GENERAL INFORMATION

REGISTRATION
Location: Grand Foyer
Sunday, September 15: 3:00 p.m. – 6:00 p.m.
Monday, September 16: 7:00 a.m. – 7:00 p.m.
Tuesday, September 17: 7:00 a.m. – 6:30 p.m.
Wednesday, September 18: 7:00 a.m. – 12:00 p.m.

SPEAKER READY ROOM
Location: Meeting Planner Office B
Sunday, September 15: 3:00 p.m. – 6:00 p.m.
Monday, September 16: 7:00 a.m. – 4:30 p.m.
Tuesday, September 17: 7:00 a.m. – 4:30 p.m.
Wednesday, September 18: 7:00 a.m. – 12:00 p.m.

EXHIBIT AREA
Location: Congressional and Grand Foyers
Monday, September 16: 9:45 a.m. – 7:00 p.m.
Tuesday, September 17: 9:45 a.m. – 4:00 p.m.

WIFI INFORMATION
Network Name/SSID: PDAFDA19
Password: Veeva (not case sensitive)

RECOMMENDED 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.

BADGES
Attendees are required to wear their Conference badge as proof of their registration and permits admission to Sessions, the Exhibit Area, and the Networking Reception.

VENUE
PDA will conduct all of the sessions and events at the Renaissance Washington, DC Downtown Hotel.

NETWORKING RECEPTION
All attendees are welcome to attend Monday evening’s Networking Reception. Guest badges are available for purchase at the Registration Desk.

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.
MONDAY, SEPTEMBER 16

7:00 a.m. – 8:00 a.m. .......... Continental Breakfast
8:00 a.m. – 10:00 a.m. .......... P1: Manufacturing Innovation and Achieving the 20/20 Vision
10:00 a.m. – 10:45 a.m. .......... Refreshment Break
10:45 a.m. – 12:15 p.m. .......... P2: Learning from Failures to Implement Sustainable CAPAs
12:30 p.m. – 1:30 p.m. .......... Concurrent Interest Group (IG) Sessions
1:45 p.m. – 3:15 p.m. .......... Concurrent Sessions
                          A1: Quality Considerations for Connected Care and Devices
                          B1: Current Compliance Issues and Case Studies
                          C1: Quality by Design Lessons Learned and Where We are Now
3:15 p.m. – 4:00 p.m. .......... Refreshment Break
4:00 p.m. – 5:30 p.m. .......... Concurrent Sessions
                          A2: Augmented Reality and Artificial Intelligence: Conceptualization through Implementation
                          B2: Facility Lifecycle
                          C2: Applying Phase Appropriate GMP: How to Approach Application of GMP for Expedited Programs
5:45 p.m. – 6:45 p.m. .......... Concurrent Interest Group (IG) Sessions
7:00 p.m. – 10:00 p.m. .......... Networking Reception

TUESDAY, SEPTEMBER 17

7:00 a.m. – 8:30 a.m. .......... Continental Breakfast
7:15 a.m. – 8:15 a.m. .......... Concurrent Breakfast Sessions
8:30 a.m. – 10:00 a.m. .......... P3: Compliance Updates
10:00 a.m. – 10:45 a.m. .......... Refreshment Break
10:45 a.m. – 12:15 p.m. .......... Concurrent Sessions
                          A3: Innovations in Aseptic Processing
                          B3: Quality Systems: Focus on Change Management Program
                          C3: The New Inspection Paradigm
12:30 p.m. – 1:30 p.m. .......... Concurrent Lunch Sessions with the Regulators
1:45 p.m. – 3:15 p.m. .......... Concurrent Sessions
                          A4: Continuous Manufacturing Update
                          B4: Investigations: Quality Risk Management and Structured Investigational Approaches
                          C4: How Effective Is Your Audit Program?
3:15 p.m. – 4:00 p.m. .......... Refreshment Break
4:00 p.m. – 5:30 p.m. .......... Concurrent Sessions
                          A5: Cell and Gene Therapy: CMC Considerations
                          B5: OOS and Effective Remediation
                          C5: The Value of Selecting the Right Consultant
5:45 p.m. – 6:45 p.m. .......... Concurrent Interest Group (IG) Sessions

WEDNESDAY, SEPTEMBER 18

7:00 a.m. – 8:30 a.m. .......... Continental Breakfast
7:15 a.m. – 8:15 a.m. .......... Concurrent Breakfast Sessions
8:30 a.m. – 10:00 a.m. .......... P4: Center Updates
10:00 a.m. – 10:30 a.m. .......... Refreshment Break
10:30 a.m. – 12:15 p.m. .......... P5: The Evolving Regulatory Landscape
12:15 p.m. .......... Adjournment

*Session locations can be found within the agenda
CONFERENCE FLOOR PLAN

MEETING ROOM LEVEL

Ancillary Meetings
SUNDAY, SEPTEMBER 15

9:00 a.m. – 4:00 p.m. ........................ **MSOP Steering Committee** *(Invite Only)*  
**Location:** Meeting Room 16

12:00 p.m. – 1:00 p.m. ........................ **Advisory Board and MSOP Steering Committee Mix and Mingle** *(Invite Only)*  
**Location:** Mount Vernon Square A

1:00 p.m. – 5:00 p.m. ........................ **Biopharmaceutical Advisory Board (BioAB)** *(Invite Only)*  
**Location:** Meeting Room 2

1:00 p.m. – 5:00 p.m. ........................ **Regulatory Affairs/Quality Advisory Board (RAQAB)** *(Invite Only)*  
**Location:** Meeting Room 4

1:00 p.m. – 5:00 p.m. ........................ **Science Advisory Board (SAB)** *(Invite Only)*  
**Location:** Meeting Room 3

5:00 p.m. – 6:00 p.m. ........................ **2019 PDA/FDA Program Planning Committee** *(Invite Only)*  
**Location:** Meeting Room 16

5:30 p.m. – 7:00 p.m. ........................ **Interest Groups Leadership Dinner** *(Invite Only)*  
**Location:** Mount Vernon Square A

THANK YOU TO PROGRAM PLANNING COMMITTEE!

*Program Co-Chairs*
John D. Ayres, MD, *Pharma Safety Solutions, LLC*
David J. Jaworski, MBA, *U.S. FDA*

Douglas A. Campbell, *InterPro QRA*
David L. Chesney, MSJ, *DL Chesney Consulting, LLC*
Rebecca A. Devine, PhD, *Biopharmaceutical Consultant*
Enrique Diloné, *Amicus Therapeutics, Inc.*
David Doleski, *Sanoft*
Rebecca E. Dombrowski, *U.S. FDA*
Mary E. Farbman, PhD, *Merck & Co., Inc.*
Rick L. Friedman, MS, *U.S. FDA*
Sharyl D. Hartsch, *Eli Lilly and Company*
Clarice Hutchens, PhD, MA, DM, *Pfizer*
Mai X. Huynh, MS, *U.S. FDA*
Shane D. Killian, MS, *Janssen R&D Quality & Compliance*
Jacqueline A. Kunzler, PhD, MBA, *Baxter Healthcare Corporation*

