The Parenteral Drug Association presents the...

11th Annual PDA Global Conference on Pharmaceutical Microbiology

Advancing quality and safety through sound science

October 24-26, 2016 | Arlington, VA

Hyatt Regency Crystal City

Exhibition: Oct. 24-25
2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision: Oct. 26-27
Courses: Oct. 27-28

Register before August 11 and save up to $600!

Conference Theme: *Microbial Control: Key to Product Quality and Patient Safety*

pda.org/2016micro
#2016micro

This preliminary agenda is current as of June 30, 2016

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Co-Chairs

Amy McDaniel, PhD
Pfizer, Inc.

Vinayak Pawar, PhD
FDA

Edward S. Balkovic, PhD
MicroBio Technical Support

Julie Barlasov
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Molly O'Neill Moir, CMP
PDA Liaison to the Program Planning Committee

Wanda Neal, CMP
PDA Liaison to the Program Planning Committee

A MESSAGE FROM THE PROGRAM CO-CHAIRS

Amy McDaniel, PhD
Pfizer, Inc.

Vinayak Pawar, PhD
FDA

On behalf of the Program Planning Committee, we would like to personally invite you to attend the *11th Annual PDA Global Conference on Pharmaceutical Microbiology,* October 24-26, 2016 in Arlington, VA. This is an exciting time for PDA as we continue to grow and build on knowledge gained over the years. Yet, we always remain adaptable and motivated by the challenges and complexities of pharmaceutical manufacturing in today's dynamic global environment, and we are committed to developing a model for sustained quality.

We will celebrate the 11th anniversary of this Conference with the theme, *Microbial Control: Key to Product Quality and Patient Safety*, not just by promoting excellence but also by bringing together both the inspired and the inspiring young microbiologists to remain at the cutting edge of pharmaceutical technology. The Conference meets the unique needs of pharmaceutical microbiologists and interdisciplinary scientists involved in pharmaceutical manufacturing and regulations. It provides opportunities to network, interact and share with and learn from professionals and experts through question & answers, posters, vendor exhibits, educational workshops and the most popular "Ask the Experts" interactive session. And, again this year, we have included an audience response system to augment your learning experience.

The centerpiece of our Conference is the program. We have convened speakers representing the pharmaceutical industry, research institutes, academia and government policy makers from across the globe who will present and discuss on key topics, including emerging infections such as the Zika Virus, solutions to overcome challenges of combination products manufacturing, environmental monitoring with dynamics of interaction between air movements and the dispersion of contaminants, contamination controls and the quality systems in microbiology.

With so much discussion about Zika virus and its likelihood to spread even more broadly this summer, this year's keynote address by Dr. Jackson will be timely. Concurrent sessions will address *Cleaning and Disinfection,* focusing on current contamination challenges with insight into both development of these programs and qualifying the agents, and *Data Integrity and Compliance,* exploring attributes of data and records supporting drug products throughout their lifecycle. An FDA representative will provide an introduction to the recently released *Draft Guidance on Data Integrity and Compliance with cGMP Guidance for the Industry.* Afternoon sessions will cover the updated challenges in endotoxin recovery by presenting the results of the *PDA Task Force on Low Endotoxin Recovery,* followed by an *FDA Perspective on Endotoxin Testing and LER.* A parallel session for those interested in quality systems in microbiology discussing *FDA's Recent Manufacturing Findings and Trends* at Pharmaceutical Facilities and *Development of an Effective Microbial Control Strategy in BioManufacturing Facility* will also be offered.

Developing the workforce for tomorrow is an interest shared by many, including the PDA membership, and these opportunities for *Emerging Leaders* and for preparing our *Current and Future Pharmaceutical Microbiologists* to collaborate to meet these newer demands will be explored in several sessions. Additional plenary, concurrent and breakfast sessions will look at implementation of ISO 14644-1 & 2 and how to meet these revised standards, new antibiotic discoveries, *Challenges of Combination Products Manufacturing, Contamination of a Non-Sterile Aqueous Product* and *Sterilization Science and Technologies for Combination Products.*

Technologies that are currently being evaluated in the microbiology laboratory today and the challenges participants are facing in performing validations of both novel and routine microbiological assays will also be addressed, along with the progressive refinement and improvement in cleanroom control and monitoring guidelines and standards. The *USP Updates* session will provide an overview of the proposed changes to USP general chapters related to Microbiology with emphasis on recent revisions and new chapters. A portion of the Conference will be devoted to regulatory issues, including sessions on the *Current State of Microbiology Operations* from an inspectional viewpoint and the ever-popular *Ask the Regulators* panel discussion.

Lunches and refreshment breaks will provide a relaxed environment in which to view posters and discuss burning issues raised during the day's presentations. The networking reception on Monday evening will allow time for visiting with vendors and fellow attendees.

For continuing education and training, PDA Education will offer several courses relevant to pharmaceutical microbiology and manufacturing immediately following the Conference.

You will have the unique opportunity to contribute to the future advancements in pharmaceutical microbiology through your participation. Please join us October 24-26, 2016 in Arlington, VA for this unique and interactive learning opportunity!

GENERAL INFORMATION, REGISTRATION

Four Ways to Register

1. Click	**pda.org/2016micro**
2. Fax	+1 (301) 986-1093
3. Mail	PDA Global Headquarters Bethesda Towers 4350 East West Highway, Suite 600 Bethesda, MD 20814 USA
4. Phone	(301) 656-5900 ext. 115

Venue

Hyatt Regency Crystal City
2799 Jefferson Davis Highway
Arlington, VA 22202
Phone: +1 (703) 418-1234
Website: crystalcity.regency.hyatt.com
Rate: Single: $255, plus applicable state and local taxes.
Cut-Off Date: Monday, September 26, 2016 (Rooms must be secured by this date in order to receive the PDA rate). Rates are guaranteed until the PDA block of rooms are sold out on a first-come basis.

Continuing Education Credits

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

11th Annual PDA Global Conference on Pharmaceutical Microbiology
ACPE # 0116-0000-16-014-L04-P | 1.717 CEUs
Type of Activity: *Knowledge*

Learning Objectives

At the completion of this Conference, participants will be able to:

- Demonstrate increased knowledge in many areas of Microbiology, including managing microbial risk and the dynamics of microbial contamination
- Identify current trends in microbiology (New Technologies)
- Summarize new advances in rapid microbiological methods and updates in endotoxin testing
- Describe the challenges posed by mold and spore contamination
- Identify local regulatory and pharmacopeial expectations
- Explain global harmonization plans

Who Should Attend

Departments: Microbiology | Compliance | Engineering | Manufacturing | QA/QC | Development | Regulatory Affairs | Research and Development | Validation | Executives | Management

Job Function: Scientist/Technician | Research | Analyst | Bench Personnel

Conference Registration Hours

Sunday, October 23:	4:00 p.m. – 6:00 p.m.
Monday, October 24:	7:00 a.m. – 5:30 p.m.
Tuesday, October 25:	7:00 a.m. – 5:15 p.m.
Wednesday, October 26:	7:00 a.m. – 12:30 p.m.

Course Registration Hours

Thursday, October 27:	7:30 a.m. – 4:00 p.m.
Friday, October 28:	7:30 a.m. – 4:00 p.m.

