2018 PDA/FDA Joint Regulatory Conference

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

PATIENT FOCUS/PATIENT FIRST
CONTINUOUS MANUFACTURING
COMPLIANCE
QUALITY ASSURANCE INNOVATION
SPEED TO MARKET/QUALITY OF GOODS
QUALITY REGULATIONS
CGMP
DRUG SHORTAGE

SUPPLY IN EVOLVING LANDSCAPE
QUALITY MANAGEMENT
PROCESS VALIDATION
10 YEARS AFTER HEPARIN
COMPLEX SUPPLY CHAIN
SUPPLY CHAIN RISK
CONTRACT MANUFACTURERS
NEW TECHNOLOGIES
LIFECYCLE
INNOVATION
SUPPLY SPEED
GLOBALIZATION TECHNOLOGY
GENE THERAPY
CONSISTENCY OF SUPPLY
QUALITY ASSURANCE
CONTINUOUS MANUFACTURING
AVAILABILITY

September 24-26, 2018 | Washington, DC
Exhibition: September 24-25
#2018PDAFDA

This Agenda is current as of July 5, 2018

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS
Program Planning Committee

Program Co-Chairs
Rebecca Devine, PhD
Consultant to the Biopharmaceutical Industry
Richard L. Friedman, MS
FDA

John D. Ayres, MD, JD, Eli Lilly and Company
Tara Gooen Bizjak, MS, FDA
Lucy Cabral, Roche - Genentech
Douglas A. Campbell, Interpro ORA
Reyes Candau-Chacon, PhD, FDA
David L. Chesney, DL Chesney Consulting, LLC
David Doleski, Sanofi
Enrique Diloné, PhD, RAC, Amicus
Clarice Haigh Hutchens, PhD, Pfizer Biotech
Mai X. Huynh, MS, FDA
David J. Jaworski, MBA, FDA
Shane Killian, MS, Johnson & Johnson
Tim G. Kilroy, PhD, BristolMyersSquibb
Jacqueline Kunzler, PhD, MBA, Baxter
Renée Kyro, MBA, AbbVie
Laurie P. Norwood, FDA
Paul Perdue, Jr., FDA
Carol L. Rehkopf, FDA
Susan Schniepp, Regulatory Compliance Associates Inc.
Myriam M. Sosa, MS, Merck & Co.
Valerie Whelan, Amgen Inc.
Kenneth E. Nolan, FDA
Denyse D. Baker, PE, RAC, PDA
Jason E. Brown, PDA
Molly O’Neill Moir, CMP, PDA

Dear Friends, Colleagues, and Peers:

It is time to mark your calendars and make plans to participate in the 2018 PDA/FDA Joint Regulatory Conference being held September 24-26, 2018 at the Renaissance Washington, DC Downtown Hotel in Washington, DC. This year marks the 27th year that PDA and FDA have collaborated on this Conference! This year’s theme is Putting Patients First: Ensuring Innovation, Quality, Compliance, and Supply in an Evolving Environment. 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 keynote addresses highlighting the synergistic partnerships between industry and the FDA that work to ensure gold standards for safety and effectiveness are upheld, while also addressing the accelerating access to groundbreaking medical products that improve public health globally.

This will be followed by a second plenary session that covers the evolving regulatory landscape, from both a U.S. and EU perspective, with presentations by Alonza Cruse, Director, Office of Pharmaceutical Operations, ORA, FDA, and John Lynch, Acting Director of Human Products Assessment and Registration, HPRA.

Additional plenary sessions will offer insight into current regulatory initiatives and industry practices that lead to robust quality. Back by popular demand, the conference will include two plenary sessions with senior FDA officials: Center Updates and Compliance Updates.

The closing plenary will address Quality Culture, with presentations by Paul Sean Hill, former Flight Director, NASA and Scott C. Nickerson, Head of Quality, Moderna Therapeutics.

This year’s breakout sessions are divided into three parallel tracks, Lifecycle Management and Innovation, Quality and Compliance, and Supply Chain, addressing important topics in each respective area.

Breakfast sessions tailored to the early-riser will focus on topics such as microbiology issues, container closure integrity, serialization, Section 503 drug compounding, water systems, and Breakfast with the FDA.

