The Parenteral Drug Association presents the...

PDA Bioburden and Biofilm Workshop

Controlling Microbial Contamination to Assure Product Quality, Patient Safety and Regulatory Satisfaction

April 9-10, 2014

JW MARRIOTT SAN ANTONIO HILL COUNTRY
SAN ANTONIO, TEXAS

Save $100 when you register for the workshop and the 2014 PDA Annual Meeting!

www.pda.org/bioburden2014

THIS PRELIMINARY AGENDA IS CURRENT AS OF DECEMBER 11, 2013.
Dear Colleagues,

Biologic product sterility assurance is a critical quality attribute for parenteral products and certain medical devices and can only be achieved through strong aseptic manufacturing processes and control. Aseptic manufacturing microbial control is also important for many non-sterile products as well. The PDA Bioburden and Biofilm Workshop will discuss critical issues encountered during aseptic manufacturing processes which may contribute to microbial contamination and focus on current opportunities and challenges for individuals or firms engaged in the development of new processes. Industry and regulatory perspectives presented throughout the workshop will focus on defining effective microbial control program encompassing product for processes as well as facility, equipment, utilities and personnel controls.

Best practices for remediation of contaminated processes and equipment will be reviewed with case studies where remediation was possible. The case studies will provide lessons learned in effective quality investigations and regulatory interactions once problems occur.

The workshop will present practical approaches to the prevention, detection, and remediation of microbial contaminations that attendees can use in daily production and laboratory operations. The workshop will also provide attendees with a first look at the outcome of the PDA survey on Bioburden and Biofilm Management along with an update on the status of the Bioburden and Biofilm Management technical report.

Please join us on April 9-10, 2014 in San Antonio, Texas for this unique and interactive learning opportunity!

Sincerely,

PDA Bioburden and Biofilm Workshop Program Planning Committee Chair
Vince Anicetti, Executive Director Quality,
Boehringer Ingelheim
Wednesday, April 9 – Thursday, April 10, 2014 Agenda

Wednesday, April 9, 2014

12:30 p.m. – 5:00 p.m.
Registration Open

1:30 p.m. – 1:50 p.m.
Welcome Remarks: Challenges and Impact of Bioburden and Biofilm on Pharmaceutical Production
Vince Anicetti, Executive Director Quality, Boehringer Ingelheim, Chair, PDA Bioburden and Biofilm Workshop Program Planning Committee

1:50 p.m. – 3:10 p.m.
P1: The Genesis of Bioburden and Biofilm in Pharmaceutical Production Processes
Vince Anicetti, Executive Director Quality, Boehringer Ingelheim

Session Description: In recent years there has been a fundamental shift in the understanding of microbial growth in various aspects. It is now widely recognized that the preferred form of microbial growth in nearly all environments is as attached microcolonies, or sessile biofilms. This session will discuss the biology and engineering aspects.

1:50 p.m. – 2:20 p.m.
Biology Aspect
Marc Mittelman, Senior Managing Scientist, Exponent

2:20 p.m. – 2:50 p.m.
Engineering Aspect
Paul Sturman, PhD, Industrial Coordinator, Montana State University-Bozeman (Invited)

2:50 p.m. – 3:10 p.m.
Q&A/Discussion

3:10 p.m. – 3:55 p.m.
Refreshment Break

3:55 p.m. – 5:30 p.m.
P2: Design, Control and Prevention Considerations
Peter Noverini, Field Applications Scientist, Azbil BioVigilant, Inc.

Session Description: The importance of putting in place a contamination control program that covers the process from beginning to end with built-in mechanisms for frequent re-evaluations and feedback throughout the product life cycle. This session will discuss the design and routine manufacturing process and how it must be supported by robust quality systems to document, review, correct and improve on the processes.