*PDA Staff*
Ruth K. Miller, JD
Tina S. Morris, PhD
Molly E. O’Neill, CMP

Renée D. Kyro, MBA, *AbbVie*
Bita Mirzai-Azarm, MS, *U.S. FDA*
Ken Nolan, *U.S. FDA*
Laurie P. Norwood, MS, *Norwood Biologics Consulting LLC*
Paul Perdue, Jr., *U.S. FDA*
Carol L. Rehkopf, MS, *U.S. FDA*
Lynnsey A. Renn, PhD, *U.S. FDA*
Neil A. Stiber, PhD, *U.S. FDA*
Nicole Trudel, *U.S. FDA*
Loni Warren Henderson, *U.S. FDA*
Valerie Whelan, BSc, *Amgen Inc.*
7:00 a.m. – 8:00 a.m. .................. Continental Breakfast  
Location: Congressional and Grand Foyers

7:00 a.m. – 8:00 a.m. .................. Orientation Breakfast (Invite Only)  
Location: Renaissance Ballroom East  
Supported in part by AMGEN

8:00 a.m. – 10:00 a.m. .................. P1: Manufacturing Innovation and Achieving the 20/20 Vision  
Location: Grand Ballroom  
Moderator: David J. Jaworski, MBA, Senior Policy Advisor, CDER, U.S. FDA

At this conference in 2009, U.S. FDA discussed its role as a public health agency which is focused on prevention of quality problems using the best available science, quality risk management, and enhanced transparency to inform the public. In the last 10 years, industry and U.S. FDA have worked together to forge the concepts discussed in 2009 into actions that are now having a positive impact on medical product quality. Today we set the stage to discuss ideas and strategies that we can use to establish our quality vision for 2020.

U.S. FDA and industry will discuss several key initiatives to advance innovation; the quality of biologics, devices, and drugs; competition; and promote public health. U.S. FDA leadership will discuss implementation of the U.S. FDA’s Strategic Policy Roadmap and 21st Century Cures Act, and top management’s ongoing responsibility to assure quality by understanding sources of variation and improving their manufacturing operations. Industry leadership will explore the continuing evolution of innovative manufacturing capabilities, lifecycle knowledge management, and maximizing human potential within their companies. They will discuss how these innovations can drive paradigm shifts in quality assurance and compliance that lead to exceptional patient outcomes. These thought-provoking presentations will provide the strategic thinking that has enabled companies to leverage innovation to yield high quality medical products.

8:00 a.m.  
Welcome and Opening Remarks from PDA Leadership and Conference Co-Chairs
John D. Ayres, MD, Risk Assessment Clinician, Pharma Safety Solutions, LLC  
Rebecca A. Devine, PhD, Biopharmaceutical Consultant  
David J. Jaworski, MBA, Senior Policy Advisor, CDER, U.S. FDA  
Richard M. Johnson, President and CEO, PDA

8:30 a.m.  
Innovative Therapies in Health Care: Efficacy, Safety, and Speed to Market vs. High Cost and Profiteering
Marschall S. Runge, MD, PhD, Executive Vice President for Medical Affairs & Dean, University of Michigan

9:00 a.m.  
Advancing Drug Innovation through Investment in Quality
Patrizia Cavazzoni, MD, Deputy Director for Operations, CDER, U.S. FDA

9:30 a.m.  
Q&A Panel
10:00 a.m. – 10:45 a.m. Refreshment Break in Exhibit Area
Location: Congressional and Grand Foyers

10:10 a.m. – 10:40 a.m. Press Conference (Invite Only)
Location: Meeting Room 15

10:45 a.m. – 12:15 p.m. P2: Learning from Failures to Implement Sustainable CAPAs
Location: Grand Ballroom
Moderator: Rick L. Friedman, MS, Deputy Director, OMQ, CDER, U.S. FDA

An effective quality system uses knowledge and manages risks to enable sound lifecycle decision-making. This lifecycle approach to quality management assures an ongoing state of control. When there are signals of inconsistent manufacturing operations, senior managers are responsible for driving robust fixes that prove to be sustainable in the long term. Corrective and Preventive Actions (CAPAs) can include facility, process, material, product, people, or other improvements. Often, for a CAPA to be sustainable, upgrades in design are necessary. Some organizations do not take this important step. In this session, senior industry leaders will discuss how effective systems create the environment for a learning organization to optimize use of accumulated information in their decision-making and implement solutions that leverage today’s technology.

10:45 a.m. Global Quality in Takeda: Transformation, Integration, and Innovation
Gerard Greco, PhD, Global Quality Officer, Takeda

11:15 a.m. A Lifecycle Approach to Quality Excellence
Jackie Elbonne, PhD, Chief Quality Officer and Senior Vice President, Global Quality, Bristol-Myers Squibb

11:45 a.m. Q&A Panel with Additional Panelist
Ronan Farrell, PhD, Head of Global Quality and Compliance, Roche/Genentech

12:15 p.m. – 1:45 p.m. Chapter Council Meeting (Invite Only)
Location: Meeting Room 16

DO YOU HAVE A REGULATORY QUESTION FOR OUR PANEL OF EXPERTS?
Fill out a question card and drop it in the collection box located at the registration desk to hear it during one of the Tuesday Lunch discussions.
12:30 p.m. – 1:30 p.m. .................. **Concurrent Interest Group (IG) Sessions**

Boxes lunches will be provided for those that are participating in Interest Groups.

**IG1: Pharmacopeial**

**Location:** Renaissance Ballroom East

**Leaders:** Anette Yan Marcussen, MPharm, Managing Consultant, NNE A/S and Janeen Skutnik-Wilkinson, Associate Director for Quality Intelligence, Biogen

**Speaker:** Fouad Atouf, PhD, Vice President, Global Biologics, USP

This session will provide participants with the latest updates from USP on standards for biologics/cell and gene therapy as well as USP’s commitment to early engagement of stakeholders.

**IG2: Quality Systems**

**Location:** Congressional Ballroom A

**Leaders:** Pia Lise Sandau, Corporate QMS Expert, Novo Nordisk A/S and Eva M. Urban, MSc, Director, Quality Risk Management, CSL Behring

**Speaker:** Cledwyn L. Davies, PhD, CChem, CSci, MRSC, Compliance Specialist, Qualified Person, Porton Biopharma Ltd

This session will provide an overview of the current discussions within the IG. In particular, the key messages from the sub-working groups will be outlined to attendees.

**IG3: Technology Transfer**

**Location:** Renaissance Ballroom West

**Leader:** Beth J. Haas, MChE, Principal Consultant, CAI

**Speaker:** Derek R. Gallo, BS, Director, Technology Transfer, Thermo Fisher Scientific

This IG has developed a novel tool to guide project management of technology transfers which is being incorporated into a new TR which will complement TR65. The session will be an introduction to the aspects of the new TR and will focus on the requirements for technology transfer supporting clinical phase 1-3 with key differences and similarities identified using the defined grid-style approach.

**IG4: Vaccines**

**Location:** Congressional Ballroom B

**Leaders:** Jane L. Halpern, PhD, Independent Consultant and A. Sabrina Restrepo, PhD, Director, Global Vaccines Technical Operations, Merck & Co., Inc.

