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Pharmaceutical Microbiology West Coast

Bolstering Strategies to Maintain Contamination Control

HYATT REGENCY MISSION BAY HOTEL, SAN DIEGO, CA, USA

CONFERENCE: 5TH - 6TH
WORKSHOPS: 4TH

JUNE 2019

CHAIR FOR 2019:

- **Ziva Abraham,** CEO, **Microrite**

KEY SPEAKERS INCLUDE:

- **Irving Ford,** Head of CAR T QC Laboratories, **Celgene**
- **Chris Knutsen,** Associate Director, Microbiology, **Bristol Myers Squibb**
- **Friedrich von Wintzingerode,** Senior Manager gASAT Microbiology, Global QC, **Genentech**
- **Ren-Yo Forng,** Scientific Director, **Amgen**
- **Anita Bawa,** Director of Quality Control, **Bayer**
- **Lucia Clontz,** Quality Director, **Xellia Pharmaceuticals**

HIGHLIGHTS IN 2019:

- **Discuss** how to overcome challenges following RMM implementation
- **Hear** the developments in creating an effective contamination control strategy
- **Evaluate** novel methods for endotoxin testing
- **Explore** strategies to create effective EM programmes to ensure compliance
- **Investigate** a case study of sterility failure and determine the entry point of contamination

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PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS | TUESDAY 4TH JUNE 2019, HYATT REGENCY MISSION BAY HOTEL, SAN DIEGO, CA, USA

A: Assessing a Holisitic Approach to Microbial Contamination Control

Workshop Leader:
Ziva Abraham, CEO, **Microrite, Inc**
08.30am - 12.30pm

B: Reviewing the Road Map to a Holistic Approach to Microbial Impurities, Endotoxins and LER

Workshop Leaders:
Friedrich von Wintzingerode, Senior Manager gASAT Microbiology, **Global QC, Genentech**
Farnaz Nowroozi, Scientist and Manager, **Genentech**
13.30pm - 17.30pm

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Pharmaceutical Microbiology West Coast

DAY ONE | 5th June 2019 www.pharma-microbiology-usa.com

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Ziva Abraham, CEO, **Microrite, Inc.**

CONTAMINATION CONTROL AND MICROBIAL IDENTIFICATION

OPENING ADDRESS

9.10 **Strategic approaches to contamination control**
- Regulatory expectations for a contamination control strategy
- Types and potential sources of microbial contamination
- Best practices in management of microbial contamination, to include best practices in materials management, personnel training and gowning as well as equipment, process, and facility design

Lucia Clontz, Quality Director, **Xellia Pharmaceuticals**

9.50 **The Conundrum of Microbial Identification**
- Understanding how bacteria fits into the current classification scheme
- Discoveries in bacterial genomics and the impact to microbial identification
- Discussion of how to improve and evolve bacterial identification and its application in biotechnology and pharmaceuticals

Heidi Anderson, Principal Scientist, Microbiology,
Abbott Laboratories

10.30 **Morning Coffee**

11.00 **Pharmaceutical water treatment in a multi-product facility**
- The processing of water in the pharma lab including bioburden control
- Use of biopesticides in water treatment
- Preventing biofilm formation and microbial contamination of water systems
- Strategies to tackle current challenges in water processing

Eric Wesoloski, Associate Director Quality Compliance, **Takeda**

11.40 **Fungal Identification: Challenges and Pitfalls**
- Overview of fungal identification methods
- Challenges with fungal identification
- Assessment of commercial identification platforms with respect to fungal identification
- Evaluation of gene targets and its utility for fungal identification

Bindhu Verghese, R&D Sr Staff Scientist
Microbial Solutions, **Charles River Laboratories**

12.20 **A risk-based approach to cleaning and disinfection**
- Overview of EU, U.S. and global industry regulations for cleaning and disinfection
- Annex-1, FDA warning letters, and 483's expectations and considerations
- Current antimicrobial products in the industry and creating a cleaning and disinfectant programme
- Sterility relating to disinfectants and sporicides

Jim Polarine, Senior Technical Service Manager,
STERIS Corporation

13.00 **Networking Lunch**

ENDOTOXIN TESTING AND LER

BACK-TO-BACK GENENTECH SPOTLIGHT SESSION

14.00 **Low Endotoxin Recovery (LER)**
- What is Low Endotoxin Recovery (LER)?
- PDA Technical Report No. 81 Low Endotoxin Recovery
- LER impact on product quality
- Quality control strategies for LER

