Ensuring Product Quality in an Era of Innovative Therapies

PDA/FDA Joint Regulatory Conference

pda.org/2017PDAFDA

#2017PDAFDA
A MESSAGE FROM THE PROGRAM CO-CHAIRS

Dear Friends, Colleagues and Peers,

It is time to make plans to participate in the 2017 PDA/FDA Joint Regulatory Conference, Sept. 11-13, 2017, at the Renaissance Washington, DC Downtown Hotel in Washington, DC. This year’s theme is Ensuring Product Quality in an Era of Innovative Therapies. The Program Planning Committee has selected topics and speakers that will offer attendees practical solutions and advice for solving some of the current issues facing today’s pharmaceutical industry.

The Conference kicks off with a keynote address by Peter W. Marks, MD, PhD, Director, Center for Biologics Evaluation and Research (CBER), FDA, who will discuss the FDA’s role in making the American biomedical industry a global leader and how the FDA is striving to accelerate access to innovative medical product development. Developments in precision medicine, considerations from the patient perspective and efforts to advance science and engineering in the field of medical products will also be explored.

The plenary sessions will offer insight into many of the challenges faced by industry and regulators. Topics will include quality challenges for pharmaceutical executives due to globalization, complexity of the supply chain and implementation of new technologies. One focus will be on major considerations for quality professionals as they interact with executives at their firms. Another plenary session will explore the future of innovation in medical products, with a panel discussion including industry and Agency representatives from oncology, orphan drugs and combination products.

The Conference will close with two plenary sessions by the Agency, back by popular demand. At the Centers Updates session, Center Directors will showcase the activities planned for 2017 and beyond; and, at the Compliance Updates session, Compliance Directors will discuss deficiencies that affect medical product safety and quality.

This year’s breakout sessions are divided into three parallel tracks on product quality, lifecycle and innovation/regulatory. The Product Quality track will look at data integrity, supply chain oversight, quality culture, quality metrics and FDA program alignment. The Lifecycle track will cover the maturity of quality systems, product change management, modernization of legacy biotechnology processes, FDA global reach for harmonization and advances in manufacturing of biological products. The Innovation/Regulatory track will feature sessions on expedited pathways, including the development of novel medical products as well as the science, testing and manufacturing procedures utilized to bring these new therapies to market.

NEW THIS YEAR: There will be three sessions focusing on regulatory issues, exploring inspection findings, inspections role-playing with real-life examples of situations and solutions raised in inspections (the “Fishbowl”) and regulatory considerations in combination products.

In addition, there will be a number of breakfast sessions tailored to the early-riser Conference attendee, including how to conduct a smoke study, CMC NDA submissions, 3D manufacturing, digital-health activities, validation, quality assurance 101, laboratory controls, role of standards in the pharmaceutical industry, and bridging quality cultures in development and manufacturing.

So, mark your calendar now and make plans to join your colleagues and us at the 2017 PDA/FDA Joint Regulatory Conference!
GENERAL INFORMATION, REGISTRATION

FOUR WAYS TO REGISTER

1. CLICK  www.pda.org/2017PDAFDA
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

Renaissance Washington, DC Downtown Hotel
999 9th Street NW
Washington, DC 20001
Phone: +1 (202) 898-9000
Website: renaissance-hotels.marriott.com/renaissance-washington-dc-downtown-hotel
Rate: Single: $315 plus applicable state and local taxes. Cut-Off Date: Friday, August 11, 2017 (Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the Conference rate.)

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. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2017 PDA/FDA Joint Regulatory Conference
ACPE # 0116-0000-17-009-L04-P | 1.5 CEUs
Type of Activity: Knowledge

LEARNING OBJECTIVES

At the completion of this event, you will be able to:

- Demonstrate how to design a program to ensure data integrity and develop a model to determine the maturity of the company’s quality system
- Recognize how to accelerate development of a quality product using new technologies
- Summarize how to decrease the risk of your supply chain by appropriately qualifying your CMOs and suppliers
- Explain how to manage product lifecycle by appropriate control of changes and modernization of facilities
- Identify current inspection findings to ensure your facility is inspection ready

WHO SHOULD ATTEND

Departments: Research & Development | Regulatory Affairs | Manufacturing | Quality | Assurance/Control | Marketing | Sales
Job Function: Supply Chain | Clinical Supply Material Preparation | Executive Management

SPEAKER READY ROOM HOURS

Sunday, September 10: 3:00 p.m. – 6:00 p.m.
Monday, September 11: 7:30 a.m. – 5:30 p.m.
Tuesday, September 12: 7:15 a.m. – 5:30 p.m.
Wednesday, September 13: 7:15 a.m. – 12:00 p.m.

CONFERENCE REGISTRATION HOURS

Sunday, September 10: 4:00 p.m. – 7:00 p.m.
Monday, September 11: 7:00 a.m. – 5:30 p.m.
Tuesday, September 12: 7:15 a.m. – 5:30 p.m.
Wednesday, September 13: 7:15 a.m. – 12:00 p.m.

DRESS/ATTIRE

Business casual attire is recommended for all events. The temperature in the meeting rooms tends to be cool, so a jacket or sweater is advised for your comfort.

SPECIAL REQUIREMENTS

For information regarding special needs accommodations, please inquire at the Registration Desk. PDA is committed to make all events accessible to all individuals.

CONTACT INFORMATION

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HHS has not endorsed any solicitations for this meeting. All donations have been applied exclusively toward defraying the expenses of non-Federal co-sponsors, not HHS. HHS is not asking for any funds in any capacity. In addition, FDA does not endorse any products or services of PDA or any of its supporters of this event.
SUNDAY, SEPTEMBER 10

4:00 p.m. – 7:00 p.m.
Registration Open

MONDAY, SEPTEMBER 11

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

7:00 a.m. – 8:00 a.m.
PDA Orientation Breakfast (Invitation only for new PDA members and first-time attendees, industry and regulatory)

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

8:00 a.m. – 8:30 a.m.
Welcome and Opening Remarks

8:00 a.m. – 8:10 a.m.
Martin VanTrieste, Chair, PDA Board of Directors
Richard M. Johnson, President and CEO, PDA

8:10 a.m. – 8:30 a.m.
David J. Cummings, MPH, Lead Interdisciplinary Scientist, OPQ, FDA, and Co-Chair, 2017 PDA/FDA Joint Regulatory Conference Program Planning Committee
Maria Guazzaroni Jacobs, PhD, Director, Quality and Regulatory Policy, Pfizer, Inc., and Co-Chair, 2017 PDA/FDA Joint Regulatory Conference Program Planning Committee

8:30 a.m. – 10:00 a.m.
P1: Opening Plenary Session
Moderator: David J. Cummings, MPH, Lead Interdisciplinary Scientist, OPQ, FDA

Session Description: In the opening session, you will hear from FDA leadership about FDA’s role in making America’s biomedical industry a global leader and how public health crises have led Congress to establish standards for safety and effectiveness. FDA’s Peter Marks, MD, PhD, will address how FDA continues to strive to accelerate access to innovative medical product development, focusing on orphan drugs, combination products, novel agents and advanced therapies, including cellular and gene therapy products. We will also hear Rosemarie Hunziker, PhD, of the National Institute of Biomedical Imaging and Bioengineering, at the National Institutes of Health, talk about how her organization is advancing medical products through tissue engineering and regenerative medicine. In this session, you will learn about advances in the area of precision medicine, considerations from the patient perspective, efforts to advance science and engineering in the area of medical products. You will also hear about the need to hire and retain highly qualified scientific and regulatory experts.