New this year, we will hold PDA Interest Group sessions during both the lunch hour and at the end of the day on Monday and Tuesday.

We look forward to seeing you in September at the 2018 PDA/FDA Joint Regulatory Conference!
2018 PDA/FDA Joint Regulatory Conference
September 24-26, 2018 | Washington, DC
Exhibition: September 24-25
#2018PDAFDA

- Understand lifecycle management for medical products, such as managing post-approval changes, updating aging facilities, and assuring adequate process validation
- Understand the latest aseptic processing requirements
- Understand how to respond to enforcement actions such as a consent decree
- Identify Quality Systems requirements and the use of quality risk management
- Decrease the risk of your supply chain by appropriately managing CMOs and suppliers
- Identify current inspection findings to ensure your facility is inspection ready

WHO SHOULD ATTEND

Job Functions  Compliance/Inspection Management | Supply Chain | Auditing | Executive Management
Departments  Research and Development | Regulatory Affairs | Manufacturing | Quality | Assurance/Control | Marketing | Sales
Academia  Pharmaceutical Sciences | Regulatory Science

CONFERENCE REGISTRATION HOURS

Sunday, September 23: 3:00 p.m. – 6:00 p.m.
Monday, September 24: 7:00 a.m. – 7:00 p.m.
Tuesday, September 25: 7:00 a.m. – 7:00 p.m.
Wednesday, September 26: 7:00 a.m. – 12:00 p.m.

DRESS/ATTIRE

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

SPECIAL REQUIREMENTS

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

CONTACT INFORMATION

Conference Inquiries
Molly O’Neill Moir, CMP, Vice President, Programs & Meetings
Tel: +1 (301) 656-5900 ext. 132 | Email: moir@pda.org
Jason E. Brown, Assistant Director, Programs
Tel: +1 (301) 656-5900 ext. 131 | Email: brown@pda.org

Registration Customer Care
Tel: +1 (301) 656-5900 ext. 115 | Email: registration@pda.org

Exhibition/Sponsorship Inquiries
David Hall, Vice President, Sales
Tel: +1 (240) 688-4405 | Email: hall@pda.org

GENERAL INFORMATION

REGISTER NOW
Online:  pda.org/2018PDAFDA
Fax: +1 (301) 986-1093
Questions? Please call +1 (301) 656-5900 ext. 115

VENUE

Renaissance Washington, DC Downtown Hotel
999 9th Street NW
Washington, DC, USA 20001
Phone: +1 (202) 898-9000
Website: https://book.passkey.com/go/PDAFDA18
Rate: Single/Double: $317, plus applicable taxes
Cut-off Date: Friday, August 10, 2018
A PDA block of rooms is available on a first-come basis and must be secured by the cut-off date to receive the PDA rate. After the cut-off date, rooms will be available at the prevailing rate based on availability.

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 email the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. No exceptions can be given. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2018 PDA/FDA Joint Regulatory Conference
ACPE # 0116-0000-18-015-L04-P | 1.5 CEUs
Type of Activity: Knowledge

LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:
• Understand the current regulatory landscape, new requirements from recent changes, and regulatory authority initiatives that impact the supply chain, quality, and compliance expectations
• Have tools for assuring a safe and secure supply chain, including being prepared for a natural disaster
• Identify mechanisms that assure product availability and avoidance of shortages

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 23

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

MONDAY, SEPTEMBER 24

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

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

8:15 a.m. – 10:00 a.m.
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 (Invited)

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
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: 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.
Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.
Lunch on your own (Exhibit Area Closed) – A listing of local restaurants is available at the PDA Registration Desk. Boxed lunches will also be available for purchase.

12:30 p.m. – 1:30 p.m.
Interest Group Sessions

**NEW THIS YEAR!** PDA will offer Interest Group Sessions both at the lunch hour and in the evenings to ensure that you’re making the most of your time at the Conference!

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**EXHIBITION AND SPONSORSHIP OPPORTUNITIES**

The 2018 PDA/FDA Joint Regulatory Conference offers exciting and unique sponsorship and exhibition packages designed to strengthen brand image, increase visibility, and help you connect with industry leaders. This Conference will bring together industry professionals specializing in quality, compliance, operations, supply chain, engineering, project management, manufacturing, regulatory affairs, and science.