3:55 p.m. – 4:40 p.m.
Comprehensive Design Principles for Overall Bioburden Prevention and Control
Carmen Wagner, PhD, Founder and President, Strategic Compliance International, Inc. (Invited)

4:40 p.m. – 5:10 p.m.
Contamination Control
Mark Pasmore, PhD, Manager, Sterility Assurance Research Center Technology Resources, Baxter Healthcare Corporation

5:10 p.m. – 5:30 p.m.
Q&A/Discussion

5:30 p.m. – 6:45 p.m.
Networking Reception

Thursday, April 10, 2014

7:00 a.m. – 5:00 p.m.
Registration Open

7:00 a.m. – 8:00 a.m.
Continental Breakfast

8:00 a.m. – 9:20 a.m.
P3: Bioburden and Biofilm Detection
Marc Mittelman, Senior Managing Scientist, Exponent

Session Description: In order to ensure a state of microbiological control during production, companies must implement scientifically sound testing programs. The compendia contain quantitative and qualitative tests for detection of microbial species in non-sterile materials. This session will take a deeper look into detection of microbial species in non-sterile materials and how detection methods are evolving.

8:00 a.m. – 8:30 a.m.
Strategies for the Detection of Microbial Contamination, Biofilm, and Endotoxin
Peter Noverini, Field Applications Scientist, Azbil BioVigilant, Inc.

8:30 a.m. – 9:00 a.m.
Evolving Detection Methods
Jeffrey Weber, Senior Scientist, Pfizer, Inc. (Invited)

9:00 a.m. – 9:20 a.m.
Q&A Discussion

9:20 a.m. – 10:05 a.m.
Refreshment Break
Thursday, April 10, 2014 Agenda (continued)

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<th>Time</th>
<th>Session</th>
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<tr>
<td>10:05 a.m. – 12:00 p.m.</td>
<td><strong>P4: Remediating Bioburden and Biofilm Events</strong>&lt;br&gt;George Verghese, Director, Technical Service, STERIS Corporation&lt;br&gt;&lt;br&gt;<strong>Session Description:</strong> Remediation methods should be considered as exceptional reactions to a process control failure rather than a routine process control strategy. This session is intended to describe the non-routine physical or chemical treatments of process materials and equipment to reduce problematic bioburden or biofilm to acceptable levels.</td>
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<td>10:05 a.m. – 11:35 a.m.</td>
<td><strong>Bioburden and Biofilm Investigations</strong>&lt;br&gt;Mark Fornalik, Principal Scientist, Bausch + Lomb (Invited)</td>
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<td>12:00 p.m. – 1:15 p.m.</td>
<td>Lunch</td>
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<td>1:15 p.m. – 3:15 p.m.</td>
<td><strong>P5: Regulatory Requirements and Perspectives</strong>&lt;br&gt;Session Moderator: Vince Anicetti, Executive Director Quality, Boehringer Ingelheim&lt;br&gt;&lt;br&gt;<strong>Session Description:</strong> This session will present an overview of current regulations and guidelines from the US and EU as well as provide attendees with a compliance case studies.</td>
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<td>1:15 p.m. – 1:45 p.m.</td>
<td><strong>FDA Perspective on Bioburden and Biofilm Control</strong>&lt;br&gt;Regulatory Speaker Invited</td>
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<td>3:15 p.m. – 3:45 p.m.</td>
<td>Refreshment Break</td>
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<td>3:45 p.m. – 4:50 p.m.</td>
<td><strong>P6: Case Studies</strong>&lt;br&gt;Session Moderator: Mark Pasmore, PhD, Manager, Sterility Assurance Research Center Technology Resources, Baxter Healthcare Corporation&lt;br&gt;&lt;br&gt;<strong>Session Description:</strong> This session will provide attendees with real case studies on how bioburden and biofilm problems were resolved, how the effectiveness of CAPAs was assessed and what important lessons were learned and incorporated into the microbial control program.</td>
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<td>3:45 p.m. – 4:10 p.m.</td>
<td><strong>Downstream Contamination Control</strong>&lt;br&gt;Tyler Tsang, Senior Manager, Quality Control, Genentech, Inc. (Invited)</td>
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<td>4:10 p.m. – 4:35 p.m.</td>
<td><strong>Facility, Utilities and Equipment Case Studies</strong>&lt;br&gt;Lucia Clotz, PhD, Expert Microbiologist and Senior Manager, Compliance, Fresenius Kabi USA (Invited)</td>
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<td>4:35 p.m. – 4:50 p.m.</td>
<td>Q&amp;A/Discussion</td>
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<td>4:50 p.m. – 5:00 p.m.</td>
<td><strong>Closing Remarks from Program Chair</strong>&lt;br&gt;Vince Anicetti, Executive Director Quality, Boehringer Ingelheim</td>
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PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Following full attendance, completion and submission of the appropriate evaluation forms, certificates will be mailed within four to six weeks of the event.

