

2019 PDA/FDA Joint Regulatory Conference

Manufacturing Innovation, Quality, and Compliance: Achieving 20/20 Vision
September 16-18, 2019 | Renaissance Washington, DC Downtown | Washington, DC

Sunday, September 15

- 9:00 a.m. – 4:00 p.m. | **MSOP Steering Committee** *(Invitation Only)*
- 12:00 p.m. – 1:00 p.m. | **Advisory Board and MSOP Steering Committee Mix and Mingle** *(Invitation Only)*
- 1:00 p.m. – 5:00 p.m. | **Biopharmaceutical Advisory Board (BioAB)** *(Invitation Only)*
- 1:00 p.m. – 5:00 p.m. | **Regulator Affairs/Quality Advisory Board (RAQAB)** *(Invitation Only)*
- 1:00 p.m. – 5:00 p.m. | **Science Advisory Board (SAB)** *(Invitation Only)*
- 3:00 p.m. – 6:00 p.m. | **Registration Open**
- 5:00 p.m. – 6:00 p.m. | **PDA/FDA Program Planning Committee** *(Invitation Only)*
- 5:30 p.m. – 7:00 p.m. | **Interest Groups Leadership Dinner** *(Invitation Only)*

Monday, September 16

- 7:00 a.m. – 7:00 p.m. | **Registration Open**
- 7:00 a.m. – 8:00 a.m. | **Continental Breakfast**
- 7:00 a.m. – 8:00 a.m. | **PDA Orientation Breakfast** *(Invitation Only)*
Supported in part by 

8:00 a.m. – 10:00 a.m. | **P1: Manufacturing Innovation and Achieving the 20/20 Vision**
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. | **Marschall S. Runge, MD, PhD**, Executive Vice President for Medical Affairs & Dean, *University of Michigan*

9:00 a.m. | **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**

10:10 a.m. – 10:40 a.m. | **Press Conference** *(Invitation Only)*

10:45 a.m.-12:15 p.m. | **P2: Learning from Failures to Implement Sustainable CAPAs**

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. | **Gerard Greco, PhD**, Global Quality Officer, *Takeda*

11:15 a.m. | **Jackie Elbonne**, SVP Global Quality and Chief Quality Officer, *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** (*Invitation Only*)

12:30 p.m. – 1:30 p.m. | **Concurrent Interest Group (IG) Sessions**

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

IG1: Pharmacopeial	This session will provide participants the opportunity to hear the latest updates from USP on monograph for biologics/cell and gene therapy and their approach to chapters on continuous manufacturing.
IG2: Quality Systems	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 the attendees.
IG3: Technology Transfer	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	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**

INNOVATION AND TECHNOLOGY	QUALITY AND COMPLIANCE	LIFECYCLE IMPLEMENTATION
<p>A1: Quality Considerations for Connected Care and Devices Moderator: Valerie Whelan, BSc, Vice President, Head of R&D Quality and Compliance, <i>Amgen Inc.</i></p> <p>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.</p> <p>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?</p>	<p>B1: Current Compliance Issues and Case Studies Moderator: David L. Chesney, MSJ, Principal and General Manager, <i>DL Chesney Consulting, LLC</i></p> <p>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.</p>	<p>C1: Quality by Design Lessons Learned and Where We are Now Moderator: Bitu Mirzai-Azarm, MS, Branch Chief, CDER, U.S. FDA</p> <p>The objective of this session is to 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 also aims to 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.</p>

<p>1:45 p.m. Carl Washburn, MBA, Senior Consultant, Digital Quality, <i>Eli Lilly and Company</i></p> <p>2:15 p.m. Quality Considerations for Connected Care and Devices John F. Murray, Jr., Partner, Consultant, <i>SoftwareCPR</i></p> <p>2:45 p.m. Q&A Panel</p>	<p>1:45 p.m. Rick L. Friedman, MS, Deputy Director OMQ, CDER, <i>U.S. FDA</i></p> <p>2:15 p.m. Maria C. Anderson, Branch Chief, Biological Drug and Device Compliance Branch, CBER, <i>U.S. FDA</i></p> <p>2:45 p.m. Q&A Panel with Additional Panelists John W. Diehl, MS, Director, Compliance Branch, ORA, <i>U.S. FDA (INVITED)</i> Marea K. Harmon, Consumer Safety Officer, CVM, <i>U.S. FDA</i></p>	<p>1:45 p.m. Kiran Krishnan, PhD, Senior Vice President, Global Regulatory Affairs, <i>Apotex</i></p> <p>2:15 p.m. Reynold Tan, PhD, Chemist, CDER, <i>U.S. FDA</i></p> <p>2:45 p.m. Q&A Panel</p>
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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**