At this Conference, you will be exposed to high-quality leads from a variety of manufacturing companies – making this a must-attend meeting. In addition, high-profile sponsorships are available for lanyards, notepads, audience response systems, tote bags, pens, refreshment breaks, lunch, and networking reception. We’ll create a customized sponsorship package to fit your needs and budget.

For more information about exhibit and sponsorship opportunities, please contact:
David Hall, Vice President, Sales | Tel: +1 (240) 688-4405 | Email: hall@pda.org
MONDAY, SEPTEMBER 24 (CONTINUED)

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

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<tr>
<td>A1: Combination Products</td>
<td>B1: Aseptic Processing/Annex 1</td>
<td>C1: Effective Supplier Quality Audit Programs</td>
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<td>Moderator: Lucy Cabral, Senior</td>
<td>Moderator: Carol L. Rehkopf, Chief, Review Management Business Operations Staff, CBER, FDA</td>
<td>Moderator: David J. Jaworski, MBA, Senior Policy Advisor, CDER, FDA</td>
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<td>Director, Global External Quality,</td>
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<td>Roche – Genentech</td>
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<td>Do you have a strong understanding</td>
<td>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>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>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>
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1:45 p.m. – 2:15 p.m.
Anthony L. Schaff, Sr., PE, Senior Engineering Advisor, Eli Lilly and Company
2:15 p.m. – 2:45 p.m.
CAPT Scott A. Colburn, MS, Director, CDRH Standards Program, CDRH, FDA
2:45 p.m. – 3:15 p.m.
Questions and Answers/Panel Discussion

1:45 p.m. – 2:15 p.m.
Tracy Moore, GMDP Operations Manager and Senior Inspector, Inspection Enforcement and Standards Division, Medicines and Healthcare Products Regulatory Agency (MHRA)
2:15 p.m. – 2:45 p.m.
Virginia Carroll, PhD, Microbiologist, CDER, FDA
2:45 p.m. – 3:15 p.m.
Panel Discussion with Presenters and Additional Participants
Hal Baseman, Chief Operating Officer, ValSource, LLC

1:45 p.m. – 2:15 p.m.
James M. Fries, MBA, CEO, Rx-360
2:15 p.m. – 2:45 p.m.
Ranjani Prabhakara, PhD, Team Leader, CDER, FDA
2:45 p.m. – 3:15 p.m.
Questions and Answers/Discussion

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

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| **A2: Aging Facilities and Quality Risk Management**  
Moderator: Paul Perdue, Jr., Branch Chief, Pharmaceutical Quality Program Operations Branch, ORA, FDA | **B2: A Successful Journey under Consent Decree**  
Moderator: David Doleski, Compliance Head for Biologics Quality Operations, Sanofi | **C2: CMO Oversight: Challenges and Opportunities**  
Moderator: Tim G. Kilroy, PhD, Director, Global Quality Audits, Bristol-Myers Squibb |

Manufacturing capability and quality problems are a major factor in shortages of drugs. While this problem can be greatly solved by upgrades in a company’s manufacturing facilities, needed upgrades are often slowed by a company’s lack of understanding of current technologies or insufficient commitment to invest in more reliable manufacturing equipment. This session will discuss real-world industry case studies of manufacturing upgrades and the economic benefits of these upgrades. The session will also discuss the amenability of regulators to higher capability manufacturing operations through adoption of modern technology and opportunities for regulatory flexibility.

This session will explain how consent decrees are negotiated and the possible elements of a consent decree. A company will describe its journey after entering into a consent decree and its acquisition and remediation of the facility. The road to remediation has required systematic improvements in quality culture and quality systems. Insight into the ongoing efforts and success factors driving this metamorphosis will be explained by senior leadership.

This session will explore CMO relationships and delve into the challenges and best practices of performing quality oversight of externally sourced contract manufacturers and partners. Themes will include risk-based approaches to quality oversight, partnering with the business to build strategic partnerships, and due diligence processes in qualifying CMOs. Speakers will present both industry and regulatory perspectives using case studies.