Dress/Attire

Business casual attire is recommended for the *11th Annual PDA Global Conference on Pharmaceutical Microbiology*. 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

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SUNDAY, OCTOBER 23 – MONDAY, OCTOBER 24, 2016 AGENDA

Sunday, October 23, 2016

4:00 p.m. – 6:00 p.m.
Registration Open

Monday, October 24, 2016

7:00 a.m. – 5:30 p.m.
Registration Open

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

8:00 a.m. – 8:15 a.m.
Welcome and Opening Remarks
Amy McDaniel, PhD, Director, Technical Operations, *Pfizer, Inc.,* and Co-Chair, *11th Annual PDA Global Conference on Pharmaceutical Microbiology* Program Planning Committee

8:15 a.m. – 9:30 a.m.
P1: Opening Plenary Session
Moderator: Amy McDaniel, PhD, Director, Technical Operations, *Pfizer, Inc.*

Session Description: Zika virus is a mosquito-borne virus that has recently come to the forefront of public concern with the increase in incidence and the discovery that Zika virus infection during pregnancy can cause a serious birth defect called microcephaly, as well as other severe fetal brain defects. In May 2015, the Pan American Health Organization issued an alert regarding the first confirmed Zika virus infection in Brazil. On February 1, 2016, the World Health Organization declared the increasing cases of neonatal and neurological disorders, amid the growing Zika outbreak in the Americas, a Public Health Emergency of International Concern. This plenary session will focus on current and emerging knowledge of the Zika virus and efforts at detection, control and prevention.

8:15 a.m. – 9:15 a.m.
The Challenges for Developing a Zika Vaccine
Nicholas Jackson, PhD, Vice President, Head of Global Research, *Sanofi Pasteur (Invited)*

9:15 a.m. – 9:30 a.m.
Question and Answers/Discussion

9:15 a.m. – 7:00 p.m.
Exhibit Hall Open

9:30 a.m. – 10:15 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

MONDAY, OCTOBER 24, 2016 AGENDA (CONTINUED)

Choose from 2 Concurrent Sessions

A1: Cleaning and Disinfection

10:15 a.m. – 12:15 p.m.
Moderator: Edward S. Balkovic, PhD, *MicroBio Technical Support*

Session Description: As the pharmaceutical industry moves to produce new biopharmaceuticals, the control of microbial contamination plays a heightened role in our aseptic manufacturing environments. Key to this control is the implementation of an effective microbial contamination control program using qualified decontaminating agents (sanitizers, disinfectants and sporicides). As microbiologists, we are typically assigned to both develop these programs and qualify the agents; this session will provide insight into both of these tasks. Expert speakers will address the key decisions leading to the preparation of the recent *PDA Technical Report No. 70 (TR 70), Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities,* the challenges in assessing agent efficacy using bacterial and fungal spores and the regulatory expectations to provide assurances of appropriate microbial contamination control.

10:15 a.m. – 10:45 a.m.
Solutions for Overcoming Testing Challenges with Fungal and Bacterial Spores in Disinfectant Coupon Studies
James Polarine, Jr., Technical Service Manager, *Steris Corporation*

10:45 a.m. – 11:15 a.m.
PDA Technical Report No. 70
Arthur Vellutato, Jr., PhD, President & CEO, *Veltek Associates, Inc.*

11:15 a.m. – 11:45 a.m.
Regulatory Expectations
CAPT Sharon Thoma, PharmD, National Expert, Pharmaceutical Inspections, ORA, *FDA*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

B1: Data Integrity and Compliance

10:15 a.m. – 12:15 p.m.
Moderator: Julie Barlasov, Senior Scientist, *Teva Pharmaceuticals*

Session Description: Data integrity is intended to describe attributes of data and records that support drug products throughout their lifecycle from the point of development through commercialization. The reliability of such data is necessary to support clinical trials, product development and manufacturing, and testing and reporting requirements. Data integrity is the cornerstone to establishing and maintaining confidence and reliability of data. This session will examine areas related to pharmaceutical microbiology, including environmental monitoring and laboratory analysis, and a regulatory perspective on the subject.

10:15 a.m. – 10:45 a.m.
Introduction of the Recently Released Draft Guidance *Data Integrity and Compliance With CGMP Guidance for Industry*
Karen Takahashi, Compliance Officer, CDER, *FDA*

10:45 a.m. – 11:15 a.m.
Lessons Learned in Microbial Data Integrity Management from a Manufacturer's Perspective
Anil Sawant, PhD, Vice President, Quality Management Systems and External Affairs, *Merck & Co, Inc.*

11:15 a.m. – 11:45 a.m.
Report from the PDA Task Force on Data Integrity within Analytical and Microbiology Laboratories for All Phases of the Drug Product Lifecycle
Dennis E. Guilfoyle, PhD, Senior Director, Regulatory Compliance, *Johnson & Johnson*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:30 p.m.
Exhibitor Roundtable Luncheon – *Exhibitors will be seated at designated tables and will be available for informal discussion with attendees. Exhibit Hall will be closed during this time.*

MONDAY, OCTOBER 24, 2016 AGENDA (CONTINUED)

Choose from 2 Concurrent Sessions

1:30 p.m. – 3:30 p.m. **A2: Challenges in Endotoxin Recovery** **Moderator: Rich Levy, PhD,** Senior Vice President, Science & Regulatory Affairs, *Parenteral Drug Association*	1:30 p.m. – 3:30 p.m. **B2: Quality Systems in Microbiology** **Moderator: Amy McDaniel, PhD,** Director, Technical Operations, *Pfizer, Inc.*
Session Description: This session will explore some of the challenges our industry is experiencing in understanding basic endotoxin testing science, the best practices of conducting endotoxin hold studies, the underlying mechanism(s) of endotoxin masking, endotoxin masking and patient safety, as well as alternative endotoxin testing methods, such as the Monocyte-Activation Test (MAT).	**Session Description:** The essential premise of a Microbial Quality System (MQS) is to ensure that appropriate microbiological resources (materials, methods, manpower and management) are strategically positioned at the various key stages of design, development and production, where they can exert the greatest positive influence on overall microbiological quality. An effective MQS should create knowledge continuity between the laboratory, production process and environment. This session will share the process of development of a Microbial Control Strategy and will include a summary of issues that occur when there are failures in the MQS, from both laboratory and manufacturing perspectives.
1:30 p.m. – 2:00 p.m. **Results of the PDA Task Force on Low Endotoxin Recovery (LER)** **Dayue Chen,** Research Advisor, *Eli Lilly & Company*	1:30 p.m. – 2:00 p.m. **Development of an Effective Microbial Control Strategy in a Biomanufacturing Facility** **Kevin Luongo,** Manager, Microbial Control Strategy, *Pfizer, Inc.*
2:00 p.m. – 2:30 p.m. **The Recombinant Factor C Alternative Endotoxin Method: Primed for the Big Time** **Jay Bolden,** Associate Senior Consultant Biologist, *Eli Lilly & Company*	2:00 p.m. – 2:30 p.m. **Quality Metrics: Tools to Strengthen Microbial Control** **Barry A. Friedman, PhD,** Consultant, *Barry A. Friedman, PhD, LLC*
2:30 p.m. – 3:00 p.m. **FDA Perspective on Endotoxin Testing and LER** **Patricia Hughes-Troost, PhD,** Team Leader, Biotech Manufacturing, CDER, *FDA (Invited)*	2:30 p.m. – 3:00 p.m. **Recent Manufacturing Findings and Trends at Pharmaceutical Facilities, with Emphasis on Microbiological Quality and Sterility Assurance** **Rick Friedman,** Deputy Director, Science & Policy, OMPQ, CDER, *FDA*
3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**	3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**

3:30 p.m. – 4:15 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

4:15 p.m. – 5:45 p.m.
P2: Emerging Leaders
Moderator: Osama (Sam) Elrashidy, Former Associate Director, Quality Control, *Bayer Healthcare Pharmaceuticals, Inc.*

Session Description: This session is designed to learn about the new generation of microbiologists and to give them the opportunity to share their ideas and views on the most current topics and challenges that face microbiologists in general. The goal is to hear new voices discuss the problems that exist in the day-to-day activities within any microbiology lab. A selected group of microbiology analysts with hands-on experience will have the chance to present their current issues, challenges and solutions, as well as pose questions and share concerns with attendees.