8:30 a.m. – 9:00 a.m.
FDA Perspective on Medical Product Innovation
Peter W. Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA

9:00 a.m. – 9:30 a.m.
NIH Perspective on Medical Product Innovation
Rosemarie Hunziker, PhD, Tissue Engineering/Regenerative Medicine Program Director, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion
MONDAY, SEPTEMBER 11, 2017 AGENDA (CONTINUED)

9:45 a.m. – 8:00 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.
P2: Current Quality Challenges for Pharmaceutical Executives
Moderator: Richard L. Friedman, MS, Deputy Director, OMQ, CDER, FDA

Session Description: As the biopharmaceutical industry continues to evolve, major challenges associated with globalization and complexity of the supply chain emerge. In addition, companies now face internal pressures related to the cost of medicines, dealing with various global regulatory frameworks and changing expectations in evolving healthcare systems. The challenges have led an industry drive to adopt new business and quality technologies and to pursue partnerships with global regulators to help companies facilitate continual improvements and modernization of their operations. This session will focus on major challenges of which quality professionals should be aware as they interact with executives at their firms, how ensuring quality can play a part in overcoming those challenges and the crucial role of the executive in driving quality within the company.

10:45 a.m. – 11:15 a.m.
Investing in Quality to Meet Business Objectives
Guy Villax, CEO, Hovione

11:15 a.m. – 11:45 a.m.
Business Challenges and the Quality Imperative
John R. Pinion, II, Chief Quality Operations Officer, Executive Vice President, Bioanalytical Research and Development, Ultragenyx Pharmaceutical

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

12:15 p.m. – 1:30 p.m.
Lunch on your own (Exhibit Area Closed) – A listing of local restaurants is available at the PDA Registration Desk
## 1:30 p.m. – 3:00 p.m.

### Concurrent Sessions

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| **A1: Data Integrity**  
Moderator: Renée Kyro, MBA, Director, Quality Assurance Compliance Program Management, Quality Assurance, AbbVie | **B1: Quality Systems: Maturity Models and Continuous Improvement**  
Moderator: Jacqueline Kunzler, MBA, PhD, Senior Vice President, Global Quality, Baxter Healthcare Corporation | **C1: Expedited Pathways: Developing a Quality Product under Accelerated Timelines**  
Moderator: Janice T. Brown, PhD, Acting Branch Chief, Division of Internal Policies and Programs, CDER, FDA |

**Session Description:** The integrity and accuracy of data generated in clinical trials and during testing and manufacturing of finished products is critical to making sound scientific-based decisions on the efficacy and safety of drugs that ultimately reach our most important customer, the patient. In this session, we will learn about the current and continuing data integrity issues facing the industry, the consequences to the supply chain and patients when data integrity is compromised and how to prevent data integrity issues from impacting your global supply chain.

**Session Description:** All of us are committed to continuous improvement, but how should it be carried out? We will discuss a program that utilizes a quality system (QS) maturity model, including maturity criteria for each QS element, to self-assess the relative health, effectiveness and maturity of the QS at manufacturing locations and corporate QS functions. In this session, we will also discuss examples of specific quality systems and what "good" and "bad" might look like from an investigator’s perspective.

**Session Description:** Expedited programs for serious conditions typically have a shorter clinical development program. The accelerated pace of the clinical program requires shorter process and product development timelines to ensure availability of quality product at the time of approval. This session will explore product quality challenges and successful approaches for product development under abbreviated timelines and early interactions to facilitate the introduction of new technologies.

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| 1:30 p.m. – 2:00 p.m. | **Regulatory Perspective on Data Integrity**  
U.S. FDA CDER Representative Invited |  |
| 2:00 p.m. – 2:30 p.m. | **Industry Perspective on Data Integrity**  
Cormac Dalton, PhD, Director, Compliance, Supply Chain and Commercial Quality, AbbVie |  |
| 2:30 p.m. – 3:00 p.m. | **Panel Discussion**  
Cormac Dalton, PhD, Director, Compliance, Supply Chain and Commercial Quality, AbbVie  
U.S. FDA ORA Representative Invited  
U.S. FDA CDER Representative Invited |  |
| 1:30 p.m. – 2:00 p.m. | **Risk Benefit Considerations in Accelerated Product Quality Development**  
Earl Dye, PhD, Director, CMC Regulatory Policy, Genentech, Inc., A Member of the Roche Group |  |
| 2:00 p.m. – 2:30 p.m. | **Early Quality Assessment Interactions for New Technologies**  
U.S. FDA CDER Representative Invited |  |

3:00 p.m. – 3:45 p.m.  
**Refreshment Break in Exhibit Area**
## 2017 PDA/FDA Joint Regulatory Conference
### September 11-13, 2017 | Renaissance Washington, DC Downtown Hotel | Washington, DC
#2017PDAFDA

## MONDAY, SEPTEMBER 11, 2017 AGENDA (CONTINUED)

### 3:45 p.m. – 5:15 p.m.
Concurrent Sessions

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### Session Description:
- **A2**: This session will examine management’s role in creating a strong quality culture. Speakers will discuss the key attributes of an effective quality culture and characteristics of ineffective cultures. Hear examples that will illustrate both type of cultures and how deficient cultures can be addressed. The speakers will also discuss the influence of culture on process performance, how to institutionalize continual quality improvement thinking, implementation challenges, tips and how to measure your quality culture.
- **B2**: ICH Q12 proposes the development of a harmonized pharmaceutical quality system that encompasses the product lifecycle and emphasizes integration of design space planning, quality risk management and manufacturing science. This session will offer you FDA and industry perspectives on change management across the product lifecycle and help you understand the opportunities and challenges in incorporating risk management principles into a change paradigm framework.
- **C2**: New technological advancements in science have led to emerging therapeutic approaches to treating disease. Cell and gene therapy products are one of many of these advanced therapies. This session will address some of the regulatory challenges that industry and the FDA have encountered as they move through the development lifecycle of these products.

### 3:45 p.m. – 4:15 p.m.
**The Impact of Quality Practices and Quality Behavior on Plant Performance: Redefining the Importance of Culture**
Thomas Friedli, Associate Professor of Management, University of St. Gallen

### 4:15 p.m. – 4:45 p.m.
**Aspiring to Measure Quality Culture: PDA Pilot Results**
Cylia Chen-Ooi, External Affairs Senior Manager, International Quality, Amgen, Inc.

### 4:45 p.m. – 5:15 p.m.
**Panel Discussion**
Cylia Chen-Ooi, External Affairs Senior Manager, International Quality, Amgen, Inc.<br>U.S. FDA CDER Representative Invited<br>Thomas Friedli, Associate Professor of Management, University of St. Gallen

### 3:45 p.m. – 4:15 p.m.
**Pharmaceutical Product Lifecycle Management: ICH Q12 and the Role of Risk Management**
U.S. FDA CDER Representative Invited

### 4:15 p.m. – 4:45 p.m.
**Industry Perspective on ICH Q12 Change Management and Risk Management**
Andrew C. Chang, PhD, Vice President, Quality and Regulatory Compliance, Product Supply Quality, Novo Nordisk Inc.