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<th>4:00 p.m. – 4:30 p.m.</th>
<th>4:00 p.m. – 4:15 p.m.</th>
<th>4:00 p.m. – 4:30 p.m.</th>
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<tr>
<td>Peter E. Gallagher, MBA, Vice President, Strategic Affairs, Teligent, Inc.</td>
<td>David L. Chesney, Principal and General Manager, DL Chesney Consulting, LLC</td>
<td>Brooke K. Higgins, MS, Senior Policy Advisor, CDER, FDA</td>
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<td>4:30 p.m. – 5:00 p.m.</td>
<td>4:15 p.m. – 5:00 p.m.</td>
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<td>Ronald A. Berk, Chief Technology Officer, Hyde Engineering + Consulting</td>
<td>Brandon Varnau, Head of Quality Operations Biologics Platform, Global Quality, Sanofi</td>
<td>Mary Collins, PhD, Executive Director, Quality, External Manufacturing, Bristol-Myers Squibb</td>
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<td>5:00 p.m. – 5:30 p.m.</td>
<td>5:00 p.m. – 5:30 p.m.</td>
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| 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, MPSI, Director of Compliance, Health Products Regulatory Authority | Questions and Answers/Discussion | Questions and Answers/Discussion |
MONDAY, SEPTEMBER 24 (CONTINUED) – TUESDAY, SEPTEMBER 25

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

NEW THIS YEAR! PDA will offer Interest Group Sessions both at the lunch hour and in the evenings to ensure that you’re making the most of your time at the Conference!

6:45 p.m. – 10:00 p.m.
Networking Reception

TUESDAY, SEPTEMBER 24

7:00 a.m. – 7:00 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 1: Microbiology Issues | Breakfast 2: Container Closure Integrity Testing | Breakfast 3: Breakfast with the FDA | Breakfast 4: 503B Compounding Pharmacy
| Moderator: Clarice Haigh Hutchens, PhD, Director, Global Chemistry Manufacturing Control Advisory Office, Worldwide Safety and Regulatory, Pfizer Biotech | Moderator: Mai X. Huynh, MS, Supervisory Team Leader, Antimicrobial Team, CVM, FDA | Moderator: Douglas A. Campbell, Senior Consultant, InterPro QRA | Moderator: Susan Schniepp, Fellow, Regulatory Compliance Associates Inc. |

In this session, presenters will discuss common microbiology issues: endotoxin method challenges, such as LER; investigating micro deviations; low bioburden EM and regulators’ expectations; viral testing; and innovative technology.

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 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.

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&A with FDA investigators and Center representatives during your attendance at this premier pharmaceutical manufacturing event.

Come and hear the latest information and developments regarding 503B Pharmacy Compounders (Outsourcing Facilities). PDA’s compounding pharmacy expert, Chris Smalley, and one of FDA’s experts in this area, Ian Deveau, will discuss the regulations affecting 503B facilities. Their presentations will be followed by an audience participation question and answer session.
Breakfast 1:
Microbiology Issues
(continued)

Breakfast 2:
Container Closure Integrity
Testing (continued)

Breakfast 3:
Breakfast with the FDA
(continued)

Breakfast 4:
503B Compounding
(continued)

received since the revision
of USP <1207>, Package
Integrity Evaluation –
Sterile Products.

7:15 a.m. – 7:30 a.m.
Jennifer M. Gogley,
Microbiologist, ORA, FDA
(Invited)

7:15 a.m. – 7:35 a.m.
Donald C. Singer,
Manager, Steriles
Microbiology,
GlaxoSmithKline

7:15 a.m. – 7:45 a.m.
Christopher J. Smalley,
PhD, Compounding
Pharmacist Advisor,
ValSource, LLC

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

7:30 a.m. – 7:55 a.m.
Panel Discussion
James L. Dunnie,
Consumer Safety Officer,
ORA, FDA (Invited)
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
Program Management,
CDER, FDA (Invited)
Simone E. Pitts, CSO
(Biologics), ORA, FDA
(Invited)