**Speaker:** Ami Shah Brown, PhD, MPH, Senior Vice President Regulatory Affairs, Inovio Pharmaceuticals, Inc.

This IG will include a working session to further develop the planned Technical Report (Vaccine Control Strategies) and a speaker who will cover 2 of the 4 conference tracks – 1) Innovation and Technology, and 2) Lifecycle Implementation.
1:45 p.m. – 3:15 p.m. Concurrent Sessions

A1: Quality Considerations for Connected Care and Devices

Location: Grand Ballroom North

Moderator: Valerie Whelan, BSc, Vice President, Head of R&D Quality and Compliance, Amgen Inc.

As big a part as technology and innovation are playing in the development and manufacture of pharmaceutical and biotechnology products, they are arguably playing a more rapidly evolving part in the experience of patients in how their medicines are administered, how their diseases are managed, and the novel ways that they can record and provide feedback on performance.

Are our traditional quality management systems and regulations suitably equipped to adapt to this changing landscape? What have we learned to better equip us all to be successful in this space and continue to rapidly adapt?

1:45 p.m.

Quality Considerations for Connected Care and Devices
John F. Murray, Jr., Partner, Consultant, SoftwareCPR
Carl Washburn, MBA, Senior Consultant, Digital Quality, Eli Lilly and Company

2:30 p.m.

Q&A Panel with Additional Panelists
Michelle R. Harris, Corporate Development Officer, American Diabetes Association

B1: Current Compliance Issues and Case Studies

Location: Grand Ballroom Central

Moderator: David L. Chesney, MSJ, Principal and General Manager, DL Chesney Consulting, LLC

It’s back by popular demand! This session will include 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.

1:45 p.m.

CDER GMP Compliance Update
Rick L. Friedman, MS, Deputy Director, OMQ, CDER, U.S. FDA

2:15 p.m.

CBER Compliance Update
Maria C. H. Anderson, MS, Branch Chief, Biological Drug and Device Compliance Branch, CBER, U.S. FDA

2:45 p.m.

Q&A Panel with Additional Panelists
CDR John W. Diehl, MS, Director, Compliance Branch, ORA, U.S. FDA
Marea K. Harmon, Consumer Safety Officer, CVM, U.S. FDA
1:45 p.m. – 3:15 p.m. .................... Concurrent Sessions (Continued)

**C1: Quality by Design: Lessons Learned and Where We are Now**

*Location*: Grand Ballroom South

*Moderator*: Bita Mirzai-Azarm, MS, Branch Chief, CDER, U.S. FDA

*This session will focus on the quality by design (QbD) for parenteral drugs and how it can be used to ensure the desired quality, safety, and efficacy of the product in line with the product label claim, with an emphasis on case studies such as extended release injection suspension packaged in pre-filled syringe and injection solution in IV bags. The session will also identify gaps in the understanding of QbD between industry and U.S. FDA and further improve collaboration by providing regulatory feedback and industry’s experience on commonly observed deficiencies.*

1:45 p.m.  
**Applying Quality by Design to Parenteral Drug Products**  
Kiran Krishnan, PhD, Senior Vice President, Global Regulatory Affairs, Apotex

2:15 p.m.  
**Regulatory Requirements: A Design Element to Ensure Quality**  
Reynold Tan, PhD, Chemist, CDER, U.S. FDA

2:45 p.m.  
**Q&A Panel**

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

*Location*: Congressional and Grand Foyers

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**DO YOU HAVE A REGULATORY QUESTION FOR OUR PANEL OF EXPERTS?**

Fill out a question card and drop it in the collection box located at the registration desk to hear it during one of the Tuesday Lunch discussions.
MONDAY, SEPTEMBER 16

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

A2: Augmented Reality and Artificial Intelligence: Conceptualization through Implementation
Location: Grand Ballroom North
Moderator: Sharyl D. Hartsock, Senior Director Quality, Global Quality Systems, Eli Lilly and Company

The digital transformation of pharma is happening at an accelerating pace and many companies are beginning to realize the potential for improved control, higher equipment reliability, and enhanced human understanding of complex process variable interactions. This session will explore learnings from current and proposed application of augmented reality and artificial intelligence with the intent to aid others in acceleration and realization of the benefits of more advance technologies and approaches. Industry speakers will describe their technology journeys from concept through implementation, highlighting several successful use cases and how this work fits into the bigger picture of “Pharma 4.0” factory of the future.

4:00 p.m.
Augmented Intelligence in Support of a cGMP Pharmaceutical Manufacturing Facility
Bob Bowden, PhD, Senior Director, Cell Collection, Advanced Therapeutics Supply Chain, Janssen

4:30 p.m.
Connected Health: A Case Study in User Centered Digital Design
Jasper Benke, Vice President, RA/QA/CA, Companion Medical, Inc.

5:00 p.m.
Q&A Panel with Additional Panelists
David J. Jaworski, MBA, Senior Policy Advisor, CDER, U.S. FDA
Sean T. Saint, PE, CEO, Companion Medical, Inc.

B2: Facility Lifecycle
Location: Grand Ballroom Central
Moderator: David Doleski, Compliance Head for Biologics Quality Operations, Sanofi

A manufacturer must manage each of its facilities to ensure equipment, processes, and the overall building remain robust. As part of a self-inspection program, it is important to have a detailed and hands-on inspection of the facility and equipment that involves appropriate SMEs, including the quality unit. This can reveal and assess the suitability of the plant and highlights areas needing mitigation and should drive pro-active improvements throughout the facility lifecycle. This includes appropriate investment in facility upgrades and process improvements that are part of the evolution of any manufacturing enterprise. This session will share an example approach and U.S. FDA will reinforce the reasons why robust equipment and facilities are so critical to assuring quality, and advantages of leveraging current technologies in CGMP facilities as part of a 2020 quality vision.

4:00 p.m.
Facility Lifecycle: 1980s vs. 2020s Technology
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, U.S. FDA

4:30 p.m.
Facility and Equipment Assessment to Ensure Microbial Control throughout the Lifecycle
Cheryl E. Essex, MS, Head of Microbiological Control, Sanofi

5:00 p.m.
Q&A Panel with Additional Panelists
Hal Baseman, MBA, Chief Operating Officer, ValSource LLC
Glenn E. Wright, MS, Head of Quality, Exelead
4:00 p.m. – 5:30 p.m. Concurrent Sessions (Continued)

C2: Applying Phase Appropriate GMP: How to Approach Application of GMP for Expedited Programs
Location: Grand Ballroom South
Moderator: Nicole Trudel, Quality Assurance Lead, DMPQ, CBER, U.S. FDA

This session will focus on GMP requirements that should be considered early in product development. Topics will include the design of clinical production facilities in order to meet future production goals and the associated GMPs, transitioning from Phase III to approval, and manufacturing challenges associated with personalized medicine, small and/or virtual companies, and fast-track/breakthrough approval cycles.