MONDAY, OCTOBER 24 – TUESDAY, OCTOBER 25, 2016 AGENDA

P2: Emerging Leaders *(continued)*

4:15 p.m. – 4:30 p.m.
From the Bench to the Floor and Back: Travels of A Manufacturing Microbiologist
Kimberly Jefferson, QC Associate Scientist, *Pfizer, Inc.*

4:30 p.m. – 4:45 p.m.
Plastics and Endotoxins: The Good, the Bad and the Ugly
Veronika Wills, MSc, Technical Services Specialist, *Associates of Cape Cod, Inc.*

4:45 p.m. – 5:00 p.m.
What Does Not Kill You Makes You Stronger: Lessons Learned from Global Troubleshooting
Jan Japp (J.J.) Schot, Specialist Microbiology, *Merck & Co., Inc. (Invited)*

5:00 p.m. – 5:15 p.m.
What Do You Get When You Cross a Physicist and a Microbiologist? Laboratory Innovations!
Miranda Hvinden, Manager QO Aseptic Manufacturing, *Pfizer, Inc.*

5:15 p.m. – 5:45 p.m.
Questions and Answers/Discussion

5:45 p.m. – 7:00 p.m.
Networking Reception and Poster Presentations in Exhibit Hall

Tuesday, October 25, 2016

7:00 a.m. – 5:15 p.m.
Registration Open

7:00 a.m. – 8:15 a.m.
Continental Breakfast

7:00 a.m. – 8:00 a.m.
Breakfast Session Roundtable 1: Workforce Development: Preparing Our Current and Future Pharmaceutical Microbiologists
Moderator: Edward S. Balkovic, PhD, *MicroBio Technical Support*

Session Description: This session will be an open discussion with the audience providing ideas as to how to develop our current and future microbiologists. We know colleges and universities are not preparing microbiologists to work in the pharmaceutical industry. So have your coffee and bring your thoughts! We will discuss what they need to know and how are we teaching and training them in relevant areas. Topics to be covered will include working in a biosafety cabinet, aseptic technique, EM and critical utility sample collection, bioburden and endotoxin testing, reading plates, data integrity, cGMP and SOP writing.

7:00 a.m. – 8:00 a.m.
Julie Barlasov, Senior Scientist, *Teva Pharmaceuticals*
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*
Kalavati Suvarna, PhD, Senior Microbiology Reviewer, CDER, *FDA*

7:00 a.m. – 8:00 a.m.
Breakfast Session Roundtable 2: ISO 14644-1 and 14644-2
Moderator: Marsha Stabler Hardiman, Senior Consultant, *Concordia ValSource, LLC*

Session Description: This session will provide information on the changes to ISO 14644 and will offer participants an example of how to perform a risk assessment for environmental monitoring. Audience participation and feedback on how participants are dealing with the changes to the ISO standards will be incorporated.

7:00 a.m. – 8:00 a.m.
Marsha Stabler Hardiman, Senior Consultant, *Concordia ValSource, LLC*

TUESDAY, OCTOBER 25, 2016 AGENDA (CONTINUED)

8:15 a.m. – 9:15 a.m.
P3: New Antibiotic Discoveries
Moderator: Kalavati Suvarna, PhD, Senior Microbiology Reviewer, CDER, *FDA*

Session Description: The development of antibiotic resistance has spurred the field of bioprospecting, leading scientists to look at unusual places (for example, a cat's nose, a golf course, a man's beard, marine sponges, soil, the Atacama Desert) in search of new antibiotics. This session will discuss the unusual ecological niches to identify new antibiotics.

8:15 a.m. – 9:00 a.m.
Antibiotic Resistance and Superbugs
Patrick McGann, PhD, Chief, Molecular Research and Diagnostics, Multidrug Resistant Organism Repository and Surveillance Network, *Walter Reed Army Institute of Research (Invited)*

9:00 a.m. – 9:15 a.m.
Questions and Answers/Discussion

9:00 a.m. – 4:15 p.m.
Exhibit Hall Open

9:15 a.m. – 10:00 a.m.
Refreshment Break, Poster Presentations and Passport Raffle Drawing in Exhibit Hall

Choose from 2 Concurrent Sessions

10:00 a.m. – 12:00 p.m.
A3: Contamination of a Non-Sterile Aqueous Product: A Case Study
Moderator: Kim Sobien, Associate Director, Quality-Regulatory Compliance, *Merck & Co., Inc.*

Session Description: This session will provide the opportunity to hear "both sides of the story" from a non-sterile aqueous product contamination case. Speakers will present both industry and FDA perspectives from an actual product contamination event and describe the path taken to resolve the problem. Attendees will discover how FDA and industry worked together to solve a microbial product issue and will hear lessons learned from the case.

10:00 a.m. – 10:30 a.m.
***Burkholderia cepacia* Complex and Aqueous Non-sterile Drugs: A CDER Perspective**
John Metcalfe, PhD, Senior Microbiologist Reviewer, CDER, *FDA*

10:30 a.m. – 11:00 a.m.
Industry Case Study: A Microbial Investigation of Contamination by *Burkholderia multivorans*
Jim Klein, Executive Director, Global Technical Operations – Sterile & Validation Center of Excellence, *Merck & Co., Inc.*

11:00 a.m. – 11:30 a.m.
CDER Case Study: A Microbial Investigation of Contamination by *Burkholderia multivorans*
John Metcalfe, PhD, Senior Microbiologist Reviewer, CDER, *FDA*

10:00 a.m. – 12:00 p.m.
B3: Challenges of Combination Products Manufacturing
Moderator: Edward Tidswell, PhD, Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

Session Description: Combination products derive their complexity from the mating of drugs or biologics and devices into a single functioning medical product; the benefits to the patient are due to the synergies of its components. This added complexity may generate new scientific and technical hurdles that must be overcome in combination product manufacturing, and may also generate some unique regulatory challenges.

10:00 a.m. – 10:30 a.m.
CGMP Compliance Considerations for Complex Combination Product Manufacturing – Taking a Product Life Cycle Perspective
Melissa Burns, Senior Program Manager, OCP, OC, *FDA (Invited)*

10:30 a.m. – 11:00 a.m.
Scientific and Technical Challenges Facing Manufacturers in Ensuring the Packaging Integrity of Complex Combination Products
Sean Hanley, Corporate Manager, Sterilization, *Boston Scientific (Invited)*

11:00 a.m. – 11:30 a.m.
Sterilization Science and Technologies for Combination Products
Byron Lambert, PhD, Advisor, Sterilization & Materials, *Abbott Vascular (Invited)*

TUESDAY, OCTOBER 25, 2016 AGENDA (CONTINUED)

	A3: Contamination of a Non-Sterile Aqueous Product: A Case Study *(continued)*	**B3: Challenges of Combination Products Manufacturing** *(continued)*
	11:30 a.m. – 12:00 p.m. **Questions and Answers/Discussion**	11:30 a.m. – 12:00 p.m. **Questions and Answers/Discussion**

12:00 p.m. – 1:30 p.m.
Lunch on Your Own. Exhibit Hall Closed – *A listing of local restaurants is available at the PDA Registration Desk.*

