PDA/FDA Joint Regulatory Conference

Putting Patients First: Ensuring Innovation, Quality, Compliance, and Supply in an Evolving Environment

September 24-26, 2018 | Renaissance Washington, DC Downtown Hotel | Washington, DC

SUNDAY, SEPTEMBER 23

3:00 p.m. – 6:00 p.m.
Registration Open

5:00 p.m. – 6:00 p.m.
2018 PDA/FDA Joint Regulatory Conference Program Planning Committee Meeting (Invitation Only)

MONDAY, SEPTEMBER 24

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

7:00 a.m. – 8:00 a.m.
PDA Orientation Breakfast (Invitation Only)
Supported in part by Amgen Inc.

7:00 a.m. – 8:30 a.m.
Continental Breakfast

8:15 a.m. – 10:00 a.m. | Grand Ballroom
P1: Taking Stock of the Drug Supply Chain
Moderator: Richard L. Friedman, MS, Deputy Director, OMQ, CDER, FDA

This year’s conference occurs 10 years after the heparin supply chain crisis. Since that time, industry has enhanced supply chain management while also adjusting to further evolutions in the global market. In addition to industry’s progression, the passage of the landmark FDASIA legislation in 2012, and subsequent amendments to the Act, provided the FDA with modern authorities that help the Agency to better regulate quality and safety of drugs in the global supply chain.

This opening plenary session will focus on current priorities of regulators and industry in the area of drug product supply, with a focus on effective risk management of today’s complex global supply chains to assure reliable manufacturing, quality, and availability of medicines. Each of these are integral to “Putting Patients First.” The value of synergistic partnerships between industry and regulators to ensure strong public health standards for safety and effectiveness, while also accelerating access to groundbreaking medical products will also be discussed.

8:15 a.m. – 8:30 a.m.
Welcome and Opening Remarks from PDA Leadership and Conference Co-Chairs
Richard Johnson, President & CEO, PDA
Rebecca Devine, PhD, Regulatory Consultant and Chair, PDA Board of Directors
Richard L. Friedman, MS, Deputy Director, OMQ, CDER, FDA

8:30 a.m. – 9:00 a.m.
Anna Abram, Deputy Commissioner for Policy, Planning, Legislation and Analysis, FDA

9:00 a.m. – 9:30 a.m.
Esteban Santos, MS, Executive Vice President, Operations, Amgen, Inc.

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

10:00 a.m. – 10:45 a.m.
Refreshment Break in Exhibit Area
Supported in part by Sparta Systems, Inc.

10:45 a.m. – 12:15 p.m.
P2: The Evolving Regulatory Landscape
Moderator: Rebecca Devine, PhD, Regulatory Consultant

This session will provide a high-level overview of the major regulatory initiatives at the FDA and in the EU. FDA will provide updates on topics such as program alignment, organizational changes, key inspectional priorities, and response to supply chain disruptions. The session will also cover EU hot topics, including changes in the EU with the impact of BREXIT, the EMA headquarters move, and other global issues affecting the pharmaceutical supply chain and drug availability. The presenters will also discuss harmonization topics, including Mutual Recognition Agreements (MRA) and PIC/S collaboration.

10:45 a.m. – 11:15 a.m.
Alonza E. Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA

11:15 a.m. – 11:45 a.m.
John Lynch, MSc, MPSI, Director of Compliance, Health Products Regulatory Authority

11:45 a.m. – 12:15 p.m.
Lunch on your own (Exhibit Area Closed) – A listing of local restaurants is available at the PDA Registration Desk. Boxed lunches will also be available for purchase.

Interest Groups
1:45 p.m. – 3:15 p.m.