4:00 p.m. Phase Appropriate GMPS in Investigational New Drug (IND) Manufacturing
Anthony F. Lorenzo, Lead Consumer Safety Officer, CBER, U.S. FDA

4:30 p.m. GMP for ATMP: Comparing US and EU Requirements
Keith M. Wonnacott, PhD, Executive Director, Regulatory Affairs, Pfizer

5:00 p.m. Q&A Panel with Additional Panelists
Jeffrey C. Baker, PhD, Deputy Director, Office of Biotechnology Products, CDER, U.S. FDA
Carolyn A. Renshaw, Branch Chief/Supervisory Biologist, CBER, U.S. FDA

HAVE YOU VOTED YET?
Online voting is now open for the 2020 PDA Board of Directors and Officers Election! Use your PDA Member ID and last name to log in at www.pda.org/vote
5:45 p.m. – 6:45 p.m. Concurrent Interest Group (IG) Sessions

**IG5: Combination Products**

*Location:* Grand Ballroom South

**Leader:** Lee H. Leichter, MBA, RAC, President, P/L Biomedical

**Speaker:** Suzette M. Roan, JD, Senior Director, GRA Devices, Sanofi

The challenge to combination product manufacturers has become how to continue to meet the ever-changing requirements within the regulatory process designed for drugs and biologics.

This session will provide an overview of the activities within the industry and U.S. FDA to balance the needs for flexibility and innovation while balancing the need for oversight ingrained within the drug approval process.

**IG6: Facilities and Engineering and Quality Risk Management**

*Location:* Grand Ballroom Central

**Facilities and Engineering Leader:** Shelley M. Preslar, MBA, PMP, General Manager, Azur Group Raleigh

**QRM Leaders:** Amanda M. McFarland, MS, Senior Consultant, Valsource LLC and Eva M. Urban, MSc, Director, Quality Risk Management, CSL Behring

**Speaker:** John Kutney, Director, Manufacturing, Novavax, Inc

This combined IG session will draw upon a case study to explore the ways that QRM is used to enable the evolving manufacturing conditions across the industry.

**IG7: GMP Links to Pharmacovigilance**

*Location:* Grand Ballroom North

**Leader:** John D. Ayres, MD, Risk Assessment Clinician, Pharma Safety Solutions, LLC

**Speaker:** CAPT Uduak M. Inokon, PharmD, MA, Program Management, OPQ, CDER, U.S. FDA

USP general chapters <787> and <788> provide that parenteral products for which the labeling specifies use of a final filter prior to administration are exempt from the requirements of those chapters, provided that scientific data are available to justify this exemption.

In the past few years some studies suggest that the use of in-line filters may decrease morbidity in certain clinical situations. Seizing on this data, some commentators have urged routine utilization of bedside in-line filtration independent of the particle counts found in the final product.

This session will explore the application of the USP exemptions and the scientific evidence sufficient to justify its adoption. In addition, the much broader recommendation for employing the use of a filter for every intravenous infusion and the applicable cGMP elements concerning filter selection and qualification will be discussed.
MONDAY, SEPTEMBER 16

5:45 p.m. – 6:45 p.m. .......... Concurrent Interest Group (IG) Sessions (Continued)

**IG8: Process Validation**

**Location:** Congressional Ballroom A

**Leader:** Scott R. Bozzone, PhD, MS, Principal, Pharm Lifecycle Validation LLC

**Speaker:** Maria M. Diaz-Cabrera, BS, RPH, Quality Systems & Compliance - Validation Senior Manager, Pfizer

*This IG will cover both quality and compliance and innovation in process validation with a presentation on Example of Tablet Sampling Plan and Alternate Statistical Criteria to USP <905> Compendia - A Case Study in Process Validation; and update and brief summary and open discussion on PDA initiatives: Continued/On-going Process Verification (CPV) - technical report and latest information on this Stage 3 of the PV lifecycle; and a cleaning validation update on the Technical Report 29 revision and latest information on regulatory aspect of cleaning validation.*

**IG9: Sterile Processing**

**Location:** Congressional Ballroom B

**Leader:** Rebecca A. Brewer, Vice President of Strategic Practices, Quality Executive Partners

**Speakers:** Hal Baseman, MBA, Chief Operating Officer, ValSource LLC and Rebecca E. Dombrowski, MS, Senior Policy Advisor, CDER, U.S. FDA

*Evolving the expectations for aseptic process simulations is required to keep pace with technology. Combination products, cell and gene therapy, innovations in isolator technology, continuous manufacturing, factories of the future – what impact are they having today on the concepts and requirements for aseptic process simulation and what does the future hold? What changes do we need to current regulation and guidance on aseptic processing to keep pace? What tools require investment by industry to improve confidence in our results (from what is commonly manual visual inspection), methods to streamline inspection, and to enhance documentation?*

**IG10: Visual Inspection of Parenterals**

**Location:** Congressional Ballroom C

**Leaders:** John Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC and Rick J. Watson, Director, Sterile & Validation CoE, Merck & Co., Inc.

*Visual inspection continues to be a critical part of the manufacturing and quality control process. This session will review the recent US and EU guidance changes and their impact on routine visual inspection processes. Inspection technology is also changing and the use of artificial intelligence and deep learning pose both opportunities for improved inspection performance as well as challenges to validation and regulatory compliance. This session will discuss current experience and possible strategies for effective implementation of these exciting new tools as well as challenges and opportunities in the visual inspection field and an opportunity to share current experiences.*

7:00 p.m. – 10:00 p.m. .......... Networking Reception

**Location:** Renaissance Ballroom
TUESDAY, SEPTEMBER 17

7:00 a.m. – 8:30 a.m. ...................... Continental Breakfast
Location: Congressional and Grand Foyers

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

**Breakfast 1: Rapid Microbiology**
Location: Congressional Ballroom C
Moderator: Clarice Hutchens, PhD, MA, DM, Senior Director, Pfizer

Rapid microbiological methods can facilitate timely monitoring and release, and support innovation. In this session, participants will learn how to overcome roadblocks through case studies of applications in environmental monitoring, in-process testing, continuous manufacturing, and cell and gene therapy. Compendia status and regulatory expectations regarding data integrity, validation, and implementation (e.g., real time release testing) will be presented.

7:15 a.m. 
Co-Evolution of Rapid Micro Methods and Pharmacopeia Requirements
David L. Jones, PhD, Director, Rapid Micro Biosystems

7:45 a.m.
Q&A Panel with Additional Panelists
Candace Y. Gomez-Broughton, PhD, Microbiologist, CDER, U.S. FDA
Ed C. Tidswell, PhD, BSc, Executive Director QA, Merck & Co., Inc.

**Breakfast 2: Optimizing Small and Medium Lot Cleanroom Practices**
Location: Renaissance Ballroom West
Moderator: Enrique Diloné, PhD, RAC, Senior Vice President, Technical Operations, Amicus Therapeutics, Inc.

The products made by any pharmaceutical or biopharmaceutical manufacturer may be subject to “manipulation” by a compounding pharmacy or any hospital pharmacy prior to being administered to the patient. These organizations range from very sophisticated operations managed by well operated 503B compounding pharmacies and teaching hospitals to small 503A compounding pharmacies and small regional hospitals that may compound only sporadically. This breakfast session will present what you can do to support these organizations to reduce risk to your product.