### 4:45 p.m. – 5:15 p.m.
**Questions and Answers/Discussion**

### 3:45 p.m. – 4:15 p.m.
**Industry Perspective on Advanced Therapies**
Industry Representative Invited

### 4:15 p.m. – 4:45 p.m.
**Regulatory Perspective on Advanced Therapies**
Deborah A. Hursh, PhD, Senior Investigator, CBER, FDA

### 4:45 p.m. – 5:15 p.m.
**Questions and Answers/Discussion**
MONDAY, SEPTEMBER 11, 2017 AGENDA (CONTINUED)

5:30 p.m. – 6:45 p.m.
Concurrent Interest Group Sessions

**IG1: Vaccines**

**Leaders:**
Jane Halpern, PhD, Health Specialist, Vaccine Translational Research Branch, Vaccine Research Program, DAIDS, NIAID, NIH
Sara E. Gagneten, PhD, Associate Director for Regulatory Policy, Division of Viral Products, CBER, FDA

**Description:** The Vaccines Interest Group (VIG) focuses on issues that affect the biological, biotechnology and vaccine industry. The Interest Group has previously discussed regulatory issues, new technologies and emerging industry trends. Recent issues include vaccine availability and supplies, homeland security and inspection trends. The group also issues a newsletter. All PDA members are welcome to attend VIG meetings, which are held in conjunction with PDA events.

**IG2: Quality Systems**

**Leader:** Jennifer Magnani, Senior Director, Quality Academy, Sanofi Pasteur

**Description:** The PDA Quality Systems Interest Group is a network of QA/QC professionals. Past topics have dealt with diverse subjects ranging from systems-based inspections, to QA/QC Organizations to risk analysis. The Quality Systems Interest Group also sponsors a quality systems forum on PDA ConnectSM site for daily networking opportunities. Members participate in Task Forces on compliance and quality related topics.

**IG3: Visual Inspection of Parenterals and Packaging Science**

**Visual Inspection of Parenterals IG Leader:** John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC

**Packaging Science IG Leader:** Roger Asselta, Senior Advisor, Genesis Packaging Technologies

**Description:** The Visual Inspection of Parenterals and Packaging Science Interest Groups will be holding a joint session at the PDA/FDA Joint Regulatory Conference. There are many topics of mutual interest and this is an excellent opportunity to discuss them together.

Particulate contamination reduction in parenteral drug products is currently a key area of focus for many pharmaceutical companies and for those who regulate the industry. We will have a brief presentation to provide an overview of current regulatory and compendial requirements and actions as well as pharmaceutical industry experience and expectations. One barrier for further particulate reduction is a lack of common test methods and baseline particulate data from container/closure component suppliers. A comparison of common test methods illustrates the gap between the compendial methods utilized by the pharmaceutical companies and the methods used by many container/closure component suppliers.

We will use this joint session to discuss your packaging and inspection experience and concerns with specific focus on potential initial steps that container/closure component suppliers and pharmaceutical manufacturers might take to better understand and control particulate contamination.

**IG4: Supply Chain Management**

**Leader:** Amelia Mutere, MS, Head, Global Quality Inspection Management, Roche

**Description:** At this meeting of the Supply Chain Management Interest Group, we will discuss the importance of good supplier control for disposables and filters. We will also discuss PDA ConnectSM, hot topics and best practices in materials management.

**Improving Consistency, Robustness and Accessibility to Supplier Information in a Time of Increased Regulatory and Supplier Transparency Expectations**

Krista Bratton, MBA, Marketing Program Manager, EMD Millipore
IG5: Quality Risk Management
Leaders:
Amanda Bishop McFarland, MS,
Consultant, ValSource, LLC,
Emma Ramnarine, Head,
Global Biologics Quality Control, Genentech, Inc., A Member of the Roche Group
Magaly Aham, MS,
RAC-US, Vice President of Compliance and US Operations, Pharma-Bio Serv

Description: The Quality Risk Management (QRM) Interest Group and its PDA ConnectSM online discussion forum are excellent avenues for you to raise questions, seek answers, share experiences, generate discussions and, in general, interact with peers. The mission of our QRM Interest Group is to learn, promote and share best practices within our Interest Group community that can help us advance QRM practices in our respective organizations and in the industry as a whole. Your participation serves a critical function in not only building and advancing communications within this Interest Group, but can also help with our own QRM implementation journeys. So join us for another engaging exchange on practical QRM application topics to get your questions answered and leverage practices/learnings from other industry colleagues.

IG6: Pharmacopeial
Leaders:
Janeen Skutnik-Wilkinson, Lead Quality Intelligence and Compendial Affairs, BIOGEN
Karen S. Ginsbury, MSc, President and CEO, Pharmaceutical Consulting Israel Ltd.

Description: This meeting of the Pharmacopeial Interest Group will cover the challenges companies face in complying with global Pharmacopoeia’s with a focus on two key areas:
1. The Chinese pharmacopeia 2015 and the pathway to 2020, including challenges faced by industry and how PDA is working to address concerns for the 2020 edition; and
2. Discussion and sharing amongst participants of best practices for compendial compliance.

6:45 p.m. – 8:30 p.m.
Networking Reception in Exhibit Area

TUESDAY, SEPTEMBER 12

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

7:00 a.m. – 8:30 a.m.
Continental Breakfast
**TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)**

**7:15 a.m. – 8:15 a.m.**
Concurrent Breakfast Sessions

| **BREAKFAST 1:** Practical Guidance on How to Conduct and Evaluate an Effective Smoke Study  
**Moderator:** Mai X. Huynh, MS, Supervisory Team Leader, CVM, FDA | **BREAKFAST 2:** Best Practices for CMC NDA Supplement Submissions  
**Moderator:** David J. Cummings, MPH, Lead Interdisciplinary Scientist, OPQ, FDA | **BREAKFAST 3:** 3D Printing in the Advancement of Medicine  
**Moderator:** Colleen F. Hoyt, Branch Director, Team Biologics Branch, ORA, FDA | **BREAKFAST 4:** Digital Health  
**Moderator:** Shane D. Killian, MS, Senior Director, Licensing and Acquisition Head, Johnson & Johnson |

**Session Description:** Smoke studies are a key activity in the qualification, maintenance and monitoring of an aseptic facility. However, discussions of the specific methods and techniques to conduct such studies have been lacking. This session aims to provide in-depth information about airflow visualization tests and key activity when conducting smoke studies to qualify and/or requalify your cleanroom.

**Session Description:** This breakfast session will focus on the best practices for CMC NDA submissions to the Office of Lifecycle Drug products. The session will also discuss common approaches, challenges and lessons learned to navigate CMC-related NDA submissions.

**Session Description:** Additive manufacturing, also known as 3D printing, has created avenues of potential in the medical product industries through newly enabled design possibilities and personalized medicine capabilities. Forecasts project significant growth of 3D printing in the medical device space by 2025. FDA's Center for Devices and Radiological Health has cleared and approved several types of 3D-printed medical devices through its existing regulatory pathways, and FDA's CDER has also approved a 3D-printed drug product. FDA, through internal and collaborative research, is working to facilitate the innovative development and assessment of innovative products in this space. This presentation will provide a snapshot of ongoing research efforts internally and in collaboration with FDA's academic partners. Some topics will include phantoms for device testing, patient-matched devices instrumentation, cleanability assessment, material optimization and drug printing optimization.