Concurrent Sessions

<table>
<thead>
<tr>
<th>LIFECYCLE MANAGEMENT AND INNOVATION</th>
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<tr>
<td><strong>A: Combination Products</strong>&lt;br&gt;Moderator: Lucy Cabral, Senior Director, Global External Quality, Roche Genentech**&lt;br&gt;Do you have a strong understanding of combination products requirements? Do your processes and systems meet the regulatory agency expectations? What do we need to put in place for smart devices? In this session, presentations will address both standards and connectivity with existing devices.</td>
<td><strong>B1: Aseptic Processing/Annex 1</strong>&lt;br&gt;Moderator: Carol L. Rehkof, Chief, Review Management Business Operations Staff, CBER, FDA**&lt;br&gt;The global healthcare system relies on numerous critical injection products to cure and mitigate disease and illness. Most of these injections are made by aseptic processing, rather than terminal sterilization. Substandard manufacturing conditions at an aseptic processing facility can pose a risk to patients both due to contamination hazards and supply shortfalls. This session will address the technological and risk management framework that ensures robustness in an aseptic processing operation. It will also explore current regulatory expectations and include an update on the Annex 1 revision.</td>
<td><strong>C1: Effective Supplier Quality Audit Programs</strong>&lt;br&gt;Moderator: David J. Jaworski, MBA, Senior Policy Advisor, CDER, FDA**&lt;br&gt;The quality of a company’s drug products is directly connected to the strength and quality of its suppliers and partners. Therefore, the effectiveness of a supplier quality audit program is critical to a firm’s success. The speakers at this session will explore practices used to identify partners and suppliers that share the same quality standards. The speakers will also discuss how to integrate risk-based approaches into effective audit programs, and they will share best practices for sustaining an effective supply chain oversight program.</td>
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<td>1:45 p.m. – 2:15 p.m.&lt;br&gt;Considerations in Development of Delivery Devices and Connected Solutions&lt;br&gt;Anthony L. Schaff, Sr., PE, Senior Engineering Advisor, Eli Lilly and Company</td>
<td>1:45 p.m. – 2:15 p.m.&lt;br&gt;Sterile Manufacturing: An MHRA Inspector’s Perspective, Including an Annex 1 Update&lt;br&gt;Tracy Moore, GMDP Operations Manager and Senior Inspector, Inspection Enforcement and Standards Division, Medicines and Healthcare Products Regulatory Agency (MHRA)</td>
<td>1:45 p.m. – 2:15 p.m.&lt;br&gt;Industry Perspective on Effective Supplier Quality Audit Programs&lt;br&gt;James M. Fries, MBA, CEO, Rx-360</td>
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| 3:15 p.m. – 4:00 p.m.<br>Refreshment Break in Exhibit Area<br>Supported in part by Corning | 3:15 p.m. – 4:00 p.m.| 4:00 p.m. – 5:30 p.m.

Concurrent Sessions

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<td><strong>A2: Aging Facilities and Quality Risk Management</strong>&lt;br&gt;Moderator: Paul Perdue, Jr., Branch Chief, Pharmaceutical Quality Program Operations Branch, ORA, FDA**&lt;br&gt;Manufacturing capability and quality problems are a major factor in shortages of</td>
<td><strong>B2: A Successful Journey under Consent Decree</strong>&lt;br&gt;Moderator: David Doleski, Compliance Head for Biologics Quality Operations, Sanofi**&lt;br&gt;This session will explain how consent decrees are negotiated and the possible elements of a consent decree. A company will describe its</td>
<td><strong>C2: CMO Oversight: Challenges and Opportunities</strong>&lt;br&gt;Moderator: Tim G. Kilroy, PhD, Director, Global Quality Audits, Bristol-Myers Squibb**&lt;br&gt;This session will explore CMO relationships and delve into the challenges and best practices of performing quality oversight of</td>
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**Concurrent Breakfast Sessions**