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)
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,
Program Management,
CDER, FDA (Invited)
Simone E. Pitts, CSO
(Biologics), ORA, FDA
(Invited)

7:15 a.m. – 7:45 a.m.
Panel Discussion with
Presenter and Additional
Panelists
Ian F. Deveau, PhD,
Supervisory Consumer
Safety Officer, CDER, FDA

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
FDAs 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
CAPT Sean Boyd,
Deputy Director for Regulatory Affairs, 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
Douglas W. Stearn, JD,
Director, Office of Enforcement and Import Operations, FDA (Invited)
TUESDAY, SEPTEMBER 25 (CONTINUED)

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

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

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

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</table>
| A3: Product Lifecycle Management and ICH Q12  
Moderator: Commander Tara Gooen Bizjak, MS, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, FDA | B3: Inspections and Compliance Update  
Moderator: David L. Chesney, Principal and General Manager, DL Chesney Consulting, LLC | C3: Shortage Prevention and Availability: Disaster Recovery Case Studies  
Moderator: Renée Kyro, MBA, Director Share Services, Quality Assurance, Abbvie Inc. |

A single post-approval change can take three to five years to implement across all regions, 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 (PAC iAM) 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.

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.

2017 was an unprecedented year of natural disasters, with earthquakes in Mexico; wild fires in California; record flooding from monsoons and torrential rainfall across the globe; and hurricanes in Texas, Florida, and Puerto Rico. These events presented significant challenges for our industry to provide assurance of supply to our patients and the handling of drug shortages. Hear from industry leaders and regulators on lessons learned and case studies from some of these catastrophic events.
<table>
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<th>Lifecycle Management and Innovation (continued)</th>
<th>Quality and Compliance (continued)</th>
<th>Supply Chain (continued)</th>
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<td>10:45 a.m. – 11:00 a.m.</td>
<td>10:45 a.m. – 11:05 a.m.</td>
<td>10:45 a.m. – 11:15 a.m.</td>
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<tr>
<td>Ashley B. Boam, MSBE, Director, OPPQ, CDER, FDA (Invited)</td>
<td>Francis Godwin, MBA, Office Director (Acting), Office of Manufacturing Quality, CDER, FDA</td>
<td>Saritza E. Ríos-Solá, Director, Quality Assurance, AbbVie Ltd.</td>
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<tr>
<td>11:00 a.m. – 11:20 a.m.</td>
<td>11:05 a.m. – 11:25 a.m.</td>
<td>11:15 a.m. – 11:45 a.m.</td>
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<tr>
<td>Shannon F. Holmes, PhD, RAC, Director, Product Development Quality, Biogen Idec</td>
<td>Maria C. Anderson, Branch Chief, Biological Drug and Device Compliance Branch, CBER, FDA (Invited)</td>
<td>Christopher M. Jones, MBA, Vice President, Operations Strategy and External Contract Manufacturing, Baxter Healthcare Corporation</td>
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<tr>
<td>11:20 a.m. – 11:40 a.m.</td>
<td>11:25 a.m. – 11:45 a.m.</td>
<td>11:45 a.m. – 12:15 p.m.</td>
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<tr>
<td>Kara Follmann, PhD, Senior Director, Pfizer Essential Health Global Regulatory Affairs, Brands CMC, Pfizer Inc.</td>
<td>Nicholas A. Violand, Consumer Safety Officer, ORA, FDA (Invited)</td>
<td>Panel Discussion with Presenters and Additional Participants</td>
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<td>11:40 a.m. – 12:00 p.m.</td>
<td>11:45 a.m. – 12:15 p.m.</td>
<td>CAPT Valerie E. Jensen, RPh, Associate Director of the Drug Shortage Staff, CDER, FDA</td>
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<td>Karolyn Gale, Senior Manager, Regulatory Affairs, Emergent BioSolutions</td>
<td>Panel Discussion with Presenters and Additional Participants</td>
<td>Andrei E. Nabakowski, PharmD, Director, Office of Emergency Operations, OC, FDA (Invited)</td>
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<td>12:00 p.m. – 12:15 p.m.</td>
<td>Panel Discussion with Presenters and Additional Participants</td>
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<tr>
<td>Panel Discussion with Presenters and Additional Participants</td>
<td>Ileana Barreto-Pettit, RN, MPH, Captain, U.S. Public Health Service, Drug National Expert, ORA, FDA (Invited)</td>
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<tr>
<td>Chikako Torigoe, Biologist, CBER, FDA (Invited)</td>
<td>Marea K. Harmon, Compliance Officer, Division of Compliance and Surveillance, CVM, FDA</td>
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<td>12:15 p.m. – 1:45 p.m.</td>
<td>12:30 p.m. – 1:30 p.m.</td>
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<tr>
<td>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.</td>
<td>Interest Group Sessions</td>
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<tr>
<td>NEW THIS YEAR! PDA will offer Interest Group Sessions both at the lunch hour and in the evenings to ensure that you’re making the most of your time at the Conference!</td>
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### TUESDAY, SEPTEMBER 25 (CONTINUED)