**Session Description:** As referenced at FDA.gov, many stakeholders, including patients, healthcare practitioners, researchers and companies new to FDA regulatory requirements, such as mobile application developers, are involved in digital-health activities. This session will discuss the exciting area of digital health and provide both industry and regulator perspectives on the challenges of bringing digital-health products to market.

| 7:15 a.m. – 7:40 a.m.  
**Airflow Pattern Testing and Documentation for Aseptic Processing**  
**Donald E. Hill, PE, President, AccuTec Services, Inc.** | 7:15 a.m. – 7:45 a.m.  
**Regulatory Perspective on Best Practices for CMC NDA Supplement Submissions**  
**U.S. FDA CDER Representative Invited** | 7:15 a.m. – 7:45 a.m.  
**Regulatory Perspective on 3D Printing in the Advancement of Medicine**  
**James Coburn, Senior Research Engineering Officer, CDRH, FDA** | 7:15 a.m. – 7:45 a.m.  
**Regulatory Perspective on Digital Health**  
**Linda J. Ricci, Associate Director, Office of Device Evaluation, CDRH, FDA** |

| 7:40 a.m. – 8:15 a.m.  
**Panel Discussion**  
**U.S. FDA CDER Representatives Invited**  
**Donald E. Hill, PE, President, AccuTec Services, Inc.** | 7:45 a.m. – 8:15 a.m.  
**Questions and Answers/Discussion** | 7:45 a.m. – 8:15 a.m.  
**Questions and Answers/Discussion** | 7:45 a.m. – 8:15 a.m.  
**Questions and Answers/Discussion** |
TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)

8:30 a.m. – 10:00 a.m.
**P3: Innovation in Medical Products: What the Future Holds**
*Moderator: Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.*

**Session Description:** The continued expansion of the therapeutic landscape, targeted therapies, novel companion and complementary diagnostics, including the further development of multiplex genomic testing platforms, represent some of the most complex medical products for the treatment of disease. Gain first-hand knowledge of new scientific and regulatory advancements from leading industry and Agency oncology, orphan drug and combination product experts, who contribute to patients’ access to innovative therapies while ensuring public safety.

**Panel Discussion**
Debra Y. Lewis, OD, MBA, Deputy Director, Office of Orphan Products Development, *FDA*
Patricia Y. Love, MD, MBA, Deputy Director, Office of Combination Products, *FDA*
Amy E. McKee, MD, Deputy Director, Oncology Center for Excellence, *FDA*
Kirsten Paulson, MS, Senior Director, Global CMC-Medical Device Lead, *Pfizer, Inc.*

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

10:00 a.m. – 10:45 a.m.
**Refreshment Break and Passport Raffle Prize Drawing in Exhibit Area**

10:45 a.m. – 12:15 p.m.
**Concurrent Sessions**

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| **A3: Quality Metrics**
*Moderator: Laurie P. Norwood, Deputy Director, Office of Compliance and Biologics Quality, CBER, FDA* | **C3: Compliance and Enforcement Trends**
*Moderator: Douglas A. Campbell, Senior Consultant, Interpro QRA* |

**Session Description:** This session will provide an industry case study on metric utilization to drive quality and prevent drug shortages. The session will also include a panel discussion with trade organization representatives on issues raised on the latest FDA revised Quality Metrics draft. FDA will be present during the panel discussion and questions and answers portion of the session.

**Session Description:** Management of a product lifecycle is an ongoing process and can be challenging for biotech products that were approved many years ago. Often times, there are obstacles that interfere with moving forward to align an older technology and manufacturing method to meet modern expectations. In this session, you will hear case studies that outline modernization attempts made by manufacturers. We will also discuss the science and regulatory path needed to leap from an old process to something new. FDA panelists will be available to address questions regarding this challenging regulatory pathway.

**Session Description:** It’s back by popular demand! This session will include short presentations from CDER and CBER Compliance Managers that are designed to provide more than just the usual “Top 10” 483 observations and a summary of the latest warning letters. These presentations will be followed by a panel discussion with panelists from each of the Agency’s Centers and will be an opportunity for participants to gather specific insight.
### TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)

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<th>Time</th>
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| 10:45 a.m. – 11:05 a.m. | Utilizing Metrics to Drive Quality and Prevent Drug Shortages  
Valerie Whelan, Vice President, Corporate Quality, Amgen, Inc. |
| 11:05 a.m. – 11:45 a.m. | Panel Discussion  
Barbara Allen, PhD, Senior Director, Global Quality Systems, Eli Lilly S.A. Irish Branch  
Deborah M. Autor, Esq., Senior Vice President, Strategic Global Quality and Regulatory Policy, Mylan Inc., and Member, Association for Accessible Medicines  
U.S. FDA CDER Representatives Invited  
Harry Jeffreys, Vice President, Regulatory Affairs and Compliance, Catalent Pharma Solutions  
Susan Schniepp, Fellow, Regulatory Compliance Associates Inc. |
| 11:45 a.m. – 12:15 p.m. | Questions and Answers/Discussion |
| 10:45 a.m. – 11:15 a.m. | Manufacturing Site Transfer for a 30-Year-Old Therapeutic Protein: Regulatory and Technical Challenges  
Susan Batcha, Global Regulatory CMC, Director, Novartis Pharmaceuticals Corporation  
11:15 a.m. – 11:45 a.m. | Technology Advancements in the Treatment of Hemophilia A: From Blood to Gene Therapy  
Peter Turecek, PhD, Senior Director, Global Medical Affairs, Scientific and Technical Expert, Hematology, Shire  
11:45 a.m. – 12:15 p.m. | Panel Discussion  
U.S. FDA CDER Representative Invited  
Susan Batcha, Global Regulatory CMC, Director, Novartis Pharmaceuticals Corporation  
Alexey Khrenov, PhD, Senior Staff Fellow, CBER, FDA  
Anthony F. Lorenzo, Team Lead, CBER, FDA  
Peter Turecek, PhD, Senior Director, Global Medical Affairs, Scientific and Technical Expert, Hematology, Shire |
| 10:45 a.m. – 11:15 a.m. | CDER Regulatory Perspective on Compliance and Enforcement Trends  
U.S. FDA CDER Representative Invited  
11:15 a.m. – 11:45 a.m. | CBER Regulatory Perspective on Compliance and Enforcement Trends  
Robert D. McElwain, Consumer Safety Officer, CBER, FDA  
11:45 a.m. – 12:15 p.m. | Panel Discussion  
U.S. FDA CDER Representatives Invited  
U.S. FDA CVM Representative Invited  
Robert D. McElwain, Consumer Safety Officer, CBER, FDA |

12:15 p.m. – 1:30 p.m.  
**Lunch on your own (Exhibit Area Closed)** – A listing of local restaurants is available at the PDA Registration Desk
**TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)**

1:30 p.m. – 3:00 p.m.

### Concurrent Sessions

<table>
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<tr>
<th>PRODUCT QUALITY</th>
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<tr>
<td><strong>A4: Overseeing Your Supply Chain</strong>&lt;br&gt;<strong>Moderator:</strong> Myriam M. Sosa, MS, Executive Director, Quality Assurance Compliance, Merck &amp; Co./Merck Sharp &amp; Dohme</td>
<td><strong>B4: Center International Affairs Leaders Discuss the Global Reach of FDA</strong>&lt;br&gt;<strong>Moderator:</strong> Colleen F. Hoyt, Branch Director, Team Biologics Branch, ORA, FDA</td>
<td><strong>C4: Fishbowl</strong>&lt;br&gt;<strong>Moderators:</strong> U.S. FDA ORA Representative Invited</td>
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**Session Description:** Managing risk in your supply chain requires meaningful quality agreements, effective audits, ongoing communications and prompt notifications regarding significant changes or problems. This session will discuss qualification of CMOs and vendors and what is needed to enable lifecycle quality assurance.