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<td>8:15 a.m.</td>
<td>Breakfast 1: Microbiology Issues Moderator: Clarice Haigh Hutchens, PhD, Pfizer Biotech</td>
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<td>8:30 a.m.</td>
<td>Breakfast 2: Container Closure Integrity Testing Moderator: Mai X. Huynh, MS, CVM FDA</td>
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<td>9:00 a.m.</td>
<td>Breakfast 3: Breakfast with the FDA Moderator: Douglas A. Campbell, InterPro QRA</td>
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<td>10:00 a.m.</td>
<td>Breakfast 4: 503B Compounding Moderator: Susan Schniepp, Pfizer Biotech</td>
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**TUESDAY, SEPTEMBER 25**

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<tr>
<td>TUESDAY, SEPTEMBER 25</td>
<td>4:00 p.m. – 4:30 p.m. Peter E. Gallagher, MBA, Vice President, Strategic Affairs, Teligent, Inc.</td>
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<td>Remediation of Aging Facilities and Equipment Ronald A. Berk, Chief Technology Officer, Hyde Engineering + Consulting</td>
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<td>5:00 p.m. – 5:30 p.m. Panel Discussion with Presenters and Additional Participants Ileana Barreto-Pettit, RN, MPH, Captain, U.S. Public Health Service, Drug National Expert, Ora, Fda (Invited) Anthony F. Lorenzo, Lead Consumer Safety Officer, Cber, Fda John Lynch, Msc, Mysi, Director of Compliance, Health Products Regulatory Authority</td>
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<td>5:45 p.m. – 6:45 p.m. Interest Groups 6:45 p.m. – 10:00 p.m. Networking Reception</td>
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<th>Breakfast 1: Microbiology Issues Moderator: Clarice Haigh Hutchens, PhD, Director, Global Chemistry Manufacturing Control Advisory Office, Worldwide Safety and Regulatory, Pfizer Biotech</th>
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<tr>
<td>In this session, presenters will discuss common issues regarding microbiological data integrity and investigations of sterility failures.</td>
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<tr>
<th>Breakfast 2: Container Closure Integrity Testing Moderator: Mai X. Huynh, MS, Supervisory Team Leader, Antimicrobial Team, Cvm, Fda</th>
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<td>The assurance of product quality depends on the ability of the product to maintain integrity throughout the stresses anticipated during storage, distribution, and use. Therefore, satisfactory package integrity is a critical parameter for all parenteral products. Choosing the appropriate integrity test method.</td>
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<th>Breakfast 3: Breakfast with the FDA Moderator: Douglas A. Campbell, Senior Consultant, InterPro Qra</th>
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<td>Set your alarm to attend this eye-opening breakfast session that will allow for your direct input and provide you with insights regarding inspections trends and center initiatives, including serialization. This session gives you the chance for a Q&amp;A with FDA investigators and Center representatives during your</td>
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<th>Breakfast 4: 503B Compounding Moderator: Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.</th>
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<td>Come and hear the latest information and developments regarding 503B Pharmacy Compounds (Outsourcing Facilities). PDA’s compounding pharmacy expert, Chris Small, and one of FDA’s experts in this area, Ian Deave, will discuss the regulations affecting 503B facilities. Their presentations will be followed by an audience.</td>
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for your container closure can be a challenge. This session will provide some key points to consider when selecting traditional versus more recent or advanced leak test methods, including discussion on feedback received since the revision of USP <1207>, Package Integrity Evaluation – Sterile Products.

attendance at this premier pharmaceutical manufacturing event.

participation question and answer session.

7:15 a.m. – 7:35 a.m.
Meaningful Investigations of Sterility Failures from the Perspective of a USFDA Microbiologist
Jennifer M. Gogley, Microbiologist, ORA, FDA (Invited)
7:35 a.m. –7:55 a.m.
Microbial Integrity
Paul Stinavage, PhD, Senior Manager, Pfizer Inc.
7:55 a.m. –8:15 a.m.
Questions and Answers/Discussion