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

<table>
<thead>
<tr>
<th>Lifecycle Management and Innovation</th>
<th>Quality and Compliance</th>
<th>Supply Chain</th>
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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 change-point 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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<tr>
<th>1:45 p.m. – 2:15 p.m.</th>
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<th>1:45 p.m. – 2:15 p.m.</th>
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<tbody>
<tr>
<td>Kenneth D. Hinds, PhD, Director, Drug Product Development, Janssen R&amp;D, LLC</td>
<td>Wayne A. Taylor, PhD, Chairman, Taylor Enterprises, Inc.</td>
<td>Donald B. Ertel, Regulatory Officer, CBER, FDA</td>
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<tr>
<td>Jose E. Melendez, Consumer Safety Officer, ORA, FDA (Invited)</td>
<td>Commander Tara Gooen Bizjak, MS, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, FDA (Invited)</td>
<td>John S. Lunger, MBA, Vice President, Manufacturing and Supply Chain, Adaptimmune Therapeutics</td>
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<tr>
<td>2:15 p.m. – 2:45 p.m.</td>
<td>2:15 p.m. – 2:45 p.m.</td>
<td>2:15 p.m. – 2:45 p.m.</td>
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<tr>
<td>Lifecycle Management and Innovation (continued)</td>
<td>Quality and Compliance (continued)</td>
<td>Supply Chain (continued)</td>
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<tr>
<td>2:45 p.m. – 3:15 p.m. Panel Discussion with Presenters and Additional Participants Alexey Khrenov, PhD, Senior Staff Fellow, CBER, FDA Michael J. Popek, Team Leader, Division of Manufacturing Technologies, CVM, FDA</td>
<td>2:45 p.m. – 3:15 p.m. Questions and Answers/Discussion</td>
<td>2:45 p.m. – 3:15 p.m. Questions and Answers/Discussion</td>
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3:15 p.m. – 4:00 p.m. Refreshment Break in Exhibit Area

4:00 p.m. – 5:30 p.m. Concurrent Sessions

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<thead>
<tr>
<th>Lifecycle Management and Innovation</th>
<th>Quality and Compliance</th>
<th>Supply Chain</th>
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<tbody>
<tr>
<td>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</td>
<td>B5: Quality Systems Moderator: Enrique Diloné, PhD, RAC, Senior Vice President, Technical Operations, Amicus Therapeutics, Inc.</td>
<td>C5: Ingredient Supplier Oversight Moderator: Lucy Cabral, Senior Director, Global External Quality, Roche Genentech</td>
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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 product quality challenges encountered with new types of biologicals products and new manufacturing platforms.

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 evolve to meet the changing needs of the business. Case studies will be presented in a separate session demonstrating how the evolution of the QMS enabled increased oversight of their outsourced biologics manufacturing and the maturation of quality culture required to ensure product safety and quality.