**PDA Bioburden and Biofilm Workshop**

ACPE # 0116-0000-14-069-L04-P | 0.924 CEUs

Type of Activity: Knowledge

**LEARNING OBJECTIVES:**

Upon completion of this workshop, you will be able to:

- Describe the principles and best practices of microbial control in pharmaceutical processes based on current best practices and regulatory expectations
- Provide a practical scientific illustration of the biology underlying bioburden development in pharmaceutical and biopharmaceutical drug substance production systems.
- Explain the mechanisms surrounding biofilm formation and the complex interactions that exist between planktonic and sessile modes of microbial contamination
- Present information on typical control levels/limits for various types and stages of biopharmaceutical production systems, including critical utility systems
- Evaluate the principles and best practices in prevention, detection, and remediation of microbial contamination in pharmaceutical/biopharmaceutical drug substance or API production systems, including current regulatory guidance and expectations
- Manage microbial quality issues and conduct effective investigations, remediation, and regulatory interactions

**WHO SHOULD ATTEND:**

Departments: Microbiology, Compliance, Engineering, Manufacturing, QA/QC, Development, Regulatory Affairs, Research and Development, Validation

Level of Expertise: Executives, Management, Scientists/Technicians

**VENUE**

The JW Marriott San Antonio Hill Country
23808 Resort Parkway, San Antonio, Texas 78261
Phone: +1 (210) 276-4420 | Website: www.jwsanantonio.com

**MAKE YOUR RESERVATION:**

Passkey Link: https://resweb.passkey.com/go/2014pda

Call-in Number: +1 (866) 992-4420 | Fax: (210) 276-2501

Rate: Single – $265.00, plus 16.75% state and local fees.

**CUT OFF DATE:** Friday, March 7, 2014 (A PDA block of rooms are available on a first come basis and must be secured by the cut-off date to receive the PDA rate). After the cut-off date, rooms will be available at the prevailing rate based on availability.

**PLEASE READ:** PDA is not affiliated or contracted with any outside hotel contracting company. If someone other than PDA or the PDA chosen hotel contacts you suggesting that they represent any PDA event, they do not. It is PDA’s recommendation that you book your hotel directly through the official PDA chosen hotel that is listed on our web site.

**WORKSHOP REGISTRATION HOURS**

**Wednesday, April 9:** 12:30 p.m. – 5:00 p.m.

**Thursday, April 10:** 7:00 a.m. – 5:00 p.m.

**DRESS/ATTIRE**

Business casual attire is recommended for the PDA Bioburden and Biofilm Workshop. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

**SPECIAL REQUIREMENTS**

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration@pda.org.

**CONTACT INFORMATION**

**Workshop inquiries:**
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Sponsorship and Exhibit Opportunities are Available!

The PDA Bioburden and Biofilm Workshop will include a tabletop exhibition where company representatives can network with attendees seeking information on aseptic manufacturing processes and microbial contamination control. Exhibiting at or sponsoring this workshop will provide an exclusive opportunity for your company to position itself as a leader in this field and gain access to a focused audience.

For exhibition and sponsorship inquiries, please contact:

David Hall, Vice President, Sales
Tel: +1 (301) 760-7373 | Cell: +1 (240) 688-4405 | Fax: +1 (301) 986-0296 | E-mail: hall@pda.org

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