Friedrich von Wintzingerode, Senior Manager gASAT Microbiology, Global QC, **Roche/ Genentech**

14.40 **New endotoxin testing methods - A mass spectrometry based approach**
- Mass spectrometry-based testing methods
- Impact of new testing methods on routine practices
- Case study of implementation

Farnaz Nowroozi, Scientist and Manager, **Genentech, Inc**

15.20 **Afternoon tea**

15.50 **Regulatory updates for BET assays**
- Endotoxin limit calculations
- USP <1085>
- Public consultation on a new general chapter in PharmEuropa 2.6.32

Veronika Wills, Manager Technical Services Group,
Associates of Cape Cod

16.30 **Alternative endotoxin test methods for products exhibiting low endotoxin recovery**
- The development of a suitable method to replace current endotoxin testing methods for products
- A strategic approach to the evaluation and validation of testing methods
- The future for finding a suitable replacement method – scope and reality check

Ren-Yo Forng, Scientific Director, **Amgen**

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

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Pharmaceutical Microbiology West Coast

DAY TWO | 6th June 2019 www.pharma-microbiology-usa.com

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**

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

ENVIRONMENTAL MONITORING AND RAPID MICROBIAL METHODS

9.10 **Investigating sterility failures**

- Current inspection trends
- How to appropriately investigate sterility failures and determine entry point of contamination
- Recommendations from the FDA for investigations
- Case study

Anita Bawa, Quality Control Director, **Bayer Healthcare**

9.50 **Sterile Compounding – Moving into the New Age**

- Old School/New School – Review of progress for the industry
- Production Trends toward Aseptic Control
- FDA Enforcement focus
- Future of 503B Outsourcing Facilities

Jason McGuire, VP, Global Quality Director, **Fargon**

10.30 **Morning Coffee**

11.00 **Building a Holistic Business Case for Rapid Micro Methods**

- Challenges of RMM implementation and business case developments
- Why should you consider a holistic business case?
- How to best implement and build RMM strategy using a business case
- Case study/strategy of how to approach a RMM business case

Lisa Yan, Principal Quality Laboratory Associate, **Shire plc**

11.40 **Rapid Microbial Methods - Reap benefits and avoiding pitfalls**

- An overview of the design, validation and implementation of RMM
- Regulatory advice for RMM implementation
- 3 key takeaways from a case study of RMM implementation

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

12.20 **Networking Lunch**

13.20 **Implementation of RMM into an effective EM programme**

- Overview of RMM uses in effective EM programmes
- Overcoming issues of implementation
- Ensuring compliance
- Take away points from a recent case study

Chris Knutsen, Associate Director, Microbiology, **Bristol-Myers Squibb PRI**

CONTAMINATION CONTROL CONSIDERATIONS FOR SPECIAL DRUG PRODUCTS

14.00 **Just in time release of CAR-T Cell therapies**

- A patient centric approach for release of CAR-T Cell therapies
- Overview of rapid sterility testing of CAR-T therapies
- Overcoming challenges and scope for the future
- 3 key lessons learned from a case study

Irving Ford, Head of CAR T QC Laboratories, **Celgene Corporation**

14.40 **Afternoon Tea**

15.10 **Assessing Regulatory and Release Strategies in Live Bacterial Therapeutics**

- The known regulatory landscape
- Potentials for product interference with traditional assays and methods for assessing contamination
- Environmental monitoring considerations

Julie Schwedock, PhD, Associate Scientific Fellow CMC - New Modalities Development, **Takeda Pharmaceuticals**

ROUNDTABLE DISCUSSION

15.50 **Risk-based contamination control strategies**

- Risk-based contamination control strategies
- Visual Inspection
- Aging Facilities

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

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

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HALF-DAY PRE-CONFERENCE WORKSHOP A
TUESDAY 4TH JUNE 2019 | 08.30 - 12.30
HYATT REGENCY MISSION BAY HOTEL, SAN DIEGO, CA, USA

Workshop Leader:
Ziva Abraham, CEO, **Microrite, Inc**

ASSESSING A HOLISTIC APPROACH TO MICROBIAL CONTAMINATION CONTROL

microrite, inc.

Overview:
To better manage microbial contamination risk and establish effective mitigation strategies, it is necessary to understand the microbial hazards involved in drug products manufacturing. A holistic risk assessment is required to be able to evaluate potential impact of contaminants on final product quality. To accomplish this, it is necessary to understand the microbial hazards involved in the manufacturing process and evaluate their impact on final product quality so that effective prevention strategies can be implemented. Science based, comprehensive, and effective approaches should be employed for contamination monitoring and controls in order to make safe products.