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. Ralph Quadflieg as he presents a risk-based approach to manage API and excipients and addresses best practices managing a large portfolio of materials and suppliers. Dr. Marla A. Phillips will follow with a presentation on how to improve supply chain security, root causes for supplier issues in the industry, and good supplier practices.
### TUESDAY, SEPTEMBER 25 (CONTINUED) – WEDNESDAY, SEPTEMBER 26

<table>
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<tr>
<th>LIFECYCLE MANAGEMENT AND INNOVATION (continued)</th>
<th>QUALITY AND COMPLIANCE (continued)</th>
<th>SUPPLY CHAIN (continued)</th>
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<tr>
<td>4:00 p.m. – 4:30 p.m. <strong>Bo Chi</strong>, Microbiologist, CDER, FDA</td>
<td>4:00 p.m. – 4:30 p.m. <strong>Jan Paul Zonnenberg</strong>, Partner, PriceWaterhouseCoopers, LLC</td>
<td>4:00 p.m. – 4:30 p.m. <strong>Ralph Quadflieg</strong>, PhD, Regional Head Global Supplier Quality Management, Roche</td>
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<td>4:30 p.m. – 5:00 p.m. <strong>Joan C. Kwong</strong>, MS, Senior Manager, Global Regulatory Affairs, Pfizer Essential Health</td>
<td>4:30 p.m. – 5:00 p.m. <strong>Laura A. Singer</strong>, Vice President, Global Quality Assurance, Amicus Therapeutics</td>
<td>4:30 p.m. – 5:00 p.m. <strong>Marla A. Phillips</strong>, PhD, Director, Xavier Health, Xavier University</td>
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<tr>
<td>5:00 p.m. – 5:30 p.m. <strong>Panel Discussion with Presenters and Additional Participants</strong></td>
<td>5:00 p.m. – 5:30 p.m. <strong>Panel Discussion with Presenters and Additional Participants</strong></td>
<td>5:00 p.m. – 5:30 p.m. <strong>Questions and Answers/Discussion</strong></td>
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<tr>
<td><strong>Anthony F. Lorenzo</strong>, Lead Consumer Safety Officer, CBER, FDA</td>
<td><strong>Grace E. McNally</strong>, Supervisory Health Scientist, CDER, FDA (Invited)</td>
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5:45 p.m. – 6:45 p.m. **Interest Group Sessions**

**NEW THIS YEAR!** PDA will offer **Interest Group Sessions both at the lunch hour and in the evenings to ensure that you’re making the most of your time at the Conference!**

### WEDNESDAY, SEPTEMBER 26

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

7:00 a.m. – 8:30 a.m. **Continental Breakfast**
### WEDNESDAY, SEPTEMBER 26 (CONTINUED)

#### Concurrent Breakfast Sessions

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<tr>
<td>Moderator: Clarice Haigh Hutchens, PhD, Director, Global Chemistry Manufacturing Control Advisory Office, Worldwide Safety and Regulatory, Pfizer Biotech</td>
<td>Moderator: Jacqueline Kunzler, PhD, MBA, Senior Vice President, Chief Quality Officer, Baxter</td>
<td>Moderator: David J. Jaworski, MBA, Senior Policy Advisor, CDER, FDA</td>
<td>Moderator: Shane Killian, MS, Senior Director, Licensing &amp; Acquisition Head, Johnson &amp; Johnson</td>
<td>Moderators: Douglas A. Campbell, Senior Consultant, Interpro QRA, and Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.</td>
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**Breakfast 5:**
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:**
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:**
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:**
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:**
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 direct benefits of a reduction in deviations, OOS, etc. Participants in this session will take away a simple concept that could provide a modern outlook and improvement to the training program.
### Breakfast 5: Sustainability and Green Chemistry (continued)

- **7:15 a.m. – 7:30 a.m.**
  - Brad Stanard, MPH, PhD, Associate Director, Occupational and Quality Toxicology, AstraZeneca
- **7:30 a.m. – 7:45 a.m.**
  - Tom Polton, MS, Senior Director, Environmental Sustainability, Pfizer Inc.
- **7:45 a.m. – 8:15 a.m.**
  - Panel Discussion with Presenters and Additional Participants
  - Thomas F. O’Connor, PhD, Chemist, CDER, FDA (Invited)