Choose from 2 Concurrent Sessions

	1:30 p.m. – 3:30 p.m. **A4: Environmental Monitoring** **Moderator: Vinayak Pawar, PhD,** Senior Microbiology Reviewer, CDER, *FDA*	1:30 p.m. – 3:30 p.m. **B4: Contamination Control** **Moderator: Marsha Stabler Hardiman,** Senior Consultant, *Concordia ValSource, LLC*
	Session Description: Environmental monitoring in today's pharmaceutical industry is imperative to avoid potential risks to consumers and to save time and cost to manufacturers by preventing the release of potentially contaminated products. In these sessions, the audience will benefit from understanding the rules governing dispersion of airborne microbial contaminants, the concept of visualization of air movements, how contaminants can accumulate in invisible vortices and airborne contamination. The audience will also learn the concept of systematic risk assessment with the Limitation of Risk (LR) Method and how to evaluate representative sampling locations for environmental monitoring during aseptic processes.	**Session Description:** Providing expertise and input for contamination control is an essential role of the microbiologist. This session will highlight novel efforts at improving contamination control through engaging operators on the manufacturing floor. It will also review efforts to control contamination when a controlled environment is disrupted and, finally, will present a case study of a contamination in a cell culture manufacturing operation.
	1:30 p.m. – 2:00 p.m. **Why Airborne Contamination Occurs: Interaction between Air Movements and the Dispersion of Contaminants** **Bengt Ljungquist, PhD,** Professor, *Chalmers University of Technology* 2:00 p.m. – 2:30 p.m. **Why Airborne Contamination Occurs: Risk Assessment with the LR Method** **Berit Reinmuller, PhD,** Associate Professor, *Chalmers University of Technology* 2:30 p.m. – 3:00 p.m. **Charting and Evaluation of EM Data for Microbial Counts and Contamination Recovery Rates** **Raphael Bar, PhD,** Pharmaceutical Consultant, *BR Consulting* 3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**	1:30 p.m. – 2:00 p.m. **Growing the Culture on the Manufacturing Floor** **Randall Thompson,** Principal Scientist, *Shire* 2:00 p.m. – 2:30 p.m. **Controlling Contamination by Planning for Recovery from Disruption to a Controlled Environment** **Dona Reber,** Senior Manager, *Pfizer, Inc.* 2:30 p.m. – 3:00 p.m. **Understanding *P. acnes* Contamination in Cell Culture Manufacturing and How to Minimize Occurrence** **Lia K. Jeffrey, PhD,** Head of RMS Culture Collection & Global Surveillance, *Roche Diagnostics* 3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**

3:30 p.m. – 4:15 p.m.
Refreshment Break, Poster Presentations and Passport Raffle Drawing in Exhibit Hall

TUESDAY, OCTOBER 25 – WEDNESDAY, OCTOBER 26, 2016 AGENDA

4:15 p.m. – 5:45 p.m.
P4: Innovation
Moderator: Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

Session Description: This session will focus on next generation and innovative microbiological methods and applications. We will learn about the development of a multiplex PCR and massively parallel sequencing technique for the detection of viral pathogens. A case study using a model biotherapeutic production cell line provides insights into the 3-day detection method's specificity, limit of detection and robustness capabilities. We will then explore a rapid and novel intrinsic fluorescence spectroscopy-based microbial identification system coupled with a growth-based detection platform. This presentation will focus on the fully automated identification of positive blood cultures, which may be applied to other pharmaceutical-based microbial applications.

4:15 p.m. – 4:45 p.m.
Massively Parallel Sequencing Methods Enable Rapid Adventitious Agent Detection with Improved Sensitivity for Biotherapeutic Cell Cultures
Brandye Michaels, PhD, Group Leader/Senior Principal Scientist, Analytical R&D, Microbiology, *Pfizer, Inc.*

4:45 p.m. – 5:15 p.m.
Positive Blood Culture Organism ID
Kevin Hazen, PhD, Professor of Pathology, *Duke University School of Medicine*

5:15 p.m. – 5:45 p.m.
Questions and Answers/Discussion

Wednesday, October 26, 2016

7:00 a.m. – 12:30 p.m.
Registration Open

7:00 a.m. – 8:15 a.m.
Continental Breakfast

7:00 a.m. – 8:00 a.m.
Breakfast Session Roundtable 3: Technology
Moderator: Amy McDaniel, PhD, Director, Technical Operations, *Pfizer, Inc.*

Session Description: This session will wake you up with a discussion of what technologies are being evaluated in the microbiology laboratories today, and what challenges participants are facing in validating both routine and novel microbial assays. Are you performing a limit of detection validation of a novel technology? Validating a sample hold time for routine samples? If your answer is yes or if you have an interest in discussing other topics related to validation of new or routine technologies, then come join the fun and share your successes or questions with us.

7:00 a.m. – 8:00 a.m.
Breakfast Session Roundtable 4: Sterile Processing Interest Group
Moderator: Edward Tidswell, PhD, Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

Session Description: The progressive refinement and improvement in cleanroom control and monitoring guidelines and standards continue. Is cleanroom environmental monitoring data from contemporary programs deterministic in the microbial risk to aseptically manufactured product? What data, if any, are available evidencing any relationship between the cleanroom microflora and aseptically manufactured product? Is a specifically designed environmental monitoring program required for a better diagnostic on product impact? Is a probabilistic real time method of risk feasible? Are guidelines and regulations changing to accommodate real time release of aseptically manufactured products? This Sterile Processing Interest Group meeting will visit all these questions providing a lively forum of debate, discussion and sharing.

WEDNESDAY, OCTOBER 26, 2016 AGENDA (CONTINUED)

Breakfast Session Roundtable 3: Technology *(continued)*	**Breakfast Session Roundtable 4: Sterile Processing Interest Group** *(continued)*
7:00 a.m. – 8:00 a.m. **Eric J. Ward,** Quality Assurance Director, *Boston Analytical* **Jeffrey W. Weber,** Senior PAT Project Manager, Analytical Sciences Group, *Pfizer, Inc.*	7:00 a.m. – 8:00 a.m. **Edward Tidswell, PhD,** Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

8:15 a.m. – 9:30 a.m.
P5: USP Updates
Moderator: Radhakrishna S. Tirumalai, PhD, Principal Scientific Liaison, *U.S. Pharmacopeial Convention (USP)*

Session Description: Compatible with its overall mission, the role of USP in Microbiology is to develop public standards pertaining to microbiology that, along with other requirements, ensure the consistent quality of products. This session will provide an overview of current and proposed activities of the USP General Chapters – Microbiology Expert Committee, with emphasis on recent revisions and new chapter proposals.

8:15 a.m. – 8:40 a.m.
Current and Proposed Future Activities of the USP Microbiology Expert Committee
David Hussong, PhD, Chair, *USP General Chapters-Microbiology Expert Committee*

8:40 a.m. – 9:05 a.m.
Current USP Perspectives on LER
Karen McCullough, Member, *USP General Chapters-Microbiology Expert Committee*

9:05 a.m. – 9:30 a.m.
Questions and Answers/Discussion

9:40 a.m. – 10:40 a.m.
P6: Regulatory Updates: The State of Microbiology, Updates and Current Trends
Moderator: Renée Blosser, Microbiologist, CVM, *FDA*

Session Description: The ever-evolving world of pharmaceutical microbiology brings about changes to current practices and improvements to methodologies. As regulators, we evaluate these changes and their potential impact on the efficacy of the finished dosage form and safety to the patient. This session will provide an update on the current status in sterile manufacturing facilities from an inspectional viewpoint and discuss strategies to evaluate new procedures and methods from the regulatory perspective.