**Session Description:** Given the complexities of supply chains for pharmaceutical products and medical devices, FDA’s work includes important global elements that must be balanced with Agency priorities and mandates. How does FDA prioritize its global engagement? Meet the international affairs leaders from CBER, CDER, CVM and ORA, who will describe their Centers’ work on the global front, including regulatory harmonization, regulatory capacity building, information sharing, international-standards setting and collaborative research.

**Session Description:** The fishbowl session is your chance to actively participate in the Conference! You will be presented with real-life case studies or scenarios where you will need to consult with members of your team and try to come up with a solution to the problems presented. You can also pick if you want to participate by roleplaying either a member of industry or a member of the U.S. FDA. Each group will have the opportunity to explain their solution and hear the solutions of others. There is no right or wrong answer, this is just a great way to interact and learn from your fellow Conference attendees.

1:30 p.m. – 2:00 p.m.

**CMOs: Quality Agreements and Audits**<br>**U.S. FDA CDER Representative Invited**

2:00 p.m. – 2:30 p.m.

**Vendor and CMO Qualification: Lessons Learned**<br>**Zena G. Kaufman,** Vice President, Quality, Roivant Sciences, Inc.

2:30 p.m. – 3:00 p.m.

**Questions and Answers/Discussion**

1:30 p.m. – 2:00 p.m.

**The New Face of Harmonization**<br>**Theresa M. Mullin,** PhD, Director, Office of Strategic Programs, CDER, FDA

2:00 p.m. – 2:30 p.m.

**Beyond Harmonization**<br>**Joan W. Blair,** MA, Senior Advisor for International Affairs, CBER, FDA

2:30 p.m. – 3:00 p.m.

**Panel Discussion**<br>**Joan W. Blair,** MA, Senior Advisor for International Affairs, CBER, FDA<br>**Niraj Mehta,** PhD, Associate Director for Global Regulatory Policy, OC, FDA<br>**Theresa M. Mullin,** PhD, Director, Office of Strategic Programs, CDER, FDA<br>**U.S. FDA CVM Representative Invited**

**Facilitators:**<br>**U.S. FDA CDER Representatives Invited**<br>**Mai X. Huynh,** MS, Supervisory Team Leader, CVM, FDA

3:00 p.m. – 3:45 p.m.

**Refreshment Break and Passport Raffle Prize Drawing in Exhibit Area**
### Concurrent Sessions

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<tr>
<td>3:45 p.m. – 4:15 p.m.</td>
<td><strong>A5: FDA Program Alignment</strong>&lt;br&gt;<strong>Moderator:</strong> Douglas A. Campbell, Senior Consultant, Interpro QRA</td>
<td><strong>B5: Advances in Manufacturing of Biological Products</strong>&lt;br&gt;<strong>Moderator:</strong> Maria “Reyes” Candau-Chacon, PhD, Biologist, CDER, FDA</td>
<td><strong>C5: Regulatory Considerations</strong>&lt;br&gt;<strong>Moderator:</strong> John D. Ayres, MD, JD, Senior Medical Fellow, Product Safety Assessments, Global Patient Safety, Eli Lilly and Company</td>
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</table>

**Session Description:** Program Alignment is a plan that will transition FDA to distinct commodity-based and vertically integrated regulatory programs. ORA and each Center have collaborated and developed action plans for specialization and coordination in an effort to better fulfill the FDA's responsibilities to meet the emerging global challenges within the regulated industries. This session will present the action plans and provide information about how the changes in FDA's structure, function and processes might have an effect on your next FDA inspection.

**Session Description:** As new technologies emerge, the pharmaceutical industry is implementing more flexible and efficient manufacturing processes. Advancements in high-yielding expression systems and high-density cell culture processes, coupled with the use of single use bioreactors and vessels, result in higher productivities, flexibility and simplified equipment preparation. Closed processes decrease microbial contamination and cross-contamination risks in multiproduct facilities. The development of high-titer membrane chromatography systems has the potential to eliminate bottlenecks in purification with the use of new high-throughput and continuous purification technologies. These process and technology advances will provide for the tools necessary to face the challenges of the current pharmaceutical needs.

**Session Description:** Generally, human factor (HF) studies are conducted to evaluate the user interface of a product. For a combination product that includes drug and device constituent parts, both the device design control requirements and drug development expectations apply to the entire combination product. HF studies are needed to ensure that use-related hazards associated with the product are eliminated or mitigated to reduce patient adverse events and medication errors. HF and the totality of available information (e.g., clinical, PK/PD, human factors, engineering, chemistry) are used in making safety and efficacy assessments for clinical trials bridging. This session will focus on HF considerations for combination products to promote consistency in their design and development. The data necessary in the bridging studies for the to-be-marketed combination product will also be considered. Additionally, usability issues facing industry and implications for combination product development will be highlighted.

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<tr>
<th>3:45 p.m. – 4:15 p.m.</th>
<th>Regulatory Perspective on FDA Program Alignment&lt;br&gt;U.S. FDA ORA Representative Invited</th>
<th>Quality Assurance&lt;br&gt;Shannon M. Hoste, MS, RAC, Senior Human Factors Engineer, CDRH, FDA</th>
<th>Quality Assurance&lt;br&gt;Shannon M. Hoste, MS, RAC, Senior Human Factors Engineer, CDRH, FDA</th>
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<tr>
<td>4:15 p.m. – 5:15 p.m.</td>
<td>Transforming Operations with Next-Generation Biomanufacturing&lt;br&gt;Arleen Paulino, Vice President, Singapore Site Operations, Amgen Singapore Manufacturing Pte. Ltd.</td>
<td>Human Factors Role in the to-be-Markedeted Combination Product Device Bridging Strategy&lt;br&gt;John Towns, PhD, Senior Research Fellow – Regulatory – Delivery Systems, Eli Lilly and Company</td>
<td>Human Factors Role in the to-be-Markedeted Combination Product Device Bridging Strategy&lt;br&gt;John Towns, PhD, Senior Research Fellow – Regulatory – Delivery Systems, Eli Lilly and Company</td>
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<th>4:15 p.m. – 5:15 p.m.</th>
<th>New Developments in the Manufacturing of Biological Products&lt;br&gt;U.S. FDA CDER Representative Invited</th>
<th>4:15 p.m. – 5:15 p.m.</th>
<th>Questions and Answers/Discussion</th>
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<tr>
<td>4:15 p.m. – 4:45 p.m.</td>
<td>Panel Discussion&lt;br&gt;U.S. FDA CDER Representatives Invited&lt;br&gt;Arleen Paulino, Vice President, Singapore Site Operations, Amgen Singapore Manufacturing Pte. Ltd.</td>
<td>4:15 p.m. – 5:15 p.m.</td>
<td>Panel Discussion&lt;br&gt;U.S. FDA CDER Representatives Invited&lt;br&gt;Arleen Paulino, Vice President, Singapore Site Operations, Amgen Singapore Manufacturing Pte. Ltd.</td>
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| 4:45 p.m. – 5:15 p.m. | Questions and Answers/Discussion | Questions and Answers/Discussion | Questions and Answers/Discussion |
TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)

5:30 p.m. – 6:30 p.m.
Concurrent Interest Group Sessions

| IG7: Regulatory Affairs | Description: The regulatory environment is continuously evolving and companies are expected to stay compliant with new and updated regulations in all the markets where they have marketed products. How to capture, understand and implement all these new requirements in a timely manner becomes more and more important. This session will showcase an example of a process designed to ensure capture, influence, analysis and implementation of new regulatory requirements. The presentation will be followed by an interactive discussion where participants can share from their own experience. The complexity of the regulatory environment and the need for harmonization will also be addressed.