7:15 a.m.
What Can We Learn from Compounding Pharmacy Producing Small Parenteral Batches?
Chris J. Smalley, PhD, Compounding Pharmacist Advisor, ValSource LLC

7:45 a.m.
Q&A Panel with Additional Panelist
Ian F. Deveau, PhD, Division Director (Acting), CDER, U.S. FDA
Concurrent Breakfast Sessions (Continued)

Breakfast 3: Regulatory Reporting
Location: Congressional Ballroom A

Moderator: Paul Perdue, Jr., Branch Chief, ORA, U.S. FDA

This session, will discuss what must be reported when submitting Field Alert Reports (FARs), Biological Product Deviation Reports (BPDRs) and MedWatch Reports. In addition, this session will present case studies demonstrating agency expectations regarding the interpretation of the regulation and clear examples of when these reports should be reported.

7:15 a.m.  Field Alert Reports (FARs) Case Study
Elise A. Murphy, Branch Chief, Quality Deviation Assessment Branch, CDER, U.S. FDA

7:35 a.m.  CDER Biological Product Deviation Reporting
CAPT Kimberly E. Rains, PharmD, Associate Director for Regulatory Affairs, CDER, U.S. FDA

7:55 a.m.  Q&A Panel

Breakfast 4: Quality Systems: Preventing Quality and Shortage Issues
Location: Congressional Ballroom B

Moderator: Douglas A. Campbell, Senior Consultant, InterPro QRA

The last several years have been consumed with discussions and events designed to raise awareness and raise a call for action to reduce drug shortages. Industry and the U.S. FDA must continue to be proactive to reduce the cause and effects of drug shortages. This session will have a Drug Shortage Task Force update and will provide input and insights related to how establishing an effective quality system will enable your company to better manage its day-to-day operations and emergencies, while also providing controls to better manage the supply of products to the market.

7:15 a.m.  Drug Shortages: FDA’s Perspective on Preventing Quality and Shortage Issues
Jeannie C. David, MS, Senior Program Management Officer, CDER, U.S. FDA

7:45 a.m.  Q&A Panel with Additional Panelist
Glenn E. Wright, MS, Head of Quality, Exelead

Breakfast 5: Data Integrity
Location: Renaissance Ballroom East

Moderator: Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc.

This session will be the first opportunity for PDA members to get an inside look at some of the information and recommendations contained in the draft TR focused on data integrity issues related to manufacturing/shop floor systems and processes. The session will be an opportunity for questions and feedback regarding the thought process behind the recommendations contained in the report.

7:15 a.m.  PDA Tech Report: Integrating Data Integrity Requirements into Manufacturing and Packaging Operations
Els Poff, Executive Director, Data Integrity Center of Excellence, Merck & Co., Inc. and PDA Data Integrity Technical Report Leader

7:45 a.m.  Q&A Panel with Additional Panelist
Maan Abduldayem, MBA, Branch Chief, CDER, U.S. FDA
TUESDAY, SEPTEMBER 17

8:30 a.m. – 10:00 a.m. .......................... **P3: Compliance Updates**
Location: Grand Ballroom

**Moderator:** John D. Ayres, MD, Risk Assessment Clinician, Pharma Safety Solutions, LLC

Featuring Compliance Directors from the U.S. FDA Centers and Office of Regulatory Affairs/Office of Enforcement, Director, this session continues as one of the highlights of the Conference. It will focus on challenges and deficiencies that U.S. FDA has found during inspections, significant regulatory actions initiated, and U.S. FDA’s current enforcement strategy for a wide array of regulated products. In a Roundtable format, U.S. 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 U.S. FDA’s thinking and expectations for Good X Practice (GXP) compliance of the industry. Most importantly, there will be ample time for the audience to ask probing questions of U.S. FDA’s top leadership.

8:30 a.m.

**Roundtable Discussion**

CDR John W. Diehl, MS, Director, Compliance Branch, ORA, U.S. FDA
Martine L. Hartogensis, DVM, Deputy Director, Office of Surveillance and Compliance, CVM, U.S. FDA
Michael Levy, JD, Deputy Director, Office of Compliance, CDER, U.S. FDA
Melissa J. Mendoza, JD, Deputy Director, Office of Compliance & Biologics Quality, CBER, U.S. FDA

10:00 a.m. – 10:45 a.m. .......................... **Refreshment Break and Passport Drawing in Exhibit Area**
Location: Congressional and Grand Foyers

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

**A3: Innovations in Aseptic Processing**
Location: Grand Ballroom North

**Moderators:** Shane D. Killian, MS, Senior Director, Licensing, Acquisition & Early Development, Janssen R&D Quality & Compliance and Lynsey A. Renn, PhD, Public Health Analyst, Office of Manufacturing Quality, CDER, U.S. FDA

Manufacturing innovation is key to aseptic filling of sterile drug products. Automation can minimize risk to exposed products by reducing operator interventions. This session will discuss new/modern approaches to aseptic processing, such as robotics, and the benefits of technological advances in drug manufacturing.

10:45 a.m.

**Innovations in Aseptic Processing: Opportunities and Challenges in Implementing Next Generation Technologies**
Chakradhar Padala, PhD, Director, Process Development, Amgen Inc.

11:15 a.m.

**A Regulatory Perspective on Innovations in Aseptic Processing**
Bryan S. Riley, PhD, Branch Chief, CDER, U.S. FDA

11:45 a.m.

**Q&A Panel with Additional Panelist**
Hal Baseman, MBA, Chief Operating Officer, ValSource LLC
TUESDAY, SEPTEMBER 17

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

**B3: Quality Systems: Focus on Change Management Program**

*Location:* Grand Ballroom Central

*Moderator:* Rebecca A. Devine, PhD, Biopharmaceutical Consultant

*Managing post-approval changes (PAC) is a challenging prospect in today’s global environment. With Life Cycle Management for Pharmaceuticals as outlined in the draft ICH Q12, the implementation of an effective change management process for regulatory filings will be important. An effective pharmaceutical quality system (PQS) will be key for implementing changes that do not have to be reported prior to implementation. This session will focus on the expectations for life cycle management, the PQS, and the risk-based approaches to PAC management. The session will cover perspectives from regulators, expectations for the PQS, and practical examples of effective PAC management from industry.*

**10:45 a.m.**

*Managing Post-Approval Changes in a Global Regulatory Environment*

Rebecca A. Devine, PhD, Biopharmaceutical Consultant

**11:15 a.m.**

*Effective Change Management in the Q12 Paradigm*

Ileana Barreto-Pettit, Drug National Expert, ORA, U.S. FDA

**11:45 a.m.**

*Q&A Panel with Additional Panelists*

Sharyl D. Hartsock, Senior Director Quality, Global Quality Systems, Eli Lilly and Company
Chikako Torigoe, PhD, Biologist, CBER, U.S. FDA

**C3: The New Inspection Paradigm**

*Location:* Grand Ballroom South

*Moderator:* Mai X. Huynh, MS, Supervisory Chemist, CVM, U.S. FDA

*How can drug inspection be improved? Based on feedback received throughout the last few years, the U.S. FDA has developed a new inspection paradigm in response to globalization, and ongoing effort to encourage manufacturing quality at regulated pharmaceutical facilities. In addition to learning the new paradigm, this session will also provide attendees insight to U.S. FDA’s current thinking how a facility can best develop an effective response to U.S. FDA Form 483 Inspectonal Observations.*

**10:45 a.m.**

*Current Activities with the U.S. FDA/EU Mutual Recognition Agreement*

David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), MHRA, UK

**11:05 a.m.**

*New Inspection Protocol Project (NIPP)*

Rosa J. Motta, BS, Associate Director, CDER, U.S. FDA

**11:25 a.m.**

*Responding to U.S. FDA Form 483*

David J. Jaworski, MBA, Senior Policy Advisor, CDER, U.S. FDA

**11:45 a.m.**

*Q&A Panel with Additional Panelists*

Laura S. Huffman, MS, Microbiologist, CVM, U.S. FDA
Nicholas A. Violand, Drug National Expert, ORA, U.S. FDA

12:15 p.m. – 1:45 p.m. .......... Portfolio Steering Committee (Invite Only)

*Location:* Meeting Room 16
**TUESDAY, SEPTEMBER 17**

12:30 p.m. – 1:30 p.m. .................. **Concurrent Lunch Sessions with the Regulators**

Grab your boxed lunch and bring questions for U.S. FDA investigators, reviewers, and compliance officers to this Q&A session that will allow for direct input and will provide you with insights regarding inspection trends and center initiatives.