9:40 a.m. – 10:10 a.m.
Current State of Microbiology Operations
Thomas Arista, National Expert, Pharmaceutical and Biotechnology, ORA, *FDA (Invited)*

10:10 a.m. – 10:40 a.m.
Questions and Answers/Discussion

10:40 a.m. – 11:00 a.m.
Refreshment Break

WEDNESDAY, OCTOBER 26, 2016 AGENDA (CONTINUED)

11:00 a.m. – 12:30 p.m.
P7: Ask the Regulators Panel Discussion
Moderators: John Metcalfe, PhD, Senior Microbiologist Reviewer, CDER, *FDA,* and **Vinayak Pawar, PhD,** Senior Microbiology Reviewer, CDER, *FDA,* and Co-Chair, *11th Annual PDA Global Conference on Pharmaceutical Microbiology* Program Planning Committee

Session Description: This session will provide attendees with an additional opportunity to engage many of the regulatory speakers in further discussions regarding trends, issues, solutions and best demonstrated practices.

Panelists:
CAPT Sharon Thoma, PharmD, National Expert, Pharmaceutical Inspections, ORA, *FDA*
Thomas Arista, National Expert, Pharmaceutical and Biotechnology, ORA, *FDA (Invited)*
Patricia Hughes-Troost, PhD, Team Leader, Biotech Manufacturing, CDER, *FDA (Invited)*
Rick Friedman, Deputy Director, Science & Policy, OMPQ, CDER, *FDA*
Brendan Cuddy, Head of Manufacturing and Quality Compliance, *EMA (Invited)*
Laurie Norwood, Deputy Director, CBER, *FDA*

12:30 p.m.
Closing Remarks and Adjournment

11TH ANNUAL PDA GLOBAL CONFERENCE ON PHARMACEUTICAL MICROBIOLOGY COURSE SERIES – OCTOBER 27-28, 2016

Following the *11th Annual PDA Global Conference on Pharmaceutical Microbiology,* PDA Education will offer four courses designed to complement what you learned at the Conference.

Continuing Education

Continuing Education for Pharmacists

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the CPE Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

Continuing Education for Engineers

PDA is an approved provider by the New Jersey State Board of Professional Engineers and Land Surveyors to offer courses to New Jersey Professional Engineers for Continuing Professional Competency (CPC) credit. Following the full participation in this course, participants will receive a Certificate of Accomplishment specifying the number of CPC credits that may be awarded. This certificate can be submitted as verification of completion to the Board for license renewal.

PDA is recognized by the North Carolina Board of Examiners for Engineers and Surveyors as an Approved Sponsor of CPC activities for Professional Engineers licensed by North Carolina. To receive a Certificate of Accomplishment specifying the number of Professional Development Hours (PDHs) that may be awarded, course participants must request the North Carolina Board of Examiners evaluation form from PDA staff. This form must be completed onsite at the conclusion of the course and returned to PDA staff.

Contact Stephanie Ko via email at ko@pda.org to learn more.

Class Schedule

All lecture courses begin at 8:30 a.m. and end at 4:00 p.m. Please arrive at your course location approximately 30 minutes before the start of the course to register and receive your name badge. Please be sure to bring your confirmation letter as proof of registration during check in. PDA will not allow persons to attend a course without payment or guarantee of payment. Continental breakfast will be served before class beginning at 7:30 a.m. Lunch will be provided from 12:00 p.m. – 1:00 p.m. Snacks will be provided during the morning break from 10:00 a.m. – 10:15 a.m. and the afternoon break from 2:30 p.m. – 2:45 p.m..

Students who pre-register will now be given access to electronic course notes, which may be printed once approximately 1-2 weeks in advance for use during the course. Hard copies of course notes will no longer be provided to pre-registered students and only a limited number of hard copies will be available for on-site and transferring registrants on a first-come, first-served basis.

11TH ANNUAL PDA GLOBAL CONFERENCE ON PHARMACEUTICAL MICROBIOLOGY COURSE SERIES – OCTOBER 27-28, 2016 (CONTINUED)

Endotoxin Attributes, Detection, Clinical Relevance and BET- Interference Resolution NEW COURSE

Location: Hyatt Regency Crystal City | Arlington, VA
Date: October 27, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.

PDA # 426 | ACPE #0116-0000-16-002-L04-P | 0.6 CEUs
Type of Activity: *Application*

This course will discuss key aspects of the biological attributes, control, detection and risk management of bacterial endotoxins. Participants will review in detail the chemical and physical characteristics of bacterial endotoxins. Attendees will be given practical examples for design of bacterial endotoxin test suitability studies, for calculation of alert and action limits for various drugs and devices.

Who Should Attend

This course will benefit technicians, microbiologists, managers, specialists and supervisors who work in biologics, small molecule or vaccine manufacturing for testing, interpreting data, performing risk mitigations, or are involved in regulatory submissions for endotoxin measurement and investigations.

Learning Objectives

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

- Describe the chemical and physical characteristics of bacterial endotoxins
- Recognize the clinical relevance of endotoxin levels
- Identify the clinical symptoms of a pyrogenic reaction
- Discuss the principal sources of endotoxin contamination in a manufacturing setting
- Conduct a validation study for depyrogenation by dry-heat, washing or chemical methods
- Organize and direct a cGMP laboratory for robust bacterial endotoxin testing (BET)
- Write regulatory compliant procedures for endotoxin measurement
- Develop selection criteria for endotoxin detection methods and instrumentation/software
- Calculate product-specific endotoxin limits and set alert and action levels
- Conduct an endotoxin recovery study to distinguish low lipopolysaccharide or endotoxin recovery from other sources of BET inhibition
- Discuss sample preparation techniques for overcoming BET-test interference conditions
- Design a study to validate BET suitability tests for in-process and finished products
- Develop training and risk assessment programs for endotoxin control
- Investigate an endotoxin excursion and identify root causes
- Prepare endotoxin sections of regulatory submissions for new drug or device applications

Faculty

James F. Cooper, Endotoxin Consultant
Cheryl Platco, Principal Scientist, Analytical Sciences, *Merck Research Laboratories*

11TH ANNUAL PDA GLOBAL CONFERENCE ON PHARMACEUTICAL MICROBIOLOGY COURSE SERIES – OCTOBER 27-28, 2016 (CONTINUED)

Charting and Trending of Environmental Monitoring Data: From Microbial Counts to Contamination Recovery Rates in Controlled Rooms NEW COURSE

Location: Hyatt Regency Crystal City | Arlington, VA
Date: October 27-28, 2016
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.

PDA # 289 | ACPE #0116-0000-15-026-L04-P | 1.2 CEUs
Type of Activity: *Application*

In this two-day course, attendees will learn the methodology of environmental monitoring data analysis by both the statistical distribution-based and the empirical distribution-free approaches. In this course, you will have the ability to examine case studies of microbial counts to detect trends, process average shifts and/or evaluate the behavior of the environmental microbial monitoring process. Working directly with Minitab 17, participants will have the opportunity to build control charts of microbial counts.

Who Should Attend

Microbiologists, production managers, quality control managers, senior management, and personnel in environmental monitoring, quality assurance, regulatory affairs, and those involved in the preparation of the annual product review will benefit from taking this course.

Prerequisites

Each participant should bring a laptop with Excel and a previously downloaded 30-day free trial of Minitab 17 (from http://www.minitab.com). This program should be downloaded a few days before the beginning date of the course and verified that it works on the laptop.