7:15 a.m. – 7:30 a.m.
Container Closure Integrity Testing <USP 1207>
Donald C. Singer, Manager, Steriles Microbiology, GlaxoSmithKline
7:30 a.m. – 7:55 a.m.
FDA Perspectives on Container Closure Integrity
Christine Harman, PhD, Chemist, CBER, FDA
Jason A. Rossi, MS, Review Chemist, Division of Manufacturing Technologies, CVM, FDA
Marla Stevens-Riley, PhD, Master Microbiology Reviewer, Quality Assessment Lead, CDER, FDA
7:55 a.m. – 8:15 a.m.
Questions and Answers/Discussion

7:15 a.m. – 8:15 a.m.
Panel Discussion
James L. Dunnie, Consumer Safety Officer, ORA, FDA (Invited)
Carl Fischer, PhD, Senior Advisor, Office of Compliance, CDRH, FDA
Marea K. Harmon, Compliance Officer, Division of Compliance and Surveillance, CVM, FDA
Brooke K. Higgins, MS, Senior Policy Advisor, CDER, FDA (Invited)
Connie T. Jung, RPh, PhD, Senior Advisor for Policy, CDER, FDA
Simone E. Pitts, CSO (Biologics), ORA, FDA

7:15 a.m. – 7:35 a.m.
Two Big “Whys” of Compounding Pharmacy
Christopher J. Smalley, PhD, Compounding Pharmacist Advisor, ValSource, LLC
7:35 a.m. – 7:55 a.m.
Insanitary Conditions and CGMP Requirements for Outsourcing Facilities
Ian F. Deveau, PhD, Supervisory Consumer Safety Officer, CDER, FDA
7:55 a.m. –8:15 a.m.
Questions and Answers/Discussion

8:30 a.m. – 10:00 a.m.
P3: Compliance Updates
Moderator: David Doleski, Compliance Head for Biologics Quality Operations, Sanofi

This session is one of the highlights of the Conference, featuring Compliance Directors from the FDA Centers and Office of Regulatory Affairs. It will focus on problem areas that FDA has found during inspections, significant regulatory actions initiated, and FDA’s current enforcement strategy for a wide array of regulated products. FDA’s top leaders in Compliance and Enforcement will describe their programs and initiatives related to inspection and compliance activities. This is the best possible opportunity for you to understand FDA’s thinking and expectations for GXP compliance of the industry. Most importantly, there will be ample time for the audience to ask probing questions of FDA’s top leadership. This very popular session is one you cannot afford to miss.

8:30 a.m. – 10:00 a.m.
Panel Discussion
Donald D. Ashley, JD, Director, Office of Compliance, CDER, FDA
Carl Fischer, PhD, Senior Advisor, Office of Compliance, CDRH, FDA
Martine Hartogensis, DVM, Deputy Director, Office of Surveillance and Compliance, CVM, FDA
Melissa J. Mendoza, Deputy Director, Director, Office of Compliance and Biologics Quality, CBER, FDA
Armando P. Zamora, Deputy Director, Office of Enforcement and Import Operations, ORA, FDA

10:00 a.m. – 10:45 a.m.
Refreshment Break in Exhibit Area
10:45 a.m. – 12:15 p.m.
Concurrent Sessions

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<td>A3: Product Lifecycle Management and Q12 Modera: CDR Tara Goen Bizjak, MS, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, FDA</td>
<td>B3: Inspections and Compliance Update Moderator: David L. Chesney, Principal and General Manager, DL Chesney Consulting, LLC It’s back by popular demand! This session will include short presentations from CDER and CBER Compliance Managers that are designed</td>
<td>C3: Shortage Prevention and Availability: Disaster Recovery Case Studies Moderator: Renée Kyro, MBA, Director Share Services, Quality Assurance, Abbvie Inc. 2017 was an unprecedented year of natural disasters, with earthquakes in Mexico; wild</td>
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resulting in additional costs and potential supply disruption. Does Q12, with established conditions, post-approval change management protocols (PACMPs), and product lifecycle management plans, lay out a path forward to further incentivize manufacturers to make improvements, increase process robustness, and facilitate change implementation? What are practical quality considerations for implementing these approaches in a pharmaceutical quality system? The speakers at this session will focus on case studies relevant to brand small molecule and biologic products. The speakers will also provide an update on PDA’s efforts on the Post-Approval Changes for Innovation in Availability of Medicines (PACIAM) with respect to Q12; including an update on an associated PDA technical report on product lifecycle and post-approval change management for biologics and pharmaceutical drug products. The session will close with a panel discussion and include a regulatory perspective.