**Inspection-Based Discussion**
Location: Renaissance Ballroom

Moderators:
Mary E. Farbman, PhD, Executive Director, Global Quality Compliance, Merck & Co., Inc.
Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc
Valerie Whelan, BSc, Vice President, Head of R&D Quality and Compliance, Amgen Inc.

Panelists:
David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), MHRA, UK
Marea K. Harmon, Consumer Safety Officer, CVM, U.S. FDA
Brooke K. Higgins, MS, Senior Policy Advisor, CDER, U.S. FDA
José E. Meléndez, Drug National Expert, ORA, U.S. FDA
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, U.S. FDA

**Review-Based Discussion**
Location: Grand Ballroom North

Moderators:
Rebecca A. Devine, PhD, Biopharmaceutical Consultant
Mai X. Huynh, MS, Supervisory Chemist, CVM, U.S. FDA
Bita Mirzai-Azarm, MS, Branch Chief, CDER, U.S. FDA

Panelists:
Renée S. Blosser, MS, Microbiologist, CVM, U.S. FDA
Bing Cai, PhD, Division Director, CDER, U.S. FDA
Zhihao Peter Qiu, PhD, Acting Director, Division of Microbiology Assessment, Office of Process and Facilities, CDER, U.S. FDA
Ramesh Raghavachari, PhD, Chemist, Chief, Branch I/OLDP/OPQ, CDER, U.S. FDA
Derek S. Smith, PhD, Associate Director for Regulatory Affairs (Acting), CDER, U.S. FDA

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

**A4: Continuous Manufacturing Update**
Location: Grand Ballroom North

Moderators: Clarice Hutchens, PhD, MA, DM, Senior Director, Pfizer

ICH released a concept paper that outlines the content for the guidance “ICHQ13: Continuous Manufacturing of Drug Substances and Drug Products” with a scope of small molecules and therapeutic proteins. U.S. FDA released a draft guidance entitled “Quality Considerations for Continuous Manufacturing Guidance for Industry” with a scope of small molecule, solid oral drug products that are regulated by CDER. Learn how ICH and U.S. FDA guidances are developing with similarities and differences noted. The roles of USP, EP, ASTM, and academia will be highlighted. Industry and regulators will present continuous manufacturing case studies to include experiences in working with the Emerging Technology Team.

1:45 p.m.
ICH Q13: Continuous Manufacturing of Drug Substances and Drug Products
Ganapathy Mohan, PhD, Executive Director, Merck & Co., Inc.

2:10 p.m.
Regulatory Perspective on Continuous Manufacturing
Sharmista Chatterjee, Supervisory Chemist, CDER, U.S. FDA

2:35 p.m.
Industrial Experience in the Application of Continuous Manufacturing (CM) for an Oral Solid Dosage Form
David M. Pappa, MS, Director, Technical Services/Manufacturing Science, Eli Lilly and Company

3:00 p.m.
Q&A Panel
TUESDAY, SEPTEMBER 17

1:45 p.m. – 3:15 p.m. .......... Concurrent Sessions (Continued)

B4: Investigations: Quality Risk Management and Structured Investigational Approaches
Location: Grand Ballroom Central
Moderator: Rebecca E. Dombrowski, MS, Senior Policy Advisor, CDER, U.S. FDA

Investigations into failures, discrepancies, and unplanned events are integral to root cause understanding and risk management, including both internal investigations and those associated with contracted organizations. This session will examine various structured approaches, systems, and methods available as part of an effective investigation to determine the root cause(s) of a discrepancy, failure, or unplanned event. Complex case studies demonstrating true root cause determination(s) and lessons learned, as well as operational phases of corrective action/preventative action implementation, through effectiveness assessments, will be presented.

1:45 p.m.
QRM and Structured Investigational Approaches: Industry Experience
Wallace I. Torres, PhD, Executive Director QA, Amgen Singapore

2:05 p.m.
Deviation Investigations
Kevin M. Jenkins, BS, MBA, Vice President, Sterile Injectables Quality, Pfizer

2:25 p.m.
The Art of a Quality Investigation
Binh T. Nguyen, PharmD, Consumer Safety Officer, CDER, U.S. FDA

2:45 p.m.
Q&A Panel

C4: How Effective Is Your Audit Program?
Location: Grand Ballroom South
Moderator: Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc

A good audit program should integrate information from regulatory, client, internal and supplier audits to offer a holistic view of your operations. This session will focus on the various types of audits that constitute an audit program, tracking and aligning the information from the various audits to ensure continued improvement and consistency across your operation and how to communicate those improvements to regulatory authorities and clients.

1:45 p.m.
Effectiveness of Auditing Program
Ghada N. Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc.

2:15 p.m.
Small/Start Up Company Perspective
Guy Villax, CEO, Hovione

2:45 p.m.
Q&A Panel with Additional Panelist
David L. Chesney, MSJ, Principal and General Manager, DL Chesney Consulting, LLC

3:15 p.m. – 4:00 p.m. ..... Refreshment Break and Passport Drawing in Exhibit Area
Location: Congressional and Grand Foyers
A5: Cell and Gene Therapy: CMC Considerations
Location: Grand Ballroom North
Moderator: Carol L. Rehkopf, MS, Deputy Associate Director, CBER IOD Review Management, CBER, U.S. FDA

Cell and gene therapy products bring much promise to patients suffering rare or serious life-threatening diseases but getting them to market at large scale proves challenging. This session will discuss the chemistry manufacturing and control (CMC) considerations to prepare for successful U.S. FDA approval and launch to market. The speakers of this session have first-hand experience with regulatory expectations and industry challenges and they will share their tips for success.

4:00 p.m.
CMC Considerations for Gene Therapy Product Development
Lilia L. Bi, PhD, CMC Reviewer, CBER, U.S. FDA

4:30 p.m.
The Road from IND to BLA
Paul J. Gil, PhD, Executive Director, Amicus Therapeutics, Inc.