Learning Objectives

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

- Build basic control charts of averages, ranges and standard deviations as well as charts of individual microbial counts
- Plot data sets of microbial counts from various controlled rooms, set control limits and evaluate the microbial monitoring process behavior for the annual product review
- Calculate, tabulate and plot contamination recovery rates and excursion rates

Faculty

Rafael Bar, PhD, *BR Consulting Faculty*

Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods

Location: Hyatt Regency Crystal City | Arlington, VA
Date: October 27-28, 2016
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.

PDA # 481 | ACPE #0116-0000-15-024-L04-P | 1.2 CEUs
Type of Activity: *Knowledge*

This course will include conversations on the revised *PDA Technical Report No. 33, Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods*. Open discussions about how this report can be used as the basis for the validation and implementation of alternative and rapid microbiological methods (RMMs) will be examined. Attendees will leave this course with knowledge of effective monitoring of manufacturing processes and how to help ensure that a state of control is maintained.

Who Should Attend

Senior management and laboratory personnel responsible for the conduct of microbiological testing and microbial control strategies in manufacturing and product/process development will benefit from this course.

Departments: Microbiology | Quality Control | Quality Assurance | Manufacturing | Validation | Regulatory Affairs | R&D | Discovery | Finance

Job Function: Directors | Managers/Supervisors | Scientists | Technicians | Operators | Auditors

Learning Objectives

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

- Discuss the benefits of alternative and RMM technologies as compared with classical microbiological methods
- Describe the scientific basis for a variety of technologies that may be qualified as alternative methods to classical microbiology procedures
- Explain the regulatory environment, guidance, policies and expectations for validation, submissions and implementation
- Develop business plans and return on investment justifications
- Apply industry best practices for validating these new technologies in order to demonstrate that the methods are acceptable for their intended use via IQ, OQ and PQ qualification strategies

Faculty

Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

11TH ANNUAL PDA GLOBAL CONFERENCE ON PHARMACEUTICAL MICROBIOLOGY COURSE SERIES – OCTOBER 27-28, 2016 (CONTINUED)

Microbiological Risk Assessment of a Pharmaceutical Manufacturing Process

Location: Hyatt Regency Crystal City | Arlington, VA
Date: October 28, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.

PDA # 382 | ACPE #0116-0000-14-032-L04-P | 0.6 CEUs
Type of Activity: *Application*

Join quality and manufacturing professionals to develop a microbiological risk assessment based on specific pharmaceutical products or process. With this course, you will have the opportunity to review how microbiological quality may be impacted in steps throughout the manufacturing process and use the FMEA approach to evaluate process and behavior. At the conclusion of this course, you will be able formulate a strategy to proactively look for areas of potential microbial contamination and minimize activities or processes that may cause risk.

Who Should Attend

This course will benefit individuals who work in the field of manufacturing/facility management, product development, project management, quality assurance and quality control, microbiology and validation.

Learning Objectives

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

- Identify the aspects of pharmaceutical manufacturing that may affect microbiological quality
- Develop a FMEA
- Quantitatively evaluate steps within a process
- Develop ways to reduce or minimize activities that may increase microbial contamination risk

Faculty

Peter Noverini, Field Applications Scientist, *Azbil BioVigilant, Inc.*

11th Annual PDA Global Conference on Pharmaceutical Microbiology (Oct. 24-26) and 2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision (Oct. 26-27)

Hyatt Regency Crystal City | Arlington, VA
Exhibition: Oct. 24-25 | Post-Workshop: Oct. 26-27 | Courses: Oct. 27-28

Four easy ways to register –
Click: www.pda.org/2016micro
Fax: +1 (301) 986-1093 (USA)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA
Call: +1 (301) 656-5900 ext 115

Print

PDA® Parenteral Drug Association

1 Contact Information

PDA Membership Number:

☐ **Check here to become a member and receive the member price for this event.** (Add $259 to your total.)

Prefix First Name Last Name

Job Title Company

Business Address

City State/Province ZIP+4/Postal Code

Country Email

Business Phone Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague. The fee difference in the prevailing rate is due at the time of substitution. Please note that if you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee.)

Special Dietary Requirements (Please be specific):

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

2 Premiere Package | CONFERENCE & WORKSHOP Registration | October 24-27, 2016

Please check appropriate fee (US$).

Save up to $750	Member	Nonmember
Before Aug. 11, 2016	☐ $ 3,540	☐ $ 3,999
Aug. 11 – Sept. 9, 2016	☐ $ 3,990	☐ $ 4,449
After Sept. 9, 2016	☐ $ 4,440	☐ $ 4,899

3 CONFERENCE Registration | October 24-26, 2016

Please check appropriate fee (US$).

	Before Aug. 11, 2016	Aug. 11 – Sept. 9, 2016	After Sept. 9, 2016
PDA Member	☐ $ 1,995	☐ $ 2,395	☐ $ 2,595
Nonmember	☐ $ 2,254	☐ $ 2,654	☐ $ 2,854
Government/Health Authority			
Member	☐ $ 700	☐ $ 700	☐ $ 700
Nonmember*	☐ $ 800	☐ $ 800	☐ $ 800
Academic			
Member	☐ $ 700	☐ $ 700	☐ $ 700
Nonmember*	☐ $ 800	☐ $ 800	☐ $ 800
Student			
Member	☐ $ 280	☐ $ 280	☐ $ 280
Nonmember*	☐ $ 310	☐ $ 310	☐ $ 310

* For this member type or discounted rate, online registration is not available and must be faxed in.

4 Current Challenges in Aseptic Processing, Potential Changes to Annex 1 Revision | WORKSHOP Registration | October 26-27, 2016

Please check appropriate fee (US$).

		On or Before Sept. 9, 2016	After Sept. 9, 2016
	PDA Member	☐ $ 1,695	☐ $ 1,895
	Nonmember	☐ $ 1,895	☐ $ 2,095
Government/ Health Authority	Member	☐ $ 700	☐ $ 700
	Nonmember*	☐ $ 800	☐ $ 800
Academic	Member	☐ $ 700	☐ $ 700
	Nonmember*	☐ $ 800	☐ $ 800
Student	Member	☐ $ 280	☐ $ 280
	Nonmember*	☐ $ 310	☐ $ 310

5 COURSE Registration | October 27-28, 2016

Please check appropriate fee (US$).

PDA#426 Endotoxin Attributes, Detection, Clinical Relevance and BET-Interference Resolution (October 27)

PDA#289 Charting and Trending of Environmental Monitoring Data: From Microbial Counts to Contamination Recovery Rates in Controlled Rooms (October 27-28)

PDA#481 Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods (October 27-28)

PDA #382 Microbiological Risk Assessment of a Pharmaceutical Manufacturing Process (October 28)

	Course #426	Course #289	Course #481	Course #382
On or Before Sept. 9, 2016				
Standard				
Member	☐ $ 985	☐ $ 1,525	☐ $ 1,525	☐ $ 985
Nonmember	☐ $ 1,255	☐ $ 1,795	☐ $ 1,795	☐ $ 1,255
Government/Health Authority/Academic				
Member	☐ $ 600	☐ $ 950	☐ $ 950	☐ $ 600
Nonmember*	☐ $ 700	☐ $ 1,050	☐ $ 1,050	☐ $ 700
After Sept. 9, 2016				
Standard				
Member	☐ $ 1,095	☐ $ 1,695	☐ $ 1,695	☐ $ 1,095
Nonmember	☐ $ 1,395	☐ $ 1,995	☐ $ 1,995	☐ $ 1,395
Government/Health Authority/Academic				
Member	☐ $ 600	☐ $ 950	☐ $ 950	☐ $ 600
Nonmember*	☐ $ 700	☐ $ 1,050	☐ $ 1,050	☐ $ 700

Have a Campaign Code?

6 Payment Options

All cards are charged in US$.