10:45 a.m. – 11:00 a.m.
**Introduction to Q12 and Established Conditions**
Ashley B. Boam, MSBE, Director, OPPQ, CDER, FDA

11:00 a.m. – 11:20 a.m.
**ECs, PACMPs, PQS, and MAb...BFFs**
Shannon F. Holmes, PhD, RAC, Director, Product Development Quality, Biogen Inc.

11:20 a.m. – 11:40 a.m.
**ICH Q12 – Global Change Management Made Easier? A Small Molecule Case Study**
Kara Follmann, PhD, Senior Director, Pfizer Essential Health Global Regulatory Affairs, Brands CMC, Pfizer Inc.

11:40 a.m. – 12:00 p.m.
**Update on PDA’s PACIAM Activities with Respect to ICH Q12**
Karolyn Gale, Senior Manager, Regulatory Affairs, EmergeBioSolutions

12:00 p.m. – 12:15 p.m.
**Panel Discussion with Presenters and Additional Participants**
Chikako Torigoe, Biologist, CBER, FDA

10:45 a.m. – 11:05 a.m.
**CDER Compliance Update**
Francis Godwin, MBA, Office Director (Acting), Office of Manufacturing Quality, CDER, FDA

11:05 a.m. – 11:25 a.m.
**CBER Compliance Update**
Maria C. H. Anderson, MS, Chief, Biological Drug and Device Compliance Branch, CBER, FDA (Invited)

11:25 a.m. – 11:45 a.m.
**ORA Inspection and Enforcement Update**
Nicholas A. Violand, Consumer Safety Officer, ORA, FDA (Invited)

11:45 a.m. – 12:15 p.m.
**Panel Discussion with Presenters and Additional Participants**
Ileana Barreto-Pettit, RN, MPH, Captain, U.S. Public Health Service, Drug National Expert, ORA, FDA (Invited)

Myriam M. Sosa, MS, President, Solamere Healthcare

10:45 a.m. – 11:15 a.m.
**The María Experience: Challenges and Opportunities**
Saritza E. Ríos-Solá, Director, Quality Assurance, AbbVie Ltd.

11:15 a.m. – 11:45 a.m.
**Emergency Preparedness and Lessons Learned from Hurricane Maria**
Christopher M. Jones, MBA, Vice President, Operations Strategy and External Contract Manufacturing, Baxter Healthcare Corporation

11:45 a.m. – 12:15 p.m.
**Panel Discussion with Presenters and Additional Participants**
CAPT Valerie E. Jensen, RPh, Associate Director of the Drug Shortage Staff, CDER, FDA

Andrei E. Nabakowski, PharmD, Director, Office of Emergency Operations, OC, FDA (Invited)

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. Boxed lunches will also be available for purchase.

12:30 p.m. – 1:30 p.m.
**Interest Groups**

1:45 p.m. – 3:15 p.m.
**Concurrent Sessions**

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<tr>
<td>A4: Process Validation Implementation: Taking Stock, Where are We? Moderator: Mai X. Huynh, MS, Supervisory Team Leader, Antimicrobial Team, CVM, FDA</td>
<td>B4: Trending for Quality Moderator: Myriam M. Sosa, MS, President, TGG, LLC</td>
<td>C4: Supply Chain Issues and Innovative Products for Cell and Gene Therapy Moderator: John D. Ayres, MD, JD, Pharma Safety Solutions, LLC</td>
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Where are we with the process validation since the publication of the 2011 FDA Guidance for Industry, “Process Validation – General Principles and Practices?” This session offers an opportunity for industry and FDA to share their experiences regarding how the principles and approaches described in the current guidance apply to the manufacturing process, including process design, process qualification, and continued process verification. The session will share lessons learned from both the industry and FDA perspectives.