### Breakfast 6: Evolving Large Volume Parenteral Manufacturing (continued)

- **7:15 a.m. – 7:45 a.m.**
  - Merle Goddard, MS, Senior Director, Global Quality, Baxter
  - Panel Discussion with Presenter and Additional Participants
  - Karen E. D’Orazio, Compliance Officer, CDER, FDA
  - Reynold Tan, PhD, Quality Assessment Lead, CDER, FDA
- **7:45 a.m. – 8:15 a.m.**
  - Panel Discussion with Presenters and Additional Participants
  - Anne Huffman, Vice President Quality Assurance – Plant Operations, Fresenius Kabi USA, LLC
  - Anthony Pavell, Plant Manager – PU GI, Fresenius Kabi USA, LLC

### Breakfast 7: Restricted Access Barrier Systems and Isolators: Current Perspectives (continued)

- **7:15 a.m. – 7:45 a.m.**
  - Stephen E. Langille, PhD, Acting Division Director, Division of Microbiology Assessment, Office of Process and Facilities, CDER, FDA
- **7:45 a.m. – 8:15 a.m.**
  - Questions and Answers/Discussion

### Breakfast 8: Water Systems (continued)

- **7:15 a.m. – 7:45 a.m.**
  - Kristy A. Zielny, Director, Regional Quality & Compliance North America, Sun Pharmaceutical Industries, Inc.
- **7:45 a.m. – 8:15 a.m.**
  - Questions and Answers/Discussion

### Breakfast 9: Training Effectiveness (continued)

- **7:15 a.m. – 7:45 a.m.**
  - CAPT Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, CDRH, FDA
- **7:45 a.m. – 8:15 a.m.**
  - Peter W. Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA
- **7:45 a.m. – 8:15 a.m.**
  - Steven Solomon, DVM, MPH, Director, Center for Veterinary Medicine, FDA
- **7:45 a.m. – 8:15 a.m.**
  - Douglas Throckmorton, MD, Deputy Center Director for Regulatory Programs, CDER, FDA

### 8:30 a.m. – 10:00 a.m.

**P4: Center Updates**

**Moderator: Laurie P. Norwood, Deputy Director, Division of Manufacturing Product Quality, OCBQ, CBER, FDA**

How is FDA adapting to the evolving environment of regulating new innovative drugs and devices and ensuring product quality, compliance, and product to the patients? Hear from FDA senior management officials from various FDA Centers and learn about their new initiatives, challenges, and plans as the Agency moves forward to maintain a constant supply of approved products and to bring new and novel products to the market. A panel discussion will follow, along with time for questions from the audience.

**Panel Discussion**

- CAPT Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, CDRH, FDA
- Peter W. Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, FDA
- Steven Solomon, DVM, MPH, Director, Center for Veterinary Medicine, FDA
- Douglas Throckmorton, MD, Deputy Center Director for Regulatory Programs, CDER, FDA
10:00 a.m. – 10:30 a.m.
Refreshment Break

10:30 a.m. – 12:15 p.m.
P5: Quality Culture
Moderator: Valerie Whelan, Vice President, Corporate Quality, Amgen Inc.

“A nation’s culture resides in the hearts and in the souls of its people” Mahatma Ghandi, the same is true for Quality culture. Over the last number of years, we have attempted to evolve the maturity of our industry in terms of our understanding of a culture of Quality and in considering how to ‘measure/evaluate’ this, our success to date has been limited. In this session, we will hear how others, outside our industry, have achieved success in similar areas. Where we are in our journey will be explored and an in-depth examination of where the future opportunities and risks lie will be undertaken. The speakers will consider what is preventing us from truly tackling the cultural challenges and realizing the full value that a culture of Quality can bring from both the business and patient perspectives.

10:30 a.m. – 11:00 a.m.
Paul Sean Hill, Former Flight Director, NASA

11:00 a.m. – 11:30 a.m.
Scott C. Nickerson, Head of Quality, Moderna Therapeutics

11:30 a.m. – 12:00 p.m.
Panel Discussion with Presenters and Additional Participants
Ashley B. Boam, MSBE, Director, OPPQ, CDER, FDA (Invited)

12:00 p.m. – 12:15 p.m.
Closing Remarks and Introduction of 2019 PDA/FDA Joint Regulatory Conference Co-Chairs
FINAL PDA/FDA FORM TO COME
FINAL PDA/FDA FORM TO COME