5:00 p.m.
Q&A Panel

B5: OOS and Effective Remediation
Location: Grand Ballroom Central
Moderator: Renée D. Kyro, MBA, Director, AbbVie

It’s been 26 years since the landmark case of Barr Laboratories vs. USA set the standard for all Out of Specification (OOS) investigations. Has our industry truly integrated and maintained the lessons learned from this case? Or with the passage of time, has history been forgotten and appropriate laboratory practices altered? Is the laboratory automatically implicated in an OOS or do manufacturing and lab personnel work together to determine root cause and remediation? In this session, participants will hear industry case studies and best practices, along with the U.S. FDA’s perspective on current laboratory OOS inspection observations.

4:00 p.m.
Inspection Observations
Brooke K. Higgins, MS, Senior Policy Advisor, CDER, U.S. FDA

4:30 p.m.
Investigation Case Studies
Sean McEwen, Vice President, Quality Assurance, AbbVie

5:00 p.m.
Q&A Panel with Additional Panelist
Rick L. Friedman, MS, Deputy Director, OMQ, CDER, U.S. FDA
C5: The Value of Selecting the Right Consultant
Location: Grand Ballroom South

Moderators: Rebecca A. Devine, PhD, Biopharmaceutical Consultant and Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc

Companies hire consultants for many reasons. Sometimes consultants are hired to perform staff activities, to prepare strategic plans for continuous improvements, to help with maintenance or re-qualification activities, or to help with preparing necessary reports for regulatory filings. However, the most prevalent reason companies hire consultants is to help them avoid serious regulatory actions because they behaved in an un-compliant or questionable manner.

In these situations, the client often doesn’t take the time to properly vet the consultant they chose and often end up with consultants that don’t fit their culture or meet their expectations. This session will focus on how to choose a consultant that meets your needs, is capable of delivering your project, and will work well with your organization.

4:00 p.m.
Considerations and Regulatory Background for Selecting Consultants
Tamara L. Ely, Senior Policy Advisor, CDER, U.S. FDA

4:30 p.m.
The Importance of Selecting the Right Consultant
Anil Sawant, PhD, MSc, Senior Vice President, Global Quality Compliance, Merck & Co., Inc.

5:00 p.m.
Q&A Panel with Additional Panelists
Douglas A. Campbell, Senior Consultant, InterPro QRA
John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC

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**TUESDAY, SEPTEMBER 17**

5:45 p.m. – 6:45 p.m. **Concurrent Interest Group (IG) Sessions**

**IG11: Filtration**  
**Location:** Renaissance Ballroom West  
**Leader:** Maik W. Jornitz, MSEng, CEO, G-CON Manufacturing, Inc.

*This session will update participants on the PDA/BPOG SFQRM (Sterile Filtration Quality Risk Management) (Pre-Use Post-Sterilization Integrity Testing (PUPSIT) initiative, its work, and results. The initiative’s four workstreams will be discussed. It will also address the interaction the task group has with the European regulatory authorities and the work together with them.*

**IG12: Inspection Trends**  
**Location:** Grand Ballroom North  
**Leader:** Christopher S. Carter, Director, Quality Assurance & Regulatory Affairs, Owens & Minor

*Europe and Britain agreed to new deadline of October 31, 2019 for Brexit implementation. Brexit was initially schedule for March 29. This session will discuss the impact of Brexit from EMA and MHRA perspectives, on Pharma industry, in terms of regulatory requirements.*

**IG13: Lyophilization and Packaging Science**  
**Location:** Grand Ballroom Central  
**Lyophilization Leader:** Edward H. Trappler, President, Lyophilization Technology, Inc.  
**Packaging Science Leader:** Roger P. Asselta, BS, Vice President, Technical Affairs, Genesis Packaging Technologies

*Glass/product interactions and vial breakage continue to be a focus of attention within the industry. In particular, vial breakage and the risk of glass contamination of surrounding product is a prominent concern. The session will open with highlights on recent discussions and highlights from the PDA Glass Conference held in January 2018. This IG will then be an open forum for discussions on these and other current topics in packaging for both liquid products and lyophilized preparations.*

*In this open forum format, topics are identified by participants, then prioritized by voting, reflecting the level of interest for discussion by the group.*

**IG14: Pre-Filled Syringes**  
**Location:** Congressional Ballroom A  
**Leader:** Olivia A. Henderson, PhD, Principal Engineer, Amgen Inc.

*The Pre-filled Syringes IG will continue its series on glass alternatives. Alternative materials such as CCOC (cyclic olefin copolymer) or COP (cyclic olefin polymer) enable silicone oil-free syringe functionality thereby mitigating risk of potential harm to patients that could be caused by immunogenicity from protein-silicone oil interactions. Alternative materials are also sought after for use in syringes to improve dimensional tolerances and manufacturing capability, reduce dependency on silicone oil and reduce dependency on manufacturing materials such as tungsten and adhesives. This session will host a discussion of plastic syringe development challenges.*
**IG15: Regulatory Affairs**

**Location:** Grand Ballroom South

**Leader:** Ruhi Ahmed, PhD, RAC, Vice President, Inozyme Pharma Inc.

**Speaker:** Mo Heidaran, PhD, Vice President, Technical, Parexel International and Don L. Henry, Acting Director, Office of Program and Regulatory Operations, OPQ, CDER, U.S. FDA

*If the manufacturing team did not face issues or if they did not innovate throughout development (and often post-approval), many in quality and regulatory chemistry, manufacturing, and controls (CMC) would be bored out of their minds! However, sometimes the issues in product development and manufacturing stop being routine and enter the realm of being serious quality and compliance issues that could impact the continued development of the product. Many of us can benefit from a dialogue with the regulatory agencies to overcome serious challenges in CMC during drug development to ensure a safe and quality product for the market. This is particularly true for the CMC programs of novel therapies that are on the expedited approval pathways. This IG will host an interactive panel discussion with real world situations to illustrate and clarify the Why? When? How? for requesting and conducting US or EMA Regulatory Agency meetings specifically for CMC/quality-related issues.*

**IG16: Supply Chain Management**

**Location:** Renaissance Ballroom East

**Leaders:** Lucy M. Cabral, BA, Head Global Supplier Quality, Genentech, A Member of the Roche Group and Amelia (Amy) L. Mutere, MS, Head Global Quality Inspection Management, Genentech, A Member of the Roche Group

**Speaker:** Bernd A. Kraemer, PhD, Head of Supplier Quality Management - Americas Region, Genentech, Inc.

*This IG will discuss innovation, quality, and compliance in supply chain management, including: 1) share best practices for meeting China and Russia pharmacopeia and Chinese regulatory Requirements, 2) supplier quality management of single-use systems and the different from the traditional supplier quality management (SQM) models (i.e., change control), and 3) supply chain management of cell gene therapies. for requesting and conducting US or EMA Regulatory Agency meetings specifically for CMC/quality-related issues.*
7:00 a.m. – 8:30 a.m. .......................... **Continental Breakfast**  
**Location:** Congressional and Grand Foyers

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

**Breakfast 6: Using Statistical Tools and Effective Statistical Control: Introduction to Statistical Process Control**  
**Location:** Congressional Ballroom C  
**Moderator:** Jacqueline A. Kunzler, PhD, MBA, Senior Vice President, Chief Quality Officer, Baxter Healthcare Corporation

*Statistical process control (SPC) is one of many great tools in the tool bag that empowers an operator to make smart adjustments to the process, before the process produces out of specification limits. If used properly, SPC can also diagnose a process that is unstable (sick) and needs a healthy dose of maintenance or corrective action prescribed for the process. This session will briefly show the basics of SPC (statistics) but will focus primarily on lessons learned and highlight real world applications (process control).*