Trending of quality data can be used to control processes to maintain their validated state and to monitor process performance for early detection of excursions from the validated state. Data for trending includes process parameters, materials, performance and quality indicators, and complaint data. Methods include Shewhart control charts and more advanced trending tools like CUSUM charts and changepoint analysis. Methods are available for both attribute (pass/fail) data and measurable characteristics. The basic process of setting up a trending program, from deciding what to trend, how to trend it and actions to take will be covered.

Innovation in cell- and gene-based therapeutics continues to advance rapidly. It is critical that supply chain and product integrity systems evolve to meet the unique demand these products present. Supply chain security is critical to avoid environmental excursions, trauma, or diversion. For cell therapies, although both allogeneic and autologous cell sources are utilized therapeutically, autologous cells present significant chain-of-custody challenges that must be demonstrated as fail-safe to ensure that the donor-recipient match (needle-to-needle) is maintained. Likewise, gene therapy presents its own unique issues related to viral and non-viral vectors and associated challenges. This session will explore these issues and considerations around integrating cGMP and quality systems for cell and gene therapy products, and recent FDA guidance for these therapies.

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<td>1:45 p.m. – 2:15 p.m.</td>
<td>Learning to Love the Validation Lifecycle: Reflections and Musings</td>
<td>Kenneth D. Hinds, PhD, Scientific Director, Janssen R&amp;D, LLC</td>
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<td>2:15 p.m. – 2:45 p.m.</td>
<td>Process Validation: Important Indicator of Process Understanding</td>
<td>José E. Meléndez, FDA Drug National Expert, ORA, FDA (invited)</td>
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<tr>
<td>2:45 p.m. – 3:15 p.m.</td>
<td>Panel Discussion with Presenters and Additional Participants</td>
<td>Alexey Khrenov, PhD, Senior Staff Fellow, CBER, FDA</td>
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<td>Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, FDA</td>
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<td>1:45 p.m. – 2:20 p.m.</td>
<td>Trends in Product Quality Improvements</td>
<td>CDR Tara Goen Bizjak, MS, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, FDA</td>
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<td>2:20 p.m. – 2:55 p.m.</td>
<td>Statistical Methods for Trending Quality Data</td>
<td>Wayne A. Taylor, PhD, Chairman, Taylor Enterprises, Inc.</td>
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<td>2:55 p.m. – 3:15 p.m.</td>
<td>Questions and Answers/Discussion</td>
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<td>4:00 p.m. – 5:30 p.m.</td>
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**LIFE CYCLE MANAGEMENT AND INNOVATION**

A5: Hot Topics in Submissions
Moderators: Reyes Candau-Chacon, PhD, Biologist, CDER, FDA and Laurie P. Norwood, Deputy Director, Division of Manufacturing Product Quality, OCBQ, CBER, FDA
How are industry and FDA adapting to meeting the shorter review timeframes for applications required for breakthrough products regulated by CBER and CDER? Are there new challenges in the review and inspection process of biosimilar applications? What are the FDA expectations for new transition biological products? In this session, FDA and industry experts will present case studies that will address manufacturing and...

**QUALITY AND COMPLIANCE**

B5: Quality Systems
Moderator: Enrique Diloné, PhD, RAC, Senior Vice President, Technical Operations, Amicus Therapeutics, Inc.
In this session, speakers will discuss quality issues facing biotech companies. Biotech companies in clinical development may not have a fully established quality management system (QMS). Their quality functions may be challenged to meet increasing compliance requirements while enabling business objectives in highly dynamic environments. As biotech companies mature from clinical development into global commercial operations, the QMS and quality culture must...