Why you should attend:
To develop a microbial contamination control strategy and assess effectiveness of all the control and monitoring measures employed, myriad risk factors should be considered holistically. Microbial contamination risk assessments cannot be considered individually; all aspects from facility design to product release should be considered by fully understanding:

- Contamination due cleanroom and barrier system integration flaws
- How material and personnel flows can become a source of contamination
- Cleaning and disinfection gaps can contaminate facility and manufacturing equipment
- How gown management and gowning procedures can become a source of contamination
- Where in the process contamination can occur and the efficiency of removal methods
- Efficiency of monitoring equipment and methods
- Understanding objectionable microorganisms
- Microbiology laboratory issues that can contaminate tests

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 **Understand contamination challenges in each type of medicinal product**
- Learn to evaluate the sources of these contaminants and how they can be prevented
- Learn from case studies
- Common facility design and integration flaws that can lead to contamination and data integrity

9.50 **Common errors made during qualification**
- Gaps in environmental monitoring that can lead to a false sense of environmental control
- Learn from personnel gowning related 483 observations and avoid gown choice and management issues

10.30 **Morning Coffee**

11.00 **Dispel myths about cleaning and disinfection**
- Understand process related risks
- Learn how to control contamination in the laboratory and avoid unreliable data

11.40 **Guidance of drafting a contamination control strategy**
Group Exercise: Workshop leader will select a product type and lead discussions on what contamination control steps should be taken in terms of facility, gowning, cleaning and testing

12.20 **Closing remarks**

12.30 **End of workshop**

HALF-DAY PRE-CONFERENCE WORKSHOP B
TUESDAY 4TH JUNE 2019 | 13.30 - 17.30
HYATT REGENCY MISSION BAY HOTEL, SAN DIEGO, CA, USA

Workshop Leaders:
Friedrich von Wintzingerode, Senior Manager gASAT Microbiology, Global QC, **Roche Diagnostics Gmbh**
Farnaz Nowroozi, Scientist and Manager, **Genentech, Inc**

REVIEWING THE ROAD MAP TO A HOLISTIC APPROACH TO MICROBIAL IMPURITIES, ENDOTOXINS AND LER

Overview:
The control of endotoxins in pharmaceutical products is imperative due to the varying level of immune responses incurred when introduced in to the blood stream. Manufacturers of all parenteral drugs must ensure appropriate control, testing and removal methods are in place throughout the process to assure patient safety. As the processes within quality control evolve, so do the endotoxin control methods and it essential to choose the right processes for your company to appropriately deal with the issue. This workshop will give an overview of novel endotoxin detection methods, insight into the best test method for your company's purpose, identifying an appropriate approach to address LER, calculating risk for contamination and a holistic approach to address the impurities.

Why you should attend:
Attendees of this workshop stand to gain:

- Overview of best practices that participants can utilise in their daily work and laboratory operations
- Understanding of crucial practices in the testingendotoxins
- An insight into effective risk assessments for microbial impurities
- Key considerations with LER

About the Workshop Leaders:
Friedrich:
Friedrich is Senior Manager at Roche-Genentech Global Analytical Science and Technology, Global QC. He is Head of Roche-Genentech global Endotoxin Expert Group and Roche-Genentech global SME on microbial impurity contaminations and LER.
After studying biology with focus on Microbiology at the Technical University of Braunschweig, Germany he earned his PhD at the Institute of Microbiology and Hygiene, Charité, Berlin, Germany.

Farnaz:
Considered the founder of the industry, Genentech, now a member of the Roche Group, has been delivering on the promise of biotechnology for over 40 years. Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. We are among the world's leading biotech companies, with multiple products on the market and a promising development pipeline.

Programme:

13.30 **Registration & Coffee**

14.00 **Workshop leaders introduction**

14.10 **Alternative technologies for endotoxin testing**
- Brief overview of alternative technologies for endotoxin testing
- Current technology trends
- Troubleshooting and overcoming issues

15.00 **LER**
- Discussion of LER causing formulations and root causes
- Conducting endotoxin hold time studies to detect LER
- Considerations for an effective Quality control strategy

15.50 **Afternoon Tea**

16.20 **CCAB: Interactive Session**
- Interactive task: Calculating risks of microbial impurities in injectables – case study
- A holistic approach to address the risk of microbial impurities on injectables

17.10 **Closing discussion**

17.30 **Closing remarks and end of workshop**

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