7:15 a.m.  
**Overview of Statistical Process Control**  
*Karthik Iyer,* Associate Director, CDER, U.S. FDA

7:35 a.m.  
**Industry Case Study Using Statistical Process Control**  
*Jayme D. Patterson,* Senior Manager Operational Excellence, Baxter Healthcare Corporation

7:55 a.m.  
**Q&A Panel**

**Breakfast 7: Using Emerging Tools to Understand Post-Market Patients’/Consumers’ Perspectives on Quality**  
**Location:** Renaissance Ballroom West  
**Moderator:** Neil A. Stiber, PhD, Associate Director for Science and Communications, Office of Surveillance, CDER, U.S. FDA

*Understanding the patient/consumer experience is key to evaluating post-market quality data. Conventional quality feedback mechanisms, including complaints, MedWatch, and adverse events, can be complemented by social media to more fully capture patient/consumer perspectives. Social media provide an innovative approach to explore patient perspectives that might otherwise remain unknown. Data and text analytics can integrate multiple data sources to discover and analyze trends and signals. The outcomes can improve future patient experiences.*

7:15 a.m.  
**Harnessing the Power of Social Listening and U.S. FDA Archival Data to Gain Insight into the Patient’s Experience**  
*Christine S. Lee,* PhD, PharmD, Scientist, OC, U.S. FDA

7:35 a.m.  
**User-Generated Web Data Predicts Quality Risk: Evidence from the Pharmaceutical Industry**  
*Hyunwoo Park,* PhD, Assistant Professor, The Ohio State University

7:55 a.m.  
**Q&A Panel**
7:15 a.m. – 8:15 a.m. ................. Concurrent Breakfast Sessions (Continued)

**Breakfast 8: Quality Culture**
*Location: Congressional Ballroom B*

**Moderator: Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc.**

PDA has recognized the importance culture has on an organization since the first quality metrics meeting in 2014. The ability of an organization to manufacture products in a compliant manner depends on people’s behavior and management’s guidance. PDA quality culture/quality metrics task force has developed a quality culture assessment tool that maps quality behaviors to quality attributes. Members of the task force will be presenting one of the training modules from this tool so attendees can understand this relationship and how it can impact the overall company performance.

7:15 a.m.

**PDA’s Quality Culture Assessment Tool**
*Cylia Chen-Ooi, Director, Quality External Affairs, Amgen Inc. and Member, PDA Quality Metrics Task Force*

**Steven R. Mendivil, BS, Independent Consultant and Member, PDA Quality Metrics Task Force**

7:45 a.m.

**Q&A Panel**

**Breakfast 9: Aseptic Processing for Cell and Gene Therapy Products**
*Location: Congressional Ballroom A*

**Moderator: Laurie P. Norwood, MS, President, Norwood Biologics Consulting LLC**

Production of cell and gene therapy products often requires aseptic processing from beginning to end. The manufacturing processes for these novel products do not always fit the usual paradigm of media fills for final finished drug product. This morning’s session will provide some insight on U.S. FDAs expectations for media simulations for these non-traditional products as well as an industry case study on how to perform a risk assessment to support the steps to be included in such media simulations.

7:15 a.m.

**FDA Perspective on Aseptic Process Simulation for Cell and Gene Therapy Product Manufacturing**
*Lily Y. Koo, PhD, Consumer Safety Officer, CBER, U.S. FDA*

7:45 a.m.

**Q&A Panel**

**Breakfast 10: Smoke Studies**
*Location: Renaissance Ballroom East*

**Moderator: Lynnsey A. Renn, PhD, Public Health Analyst, Office of Manufacturing Quality, CDER, U.S. FDA**

Smoke studies are critical to understanding airflow in an aseptic area. Executing suitable smoke studies can be challenging. This session aims to provide information about how to design and conduct an effective smoke study, as well as, critique air patterns.

7:15 a.m.

**Airflow Visualization**
*David K. Matsuhiro, Senior Consultant, Cleanroom Compliance Inc.*

7:45 a.m.

**Q&A Panel with Additional Panelists**
*Tamara L. Ely, Senior Policy Advisor, CDER, U.S. FDA*
*José E. Meléndez, Drug National Expert, ORA, U.S. FDA*
WEDNESDAY, SEPTEMBER 18

8:30 a.m. – 10:00 a.m. ............... P4: Center Updates
Location: Grand Ballroom
Moderator: Tina S. Morris, PhD, Vice President, Scientific and Regulatory Affairs, PDA

The global regulatory landscape is evolving, and innovative approaches to product life cycle and quality paradigms are met by new real-life challenges and complexities every day – patient-individualized medicines, supply challenges for legacy products, transition to new technologies, highly globalized supply chains. How can U.S. FDA continue to lead and fulfill the promises of recent ICH advancements to product quality while assuring the availability of high-quality medicines every day? Discuss these issues with U.S. FDA senior management officials from various U.S. FDA Centers in this highly interactive session! In a round table format, the conversation will focus on key issues that are cross-cutting to the different centers and relevant to the entire pharmaceutical space. The session organizers are looking for your questions and input, so come prepared to raise questions and discuss with these senior leaders.

8:30 a.m.
Roundtable Discussion
Alonza E. Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, U.S. FDA
Peter W. Marks, MD, PhD, Director, CBER, U.S. FDA
Steven M. Solomon, DVM, MPH, Director, CVM, U.S. FDA
Douglas R. Throckmorton, MD, CDER Deputy Director of Regulatory Programs, CDER, U.S. FDA

10:00 a.m. – 10:30 a.m. ............... Refreshment Break
Location: Congressional and Grand Foyers

10:30 a.m. – 12:15 p.m. ............... P5: The Evolving Regulatory Landscape
Location: Grand Ballroom
Moderator: John D. Ayres, MD, Risk Assessment Clinician, Pharma Safety Solutions, LLC

One of the great challenges related to innovation involves the capacity of the regulatory environment to be flexible enough to adapt yet explicit enough to provide clear-cut compliance guidance. To ensure manufacturing quality standards do not degrade, executive support for robust pharmaceutical development and manufacturing flexibility are critical to promote meaningful advancements. Likewise, clear compliance standards are equally important to ameliorate risk related to the uncertainty inherent in the application of innovative technologies. This plenary session will focus on those competing tensions and the opportunities to promote a regulatory environment that simultaneously encourages innovative behaviors, provides safeguards against unforeseen consequences, and leads to peak pharmaceutical innovation and quality.

10:30 a.m.
Facilitating the Development of Advanced Therapies
Peter W. Marks, MD, PhD, Director, CBER, U.S. FDA

11:00 a.m.
Trends in Innovation Drive the Need for Integrated Quality
Greg C. Guyer, PhD, MBA, Senior Vice President, Operations, Bristol-Myers Squibb

11:30 a.m.
Q&A Panel with Additional Panelist
Ilisa B. Bernstein, PharmD, JD, Deputy Director, CDER, U.S. FDA

12:00 p.m.
Closing Remarks from Conference Co-Chairs
SEE YOU NEXT YEAR!

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