH is a leading biotech company offering highly innovative technology for removal and detection of Endotoxins, located in Biotechnology Center Bernried, Munich area, Germany. Being an IAFP Safety Innovation Awardee we apply our proprietary technology for developing highly specific bacteriophage-derived proteins for improved detection and removal of harmful bacteria and bacterial toxins such as Lipopolysaccharides (LPS). Hyglos was founded in 2009 and fulfils all development and production requirements according to ISO 9001 and 13485.

PHARMACEUTICAL MICROBIOLOGY

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