Leaders:
Ruhi Ahmed, PhD, RAC, Vice President, Regulatory Affairs, Inoyme Pharmaceutical Inc.
Ursula Busse, PhD, MBA, Quality Intelligence, External Relations, Novartis

Speakers: Anette Yan Marcussen, Director, Quality Intelligence, Novo Nordisk A/S, and Regulatory Representative Invited |

| IG8: Inspection Trends | Description: A review of the recent inspectional observation by topics will be discussed in an interactive manner. Past topics have included data integrity, aseptic practices and facility conditions.

Leaders:
Christopher S. Carter, Senior Manager, Global Quality Systems, Mylan Pharmaceuticals
Dipti Gulati, MBA, PhD, President, PJI Biotech |

| IG9: Lyophilization and Sterile Processing/Parenteral Drug Manufacturing | Description: Recent inquiries and inspection observations have raised questions about proper approaches to the design of Aseptic Process Simulations (APS). These include such topics as the length of time filled vials need to sit in the lyophilizer and the need to incorporate different filling line change parts within a matrix. The session will open with highlights on recent considerations in the design of an APS. The IG session will then be an open forum for discussions on these and other current topics in sterile products and lyophilized preparations.

This session will encompass both liquid and lyophilized products, with a focus on considerations for regulatory inspections. In this open forum format, topics are identified by participants for discussions by the group. This provides a unique opportunity to learn from a variety of experiences and perspectives, and provides an excellent benchmark for current industry practices.

Lyophilization IG Leader:
Edward H. Trappler, President, Lyophilization Technology, Inc.

Sterile Processing/Parenteral Drug Manufacturing IG Leader:
Rebecca Brewer, Strategic Practice Lead, Quality Executive Partners, Inc. |

| IG10: Facilities and Engineering | Description: The Facilities and Engineering Interest Group provides a forum for the discussion of topics and interests related to the design, construction, operation and maintenance of the production and research facilities used for GMP and GLP purposes. Discussions are held in conjunction with two of the PDA meetings: the Annual Meeting and the PDA/FDA Joint Regulatory Conference and on PDA ConnectSM, PDA’s online discussion forum.

The format of the Facilities and Engineering Interest Group meetings are an open forum for discussion, where attendees select the topic for discussion and the leader moderates the discussion of peers seeking to reach a better understanding of regulatory expectations and opportunities to share and learn best practices. Where appropriate, the Facilities and Engineering Interest Group will compile these understandings and best practices into technical reports with the contributions and review of interested members.

Leader:
Shelley Preslar, MBA, PMP, General Manager, Azzur Group |
TUESDAY, SEPTEMBER 12, 2017 AGENDA (CONTINUED)

IG11: GMP Links to Pharmacovigilance

Leaders: Agnieszka Majcher-Dann, MD, Head of Safety Sciences and Policy, Consumer Segment, Johnson & Johnson
John D. Ayres, MD, JD, Senior Medical Fellow, Product Safety Assessments, Global Patient Safety, Eli Lilly and Company

Description: The GMP Links to Pharmacovigilance Interest Group will facilitate the incorporation of medical expertise and oversight in the form of a clinical assessment of the potential safety issues with product performance and quality system elements. Quality attributes of a product, including product specifications, are linked to patient experiences and add value to fundamental quality activities. The focused elements for this Interest Group are as follows:

- Risk control linked to medical patient risk
- To link quality system elements to pharmacovigilances and approved risk evaluation and mitigation strategies to address link recalls, complaints and adverse effects
- The establishment of and deviation from critical quality attributes and the link to the quality target product profile
- The link to regulatory filing issues (e.g., label claims)

The mission is achieved by:

- An improved understanding of the clinical (patient experiences) and GMP quality systems (product specifications)
- Discussing case studies of positive and negative experiences in this venue
- Contributing to global regulations and guidance as appropriate
- Sponsoring plenary sessions, break-out sessions and possibly a conference to bring together experts in this field

IG12: Technology Transfer

Leaders: Mirko Gabriele, Senior Manager, Global DPS Technology Transfer, Patheon
Melissa Seymour, MBA, Vice President, Global Quality Control, Biogen

Description: This Interest Group is focused on the benchmarking of our experience in technology transfer projects. In this session, we will explore ongoing activities within the Tech Transfer Interest Group. This includes generation of a matrix that can serve as a template to standardize approaches within industry, discussion of overall governance and strategy with respect to Tech Transfer as well as a library of guidance documents. The meeting is an open discussion format with a moderator and will provide an open forum for discussion around any and all tech transfer-related activities including manufacturing process transfer, analytical transfer and equipment user requirements definition. The group discussion at PDA/FDA will focus on “Benchmarking Tech Transfer Activities,” including:

- What are the expectations with respect to documentation?
- How many regulations apply to tech transfer? In which markets?
- What kind of governance and oversight is needed for tech transfers?
- How can I assess risk and use this to define my Tech Transfer Deliverables?
- Potential development of an interactive tool/standard for how to measure the variance to the benchmark based on the change in cumulative risk
  - Allows association of deliverable sets to changes in cumulative risk profile (i.e., total number of documents)
  - Provide deliverable duration estimates associated with document rigor as determined by cumulative risk (i.e., complexity of documents)

If you have other related issues or questions you would like to raise you can add new and different ideas to this session.

7:00 p.m. – 9:00 p.m.
Reception
## WEDNESDAY, SEPTEMBER 13

<table>
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<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>7:15 a.m. – 12:00 p.m.</td>
<td>Registration Open</td>
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<tr>
<td>7:00 a.m. – 8:30 a.m.</td>
<td>Continental Breakfast</td>
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<tr>
<td>7:15 a.m. – 8:15 p.m.</td>
<td>Concurrent Breakfast Sessions</td>
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### BREAKFAST 5: Process Validation of Sterile Products
**Moderator:** David J. Jaworski, MBA, Senior Policy Advisor, CDER, FDA

**Session Description:** This session will explore validation of aseptic processes and the issues that are encountered, including designing aseptic processes to minimize contamination risk, handling media fill failures, minimizing and optimizing interventions, assessing hazards posed by ISO 5 contamination incidents and evaluating control system failures.

### BREAKFAST 6: Quality Assurance 101
**Moderator:** Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

**Session Description:** If you are an avid follower of warning letters, then you know that many of the infractions on which companies are being cited are very basic concepts. Not following SOPs, not following good documentation practices, data integrity citations and incomplete investigations are among the top observations. Come and hear an expert panel talk about the importance of getting back to basics, so that you can avoid these all-too-common pitfalls.

### BREAKFAST 7: Microbiology Laboratory Controls
**Moderator:** Jacqueline Kunzler, MBA, PhD, Senior Vice President, Global Quality, Baxter Healthcare Corporation

**Session Description:** Often taken for granted, the microbiology laboratory could have a significant impact on assuring sterility of parenteral drugs. This session will discuss the multi-faceted issues that can affect the validity of management information and product release decisions (e.g., sample handling controls, data integrity issues, identification problems, investigations and the impact of facility and equipment functionality).