Group Registration: Register 4 people from the same organization as a group (at the same time) for the CONFERENCE and receive the 5th registration free. Other discounts cannot be applied. All forms MUST be faxed in together.

☐ By Credit Card – Clearly indicate account number, expiration date and billing address.

Please bill my: ☐ American Express ☐ MasterCard ☐ VISA ☐ Credit Card Guarantee Only

Total amount $

Account Number Exp. Date

Name (exactly as it appears on card) Signature

Billing Address (Billing address must match credit card statement)

City State Zip

PDA Federal Tax I.D. #52-1906152

Country

Wire Transfer Payments: If you require wire transfer, please contact registration@pda.org.

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by **August 25, 2016**, your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on-site at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee. If you are pre-registering as a subsitute attendee, indicate this on the registration form. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Conference/Workshop:** If your written request is received on or before **August 25, 2016**, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA reserves the right to modify the material or speakers/instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900. **PLEASE NOTE THAT PHOTO ID WILL BE REQUIRED IN ORDER TO PICK UP BADGE MATERIALS ON-SITE. THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS. REFUNDS FOR COURSES:** If your written request is received by **September 27, 2016**, you will receive a full refund minus a $200 processing fee. After that time, no refunds will be approved. PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. **RECORDING/PHOTO RELEASE:** By registering for these events, I authorize PDA to record and photograph me and to use the recordings/photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the recordings/photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership. Tape recordings are prohibited at all PDA conferences.

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The Parenteral Drug Association presents the...

ARLINGTON, VA –

2016 PDA Workshop:

Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision

Points to consider in the modern aseptic manufacturing – with special reference to the on-going revision of the European GMPs for sterile medicines

October 26-27 | Arlington, VA

Hyatt Regency Crystal City

Exhibition: October 26-27

Conference Theme: *Addressing the Unanswered Questions of How to Use Risk- and Science-Based Approaches to Meet Global Health Authority Expectations and Improve Aseptic Processing*

pda.org/2016annex1east
#2016Annex

This preliminary agenda is current as of June 30, 2016

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Co-Chairs:

Hal Baseman
ValSource, LLC

Gabriele Gori
GlaxoSmithKline Vaccines

Jette Christensen
Novo Nordisk A/S

Bill Miele, PhD
Pfizer, Inc.

Richard Johnson
Parenteral Drug Association

Janie Miller
Parenteral Drug Assocation

Wanda Neal, CMP
Parenteral Drug Association

Georg Roessling
Parenteral Drug Association Europe

Melissa Pazornik
PDA Liaison to the Program Planning Committee

A MESSAGE FROM THE PROGRAM CO-CHAIRS

Hal Baseman
ValSource, LLC

Gabriele Gori
GlaxoSmithKline Vaccines

Dear Friends, Colleagues and Peers,

PDA will hold the last in a series of four global interactive workshops on October 26-27, the *2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision,* to address new developments in aseptic processing. The objective of this Workshop is to provide a forum for industry and health authorities to discuss science- and risk-based approaches supporting modern aseptic processing and control strategy.

If you are involved in aseptic processing, then you know that the industry has long wrestled with the same issues. Real improvement of aseptic processing is necessary. Achieving meaningful improvement in today's business and regulatory environment is not easy; however, the tools and methods to achieve such improvement are right in front of us.

This Workshop will facilitate the use of critical thinking to identify what is needed and what works best, and how to articulate the value of these improvements and put them into practice.

The Program Planning Committee has put together a comprehensive agenda that will focus on current thinking and expectations, exploring how to meet those expectations with sound science based approaches, and identifying what should still be changed.

This Workshop will offer a truly global perspective on these critical issues as experts and participants from around the world will convene to share knowledge and look ahead to the future of aseptic processing.

The recently released *PDA Points to Consider for Aseptic Manufacturing Part 2* will be used to showcase the most frequently asked questions raised by regulators and industry. The Workshop will incorporate discussion by industry and Health Authority experts on current trends and expectations and recommended practices.

The EMA, through its joint EMA-PIC/S Committee's revision of the European GMP Annex 1 for the manufacturing of sterile medicinal products, has signaled its intent to refine its expectations and requirements based on science and risk. For the industry, it is not just a matter of anticipating what the regulators want to see, it is a matter of going beyond compliance by using critical thinking to better understand the aseptic process and the associated risk of contamination, and to develop optimal process control strategies. A draft of the revisions to Annex 1 is anticipated for public review and comment this fall. This Workshop will report and build on the proceedings of the previous three global Workshops to provide input into the challenges facing aseptic processing and the possible resolution of those challenges.

Topics covered will be pulled from the areas of greatest debate, including existing and most effective risk- and science-based approaches to clean room environment design and control; personnel practices and monitoring; aseptic process simulation design; and, disinfection and sterilization. Panel discussions and interactive breakout sessions will provide opportunity to further explore and discuss these topics to achieve better understanding and develop viable solutions to challenges raised.

This Workshop will provide an opportunity for dialogue between industry and regulatory experts and is a unique opportunity to help shape the future of aseptic processing. We look forward to seeing you at this important event!

GENERAL INFORMATION, REGISTRATION

Four Ways to Register

1. Click	**pda.org/2016annex1east**
2. Fax	+1 (301) 986-1093
3. Mail	PDA Global Headquarters Bethesda Towers 4350 East West Highway, Suite 600 Bethesda, MD 20814 USA
4. Phone	(301) 656-5900 ext. 115

Venue

Hyatt Regency Crystal City
2799 Jefferson Davis Hwy
Arlington, VA 22202
Phone: +1 (703) 418-1234
Website: crystalcity.regency.hyatt.com
Rate: Single: $255.00, plus applicable state and local taxes.
Cut-Off Date: Monday, September 26, 2016 (Rooms must be secured by this date in order to receive the PDA rate). Rates are guaranteed until the PDA block of rooms are sold out on a first-come basis.

Continuing Education Credits

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

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2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision – Arlington, VA
ACPE # 0116-0000-16-003-L04-P | 1.2 CEUs
Type of Activity: *Knowledge*

Learning Objectives

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

- Discuss the challenges of aseptically manufacturing healthcare sterile products in a modern, global, technological and regulatory environment
- Interpret the latest regulatory expectations and industry standards for aseptic processing and clean room operation
- Explain the use of risk- and science-based approaches to aseptic process design, validation and monitoring
- Identify best practices for clean room personnel, material decontamination and work flows in the aseptic environment
- Summarize the challenges faced by peers in the aseptic process industry

Who Should Attend

Personnel from: Microbiology | Validation | Engineering | Quality | Regulatory | Sterility Assurance | Sterile Operations | Product and Process Development | Operations and Quality | GMP Consultants | GMP Service Providers

Departments: Manufacturing | Formulation | Compliance | Engineering | QA/QC | Process Design | Regulatory Affairs | Research and Development | Technical Operations | Validation

Workshop Registration Hours

Wednesday, October 26: 11:30 a.m. – 5:30 p.m.
Thursday, October 27: 7:15 a.m. – 5:30 p.m.

Dress/Attire

Business casual attire is recommended for the *2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision*. 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

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WEDNESDAY, OCTOBER 26, 2016 AGENDA

11:30 a.m. – 5:30 p.m.
Registration Open

1:15 p.m. – 1:20 p.m.
Welcome and Opening Remarks
Hal Baseman, Chief Operations Officer, *ValSource, LLC,* and Co-Chair, *2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision* Program Planning Committee

1:20 p.m. – 2:20 p.m.
P1: Opening Plenary Session
Moderator: Hal Baseman, Chief Operations Officer, *ValSource, LLC*

Session Description: This session will outline some of the key issues in aseptic processing, including those that may be addressed in the revision of Annex 1, and will set the stage for how the revision process works, how PDA is developing its position and what some of the regulatory inspection findings are pointing as areas for improvement.