**SUPPLY CHAIN**

CS: Ingredient Supplier Oversight
Moderator: Lucy Cabral, Senior Director, Global External Quality, Roche Genentech
How robust is your company’s process for qualification, management, and risk reduction of your suppliers of API and excipients? Does your process prevent quality failures and ensure uninterrupted supply to the patients your company serves? In this session, participants will hear from Dr. Marla Phillips as she presents practical paradigm-shifting supply chain practices you can implement today from the Xavier University Good Supply Practices (GSPs) Initiative led by FDA officials and industry professionals across the pharma...
Concurrent Breakfast Sessions

7:15 a.m.
Continental Breakfast

Interest Group Sessions

WEDNESDAY, SEPTEMBER 26

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

7:00 a.m. – 8:30 a.m.
Continental Breakfast

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

Breakfast 5: Green Chemistry and Product Sustainability
Moderator: Clarice Haigh Hutchens, PhD, Director, Global Chemistry Manufacturing Control Advisory Office, Worldwide Safety and Regulatory, Pfizer Biotech

This session will focus on three dimensions of Sustainability relevant to Pharma — (1) EHS Site Facilities’ focus on energy, waste, and water; (2) researchers’ focus on green chemistry and sustainable processes; and (3) product sustainability and branding perspective with approaches to telling the “story.”

Breakfast 6: Evolving Large Volume Parenteral Manufacturing
Moderator: Jacqueline Kunzier, MBA, PhD, Senior Vice President, Chief Quality Officer, Baxter

This session will review the history of large volume parenteral (LVP) manufacturing and contemplate where the future should lead. What is the Agency’s perspective on areas that need additional focus in LVP manufacturing? How can industry drive meaningful change in a commoditized market?

Breakfast 7: Restricted Access Barrier Systems and Isolators: Current Perspectives
Moderator: David J. Jaworski, MBA, Senior Policy Advisor, CDER, FDA

This session is focused on the significant sterility assurance benefits of using restricted access barrier and isolator systems to manufacture sterile biologic and drug products. These systems, when used and maintained properly, are exceptional; however, as the speakers will discuss, there are a number of critical variables that must be carefully controlled to assure quality.

Breakfast 8: Water Systems
Moderator: Shane Killian, MS, Senior Director, Licensing & Acquisition Head, Johnson & Johnson

Maintaining a qualified pharmaceutical water system requires key design elements and a reliable maintenance plan, especially if you are dealing with an aging facility. This session will bring us “back to basics” with water system types, design elements, maintenance, and monitoring.

Breakfast 9: Training Effectiveness
Moderators: Douglas A. Campbell, Senior Consultant, Interpro QRA and Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

There is a common effort throughout the industry to better manage the training program. There is also a general understanding of the cycle of training/re-training as a component of many corrective actions. This session is designed to provide insight related to the evaluation of the effectiveness of training. These types of evaluations can provide value added, not only to the training program and the qualifications of the employees, but also to the organization through the
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<th>Time</th>
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<tr>
<td>7:15 a.m.</td>
<td>Green Chemistry in Research and Facilities</td>
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<td>7:15 a.m.</td>
<td>Visual Inspection Advancesments in Flexible Packaging</td>
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<td>7:45 a.m.</td>
<td>Panel Discussion with Presenter and Additional Participants</td>
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<td>7:15 a.m.</td>
<td>Control of Pharmaceutical Water Systems: A Regulatory Perspective</td>
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<td>7:15 a.m.</td>
<td>Achieving Success through an Effective Training Program</td>
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Moderator: Ashley B. Boam, MSBE, Panel Discussion

11:00 a.m. – 11:30 a.m.

Lead Proudly to Failure, or Ask Why
Paul Sean Hill, Former NASA Flight Director

11:00 a.m. – 12:00 p.m.

Panel Discussion with Presenters and Additional Participants
Ashley B. Boam, MSBE, Director, OPPQ, CDER, FDA
12:00 p.m. – 12:15 p.m.
Closing Remarks and Introduction of 2019 PDA/FDA Joint Regulatory Conference Co-Chairs