### BREAKFAST 8: Role of Standards in the Pharmaceutical Industry
**Moderator:** Maria Guazzaroni Jacobs, PhD, Director, Quality and Regulatory Policy, Pfizer, Inc.

**Session Description:** This session will discuss the use of standards, such as ANSI, ASTM, USP and others in the pharmaceutical industry. CDER’s Office of Pharmaceutical Quality leads interactions with the USP and with voluntary standards development organizations. This interagency collaboration supports guidance development and standards related policy-setting activities relevant to pharmaceutical quality. The session will start with a presentation by an OPQ/CDER representative followed by questions and answers.

### BREAKFAST 9: Bridging Cultures in Pharmaceutical Development and Manufacturing
**Moderator:** Renée Kyro, MBA, Director, QA Compliance Program Management, Quality Assurance, AbbVie

**Session Description:** Rapidly developing and registering innovative medical products is greatly influenced by the ability of cross-functional teams to effectively and efficiently work together. Cultures within R&D and Operations functions have historically been very different. In this session, you will hear how industry is closing the cultural gaps to ensure successful scale up, product realization and knowledge transfer throughout the product transfer lifecycle.
**WEDNESDAY, SEPTEMBER 13, 2017 AGENDA (CONTINUED)**

<table>
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<tr>
<th>BREAKFAST 5: Process Validation of Sterile Products (continued)</th>
<th>BREAKFAST 6: Quality Assurance 101 (continued)</th>
<th>BREAKFAST 7: Microbiology Laboratory Controls (continued)</th>
<th>BREAKFAST 8: Role of Standards in the Pharmaceutical Industry (continued)</th>
<th>BREAKFAST 9: Bridging Cultures in Pharmaceutical Development and Manufacturing (continued)</th>
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<tr>
<td>7:15 a.m. – 7:45 a.m. Aseptic Process Design and Media Fill Validation U.S. FDA CDER Representative Invited</td>
<td>7:15 a.m. – 7:45 a.m. Industry Perspective on Microbiology Laboratory Controls Industry Representative Invited</td>
<td>7:15 a.m. – 7:45 a.m. FDA Interaction with Standard-Setting Organizations and Use of Standards in the Pharmaceutical Industry U.S. FDA CDER Representative Invited</td>
<td>7:15 a.m. – 7:45 a.m. Industry Perspective on Bridging Cultures in Pharmaceutical Development and Manufacturing Industry Representative Invited</td>
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<tr>
<td>7:45 a.m. – 8:15 a.m. Questions and Answers/Discussion</td>
<td>7:45 a.m. – 8:15 a.m. Questions and Answers/Discussion</td>
<td>7:45 a.m. – 8:15 a.m. Panel Discussion Scott A. Colburn, CAPT, USPHS, Director, Standards Program, CDRH, FDA Mai X. Huynh, MS, Supervisory Team Leader, CVM, FDA U.S. FDA CDER Representative Invited</td>
<td>7:45 a.m. – 8:15 a.m. Questions and Answers/Discussion</td>
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<td>8:30 a.m. – 10:00 a.m. P4: Center Updates</td>
<td>10:00 a.m. – 10:30 a.m. Refreshment Break</td>
<td><strong>8:30 a.m. – 10:00 a.m.</strong>  <strong>P4: Center Updates</strong>  <strong>Moderator: Shane D. Killian, MS, Senior Director, Licensing and Acquisition Head, Johnson &amp; Johnson</strong>  <strong>Session Description:</strong> Hear directly from senior management officials representing the various Agency Center Directors and learn about the latest regulatory expedited pathways, policy developments, priority initiatives and other activities planned for 2018 and beyond. A panel discussion will follow along with time for questions from the audience.  <strong>Panel Discussion</strong>  Christopher C. Joneckis, PhD, Senior Advisor, CBER, FDA Robin W. Newman, MSN, EdD, CPNP, Director, Office of Compliance, CDRH, FDA Steven M. Solomon, DVM, Director, CVM, FDA Douglas C. Throckmorton, MD, Deputy Center Director for Regulatory Programs, CDER, FDA</td>
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WEDNESDAY, SEPTEMBER 13, 2017 AGENDA (CONTINUED)

10:30 a.m. – 12:00 p.m.
P5: Compliance Update
Moderator: Steven R. Mendivil, Senior Advisor, International Quality External Affairs, Amgen, Inc.

Session Description: Attend this “save-the-best-for-last” session featuring the Compliance Directors from the FDA Centers and Office of Regulatory Affairs. In this session, learn more about FDA’s new initiatives, programs and significant manufacturing compliance deficiencies that could affect medical products. Don’t miss this opportunity to ask those questions you have always wanted to ask a panel of experts in an open forum setting.

Panel Discussion
Donald D. Ashley, JD, Director, Office of Compliance, CDER, FDA
Sean M. Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, CDRH, FDA
Martine L. Hartogensis, DVM, Deputy Director, Office of Surveillance and Compliance, CVM, FDA
Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, CBER, FDA
Douglas W. Stearn, JD, Director, Office of Enforcement and Import Operations, ORA, FDA

12:00 p.m.
Looking to the Future: Announcement of 2018 Co-chairs and Focus for the Coming Year
CONTINUING EDUCATION INFORMATION

Following the 2017 PDA/FDA Joint Regulatory Conference, from September 14-15, 2017, PDA Education will independently offer four courses to advance your knowledge.

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.

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

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.

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.

7:30 a.m. – 8:30 a.m.: Continental Breakfast
10:00 a.m. – 10:15 a.m.: Morning Break
12:00 p.m. – 1:00 p.m.: Lunch
2:30 p.m. – 2:45 p.m.: Afternoon Break

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 onsite and transferring registrants on a first-come, first-served basis.
2017 PDA REGULATORY COURSE SERIES

Following the 2017 PDA/FDA Joint Regulatory Conference, from September 14-15, 2017, PDA Education will independently offer four courses to advance your knowledge.

CMC Regulatory Requirements in Drug Applications

Location: Renaissance Washington, DC Downtown Hotel | Washington, DC
Date: September 14, 2017
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 253
CPE: ACPE #0116-0000-16-004-L04-P | 0.6 CEUs
Type of Activity: Knowledge

This course provides a basic understanding of chemistry, manufacturing and control (CMC) requirements in drug applications. It will help prepare those in regulatory affairs to better address the key points required in the CMC sections of drug applications. Topics to be covered include CMC in investigational new drug applications, new drug applications, abbreviated new drug applications, drug master files and post-approval change supplements. Manufacturing GMP compliance and an introduction to biological licensed application will also be briefly discussed.

WHO SHOULD ATTEND
Personnel in CMC Regulatory Affairs, QA and QC, and chemical research and development will benefit from this course.

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

- Identify different drug applications/supplements
- Explain CMC requirements for different drug applications or supplements
- Discuss key points in preparation of CMC sections for different drug applications

FACULTY
Zi-Qiang Gu, PhD, Pharmaceutical Consultant, Former FDA CMC reviewer and GMP Compliance Officer

Quality Culture and Investigations: Best Practices

Location: Renaissance Washington, DC Downtown Hotel | Washington, DC
Date: September 14-15, 2017
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 524
CPE: ACPE #0116-0000-17-001-L04-P | 1.2 CEUs
Type of Activity: Knowledge

This course is designed to present the critical support elements of investigations, including quality culture, integration of quality risk management and continuous improvement. Topics will also include understanding how effective investigations and well-written reports yield business improvement opportunities. You will learn the necessary components in designing an investigation and conducting a root cause analysis that will determine the true root causes and yield the most effective CAPAs.