1:20 p.m. – 1:40 p.m.
PDA Aseptic Processing Task Force Update
Hal Baseman, Chief Operations Officer, *ValSource, LLC*

1:40 p.m. – 2:20 p.m.
Regulatory Perspectives on Inspectional Findings and Revision of Aseptic Processing Guidance
Thomas Arista, National Expert, Pharmaceutical and Biotechnology, ORA, *FDA*

2:05 p.m. – 7:30 p.m.
Exhibit Area Open

2:20 p.m. – 2:45 p.m.
Refreshment Break in Exhibit Area

2:45 p.m. – 3:55 p.m.
P2: Physical Environment (Section I. of PtC) and Material Transfer (Section V. of PtC)
Moderator: William (Bill) Miele, PhD, Director, Team Leader, Microbiology & Aseptic Support, *Pfizer, Inc.*

Session Description: Aseptic processing must be performed in controlled environments and the design, layout and evaluation of those environments are critical to the ability to produce sterile products.

2:45 p.m. – 3:10 p.m.
Impact of Revised ISO 14644-1 on Aseptic Processing
Marsha Stabler Hardiman, Senior Consultant, *Concordia ValSource, LLC*

3:10 p.m. – 3:35 p.m.
Physical Environment and Material Transfer
William (Bill) Miele, PhD, Director, Team Leader, Microbiology & Aseptic Support, *Pfizer, Inc.*

3:35 p.m. – 3:55 p.m.
Questions and Answers/Discussion

3:55 p.m. – 4:10 p.m.
Refreshment Break in Exhibit Area

WEDNESDAY, OCTOBER 26 – THURSDAY, OCTOBER 27, 2016 AGENDA (CONTINUED)

4:10 p.m. – 5:15 p.m.
P3: Personnel (Section IV. of PtC) and Environmental Monitoring (Section V. of PtC)
Moderator: Ed Tidswell, PhD, Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

Session Description: Most, if not all, aseptic processing involves trained personnel performing various activities in specific ways. Paradoxically, personnel often represent the highest risk of introduction of contamination. This session will address some of the key issues, challenges and best practices for material transfer into and out of the aseptic area.

4:10 p.m. – 4:30 p.m.
Personnel
Carol Lampe, Former Senior Consultant

4:30 p.m. – 4:55 p.m.
Key Issues on Environmental Monitoring and Control
Ed Tidswell, PhD, Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

4:55 p.m. – 5:15 p.m.
Questions and Answers/Discussion

5:15 p.m. – 6:15 p.m.
Roundtable Discussion

Lead Facilitator: Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GlaxoSmithKline Vaccines*

Session Description: The attendees will break into groups to debate some of the key issues related to the previous sessions. This session will include a number of specific questions for discussion, and members of the Program Planning Committee will facilitate the discussion to try to develop consensus. The results of the discussion will be collated and shared with the audience at the end of the Workshop.

6:15 p.m. – 7:30 p.m.
Networking Reception in Exhibit Area

Thursday, October 27, 2016

7:15 a.m. – 5:30 p.m.
Registration Open

7:15 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 10:00 a.m.
P4: Process Simulation (Section III. of PtC)
Moderator: Richard Johnson, President & CEO, *Parenteral Drug Association*

Session Description: An important tool in assessing the capability of an aseptic process to consistently produce sterile product is a well-designed process simulation. This session will address some of the more critical issues in process simulation.

8:30 a.m. – 9:00 a.m.
Execution of Process Simulation – Dos and Don'ts
Hal Baseman, Chief Operations Officer, *ValSource, LLC*

9:00 a.m. – 9:30 a.m.
Acceptance Criteria and Interpreting the Results
Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GlaxoSmithKline Vaccines*

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

THURSDAY, OCTOBER 27, 2016 AGENDA (CONTINUED)

9:45 a.m. – 4:00 p.m.
Exhibit Area Open

10:00 a.m. – 10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. – 12:15 p.m.
P5: Cleaning, Disinfection, Sterilization (Section VI. of PtC) and Critical Utilities (Section VII. of PtC)
Moderator: Hal Baseman, Chief Operations Officer, *ValSource, LLC*

Session Description: A key aspect of sterile product manufacturing is the control of contamination of equipment, facilities and systems that support aseptic processes. This session will explore some of the more challenging issues faced by industry regarding the development of control strategies for the elimination of contamination from cleanroom and equipment surfaces. Sterilization of product contact surfaces will also be discussed.

10:45 a.m. – 11:15 a.m.
Cleaning and Disinfection
Richard Johnson, President & CEO, *Parenteral Drug Association*

11:15 a.m. – 11:45 a.m.
Sterilization and Critical Utilities
Michael Sadowski, Director, Research, *Baxter Healthcare Corporation*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.
Lunch on Your Own. Exhibit Area Closed – *A listing of local restaurants is available at the PDA Registration Desk.*

1:45 p.m. – 3:15 p.m.
Roundtable Discussion

Lead Facilitator: Hal Baseman, Chief Operations Officer, *ValSource, LLC*

Session Description: The attendees will break into groups to debate some of the key issues related to the previous sessions. This session will include a number of specific questions for discussion and members of the Program Planning Committee will facilitate the discussion to try to develop consensus. The results of the discussion will be collated and shared with the audience at the end of the Workshop.

3:15 p.m. – 4:00 p.m.
Refreshment Break in Exhibit Area

4:00 p.m. – 5:30 p.m.
P6: Closing Plenary Session – Aseptic Processing Moving Forward
Moderator: Richard Johnson, President & CEO, *Parenteral Drug Association*

Session Description: This closing session will further explore the topics addressed during the Workshop and present closing views from key speakers based on the Workshop proceedings. The objective of the session will be to continue the dialogue, linking health authority expectations with risk- and science-based aseptic processing practices, addressing the needs and challenges of modern sterile product manufacturing.

Note: A compilation of Audience Response Questions from this session will be reviewed with the audience, along with the results from roundtable discussions.

THURSDAY, OCTOBER 27, 2016 AGENDA (CONTINUED)

P6: Closing Plenary Session – Aseptic Processing Moving Forward *(continued)*

4:00 p.m. – 4:15 p.m.
Day 1 Roundtable Discussion Readout
Gabriele Gori, Vice President, Audit and Risk Management, Global Quality, *GlaxoSmithKline Vaccines*

4:15 p.m. – 4:30 p.m.
Day 2 Roundtable Discussion Readout
Hal Baseman, Chief Operations Officer, *ValSource, LLC*

4:30 p.m. – 5:30 p.m.
Panel Discussion
Thomas Arista, National Expert, Pharmaceutical and Biotechnology, ORA, *FDA*
Hal Baseman, Chief Operations Officer, *ValSource, LLC,* and Co-Chair, *2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision* Program Planning Committee
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Carol Lampe, Former Senior Consultant
William (Bill) Miele, PhD, Director, Team Leader, Microbiology & Aseptic Support, *Pfizer, Inc.*
Michael Sadowski, Director, Research, *Baxter Healthcare Corporation*
Ed Tidswell, PhD, Executive Director, Microbiology Quality Assurance, *Merck & Co., Inc.*

5:30 p.m. – 5:45 p.m.
Closing Remarks and Adjournment
William (Bill) Miele, PhD, Director, Team Leader, Microbiology & Aseptic Support, *Pfizer, Inc.*