WHO SHOULD ATTEND
This course is for upper level management, operational supervisors and professionals in quality assurance/quality control, risk management, regulatory affairs, manufacturing, product development, CAPA, supply chain and purchasing, production, engineering, project management and R&D.

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

- Examine key cultural aspects affecting investigations, assess how they impact investigations and develop a strategy for dealing with them
- Conduct a review/assessment of your company culture and provide ways to help senior management to understand the value of well-done investigations
- List appropriate skill sets and functions necessary to participate on the investigation team
- Conduct effective investigations that determine true root cause and cost-effective CAPAs
- Define after-action reviews to determine effectiveness and lessons learned
- Recognize quality risk management principles to evaluate/prioritize deviations to determine the extent and depth of investigations
- Identify the components of investigation reports that accurately summarize investigation findings and lead to clear conclusions and follow up
- Explain the business value and impact of well-done investigations and how they can reduce repetitive investigations and lower business costs

FACULTY
Craig Elliott, Sr. Vice President, Education, PDA
CMC Regulatory Compliance for Biopharmaceutical Manufacturing

Location: Renaissance Washington, DC Downtown Hotel | Washington, DC
Date: September 14-15, 2017
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.

Course Number: 526
CPE: ACPE #0116-0000-16-046-L04-P | 1.2 CEUs
Type of Activity: Knowledge

This course will provide insights and practical guidance for CMC teams to develop an acceptable cost-effective CMC regulatory compliance strategy for biopharmaceuticals from early clinical stage development through market approval. The course emphasis will include FDA, EMA and ICH guidances.

WHO SHOULD ATTEND
This course is designed specifically for those involved in or interested in the manufacture and control and CMC regulatory issues of biopharmaceuticals, including senior management, directors and managers/supervisors, QA/QC, regulatory affairs, manufacturing and process development personnel.

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

• Explain the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move your products through clinical development into the marketplace
• Explain the importance and underlying principles for CMC regulatory compliance of biopharmaceuticals and how this leads regulatory agencies to have different CMC regulatory requirements for biotech products compared to pharmaceuticals of chemical origin

FACULTY
John Geigert, PhD, RAC, President, BioPharmaceutical Quality Solutions

Preparing for Regulatory Inspections for the FDA and EMA

Location: Renaissance Washington, DC Downtown Hotel | Washington, DC
Date: September 14-15, 2017
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.

Course Number: 307
CPE: ACPE #0116-0000-16-047-L04-P | 1.2 CEUs
Type of Activity: Knowledge

The objective of this two-day lecture course is to assist you when you prepare to host an inspection. This course will take an in-depth look at FDA and EMA inspection authority and practices, highlight important references to use for preparation and provide practical, real-life examples of best practices and pitfalls to avoid. Recent changes to the FDA inspection authority for pharmaceutical inspections were brought about by the FDA Safety and Innovation Act (FDASIA) legislation. This course will address those changes and the resulting changes that may be needed in company inspection management procedures and training. Concepts discussed will have relevance both for GMP and GCP inspections, with the primary focus being GMP.

WHO SHOULD ATTEND
This course is designed for manufacturing, regulatory and quality personnel involved in hosting and managing an EMA or FDA site inspection.

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

• Discuss background information regarding the EU, EU governing documents, GMP rules and the EMA
• Identify the inspection techniques and methodologies used by the EMA inspectorate
• Discuss and apply the EU GMP rules – Eudralex Volume 4 and Annexes and other guidance documents that impact inspections
• Discuss strategies for hosting and managing FDA and EMA inspections
• Compare and contrast FDA and EMA inspections
• Create resolutions to a variety of issues that may arise during an inspection

FACULTY
Dave Chesney, Principal and General Manager, DL Chesney Consulting, LLC
Contact Information

PDA Membership Number

Prefix  First Name                  Last Name

Job Title                     Government/Health Authority

Business Address (must match credit card statement)

Name (exactly as it appears on card)        Signature

PDA USE ONLY

Date:        Check:             Amount:        Account:

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2017 PDA Joint Regulatory Conference (September 11-13) Renaissance Washington, DC Downtown Hotel | Washington, DC Exhibition: September 11-12 PDA will independently present:
2017 PDA PAC IAM Workshop: September 13-14, co-sponsored by IFPMA 2017 PDA Regulatory Course Series: September 14-15

2017 PDA/FDA Joint Regulatory Conference

2017 PDA PAC IAM Workshop | September 13-14

Please check appropriate fee (US$).

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2017 PDA/Health Authority/Academic

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The cost of food functions is $350.

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.

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Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted).

Refunds for Courses: If your written request is received by August 15, 2017, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. Onsite registrants are not guaranteed to receive Conference materials until all advance 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 cancelled, 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 cancellation. For more details, contact PDA at info@pda.org or +1 (301) 965-5000.

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 August 15, 2017, you will receive a full refund minus a $200 processing fee. After that time, no refunds will be approved. COURSE CANCELLATION: PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be cancelled, 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 cancellation. 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.
The Parenteral Drug Association will independently present the...

2017 PDA PAC iAM Workshop
September 13-14, 2017 | Washington, DC
Renaissance Washington, DC Downtown Hotel
Exhibition: September 13-14
#2017PAC


dai.org/2017PAC

Science- and Risk-Based Approaches to Technical Change Management

The 2017 PDA PAC iAM Workshop will provide overviews and insights on how industry and regulatory authorities are working together to streamline and harmonize post-approval changes (PAC). It will also include updates on the development of a new guidance, ICH Q12.

At this Workshop, take part in interactive plenary and small group discussion sessions that will explore global harmonization of post approval change including use of change management protocols, and lifecycle management. Members of the ICH Q12 EWG will be in attendance to listen to your current PAC management challenges and discuss future concepts.

Learn more and register at pda.org/2017PAC

2017 PDA/FDA Joint Regulatory Conference
Sept. 11-13, 2017 | Washington, DC
Renaissance Washington, DC Downtown Hotel
EXHIBITION: SEPTEMBER 11-12

Exhibit and Support Opportunities Available!

Network, Collect Intelligence and Forge Key Relationships
The PDA/FDA Joint Regulatory Conference is one of PDA’s Signature Events, and one of our most popular meetings, typically attracting more than 700 Conference attendees. With multiple networking breaks and reception, exhibitors have ample time to connect with their desired audience of industry leaders, strengthen business relationships and create new sales leads. As an exhibitor, you will gain access to hundreds of industry professionals with direct responsibility in biopharmaceutical manufacturing, quality, compliance, operations, supply chain, engineering, project management, regulatory affairs and science.

Increase Brand Recognition
High-profile support packages are available for lanyards, notepads, wireless internet service, audience response systems, tote bags, hotel keycards, mobile device charging stations, refreshment breaks, lunch and networking reception. We’ll create a customized support package to fit your needs and budget.

For more information about exhibit and support opportunities, please contact:

David Hall
Tel: +1 (240) 688-4405
Email: hall@pda.org

Alison Caballero
Tel: +1 (301) 656-5900 ext. 135
Email: caballero@pda.org

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