INNOVATION AND TECHNOLOGY	QUALITY AND COMPLIANCE	LIFECYCLE IMPLEMENTATION
<p>A2: Augmented Reality and Artificial Intelligence: Conceptualization through Implementation Moderator: Sharyl D. Hartsock, Senior Director Quality, Global Quality Systems, <i>Eli Lilly and Company</i></p> <p>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. New technologies, like augmented reality (AR) and artificial intelligence (AI), continue to drive innovation within this space. This session will explore learnings from current and proposed application of augmented reality and artificial intelligence use cases 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 (AR/AI) use cases and how this work fits into the bigger picture of “Pharma 4.0” factory of the future.</p>	<p>B2: Facility Lifecycle Moderator: David Doleski, Compliance Head for Biologics Quality Operations, <i>Sanofi</i></p> <p>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 that is used within a company. Also, 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.</p>	<p>C2: Applying Phase Appropriate GMP: How to Approach Application of GMP for Expedited Programs Moderator: Nicole Trudel, Quality Assurance Lead, DMPQ, CBER, <i>U.S. FDA</i></p> <p>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.</p>
<p>4:00 p.m. Artificial Intelligence in a Manufacturing Environment Bob Bowden, PhD, Senior Director, Cell Collection, Advanced Therapeutics Supply Chain, <i>Johnson and Johnson</i></p> <p>4:30 p.m. Jasper Benke, Vice President, RA/QA/CA, <i>Companion Medical, Inc.</i></p> <p>5:00 p.m. Q&A Panel with Additional Panelist</p>	<p>4:00 p.m. Facility Lifecycle: 1980s vs. 2020s Technology Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, <i>U.S. FDA</i></p> <p>4:30 p.m. Facility and Equipment Assessment to Ensure Microbial Control throughout the Lifecycle Cheryl E. Essex, MS, Head of Microbiological Control, <i>Sanofi</i></p>	<p>4:00 p.m. Anthony F. Lorenzo, Lead Consumer Safety Officer, CBER, <i>U.S. FDA</i></p> <p>4:30 p.m. Keith Wonnacott, Executive Director, Regulatory Affairs, <i>Pfizer</i></p> <p>5:00 p.m. Q&A Panel with Additional Panelists Jeffrey C. Baker, PhD, Deputy Director, Office of Biotechnology Products, CDER, <i>U.S. FDA (INVITED)</i></p>

<p>David J. Jaworski, MBA, Senior Policy Advisor, CDER, <i>U.S. FDA</i></p>	<p>5:00 p.m. Q&A Panel with Additional Panelists Hal S. Baseman, Chief Operations Officer, <i>ValSource, LLC</i> Glenn E. Wright, Quality Head, <i>Exelead BioPharma Inc.</i></p>	<p>Carolyn Renshaw, Branch Chief, CBER, <i>U.S. FDA (INVITED)</i></p>
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5:45 p.m. – 6:45 p.m. | **Concurrent Interest Group (IG) Sessions**

<p>IG5: Combination Products</p>	<p>Medical device development has always been based on a commitment to continuous improvement. Years ago, the average lifecycle for a medical device design was less than 2 years. More recently, this has been accelerated due to the ever-increasing pace of changes in technology and in user needs and expectations.</p> <p>When a device is paired with a drug, either through integration, co-packaging or cross-labeling, it is highly likely to be classified as a combination product and required to be approved, and changes controlled under a BLA or NDA. Unlike the regulatory process afforded to devices, where marketing decisions for many devices and device changes are left to internal quality systems, not U.S. FDA review, the process covering changes for drug is much more burdensome.</p> <p>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.</p> <p>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.</p>
<p>IG6: Facilities and Engineering and QRM</p>	<p>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</p>
<p>IG7: GMP Links to Pharmacovigilance</p>	<p>This IG will facilitate the incorporation of medical expertise and oversight in the form of a clinical assessment of the potential safety issues with product performance and Quality System elements. Quality attributes of a product, including product specifications, are linked to patient experiences and add value to fundamental quality activities.</p>
<p>IG8: Process Validation</p>	<p>This IG will cover both quality and compliance and innovation in process validation with:</p> <ol style="list-style-type: none"> 1. A Presentation on Example of Tablet Sampling Plan and Alternate Statistical Criteria to USP <905> Compendia - A Case Study in Process Validation. Innovative, scientific sampling plans and statistical data analysis are critical aspects to effective process validation programs. Also, participants can share and benchmark sampling plans for solutions, suspensions and semisolids in Stage 2. 2. Update and brief summary and open discussion on PDA initiatives: <ol style="list-style-type: none"> a. Continued/On-going Process Verification (CPV)- technical report and latest information on this Stage 3 of the PV lifecycle. 3. Cleaning Validation update- Technical Report 29 revision and latest information on regulatory aspects of cleaning validation.
<p>IG9: Sterile Processing</p>	<p>Evolving the expectations for aseptic process simulations (APS) 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?</p>
<p>IG10: Visual Inspection of Parenterals</p>	<p>Visual inspection continues to be a critical part of the manufacturing and quality control process. Guidance in both the United States and Europe have seen recent changes. This session will be an excellent opportunity to review these recent changes and discuss their impact on routine visual inspection processes. Inspection technology is also changing and the use of artificial Intelligence (AI) and deep learning pose both opportunities for improved inspection performance as well as challenges to validation and regulatory compliance. This session will provide a forum to discuss current experience and possible strategies for effective implementation of these exciting new tools. Time will also be provided for general discussion of challenges and opportunities in the visual inspection field and an opportunity to share current experiences.</p>

7:00 p.m. – 10:00 p.m. | **Grand Opening Reception**

Tuesday, September 17

7:00 a.m. – 6:30 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**

<p>Breakfast 1: Rapid Microbiology Moderator: Clarice Hutchens, PhD, MA, DM, Senior Director, <i>Pfizer</i></p> <p>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.</p>	<p>Breakfast 2: Optimizing Small and Medium Lot Cleanroom Practices Moderator: Enrique Diloné, PhD, RAC, Senior Vice President, Technical Operations, <i>Amicus Therapeutics</i></p> <p>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. Some of these organizations range from very sophisticated clean room and aseptic 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.</p>	<p>Breakfast 3: Regulatory Reporting Moderator: Paul Perdue, Jr., Branch Director, ORA, <i>U.S. FDA</i></p> <p>In this session, we 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 discuss case studies demonstrating the agency expectations regarding the interpretation of the regulation and clear examples of when FARs, BPDRs, and MedWatch Reports should be reported.</p>	<p>Breakfast 4: Quality Systems: Preventing Quality and Shortage Issues Moderator: Douglas A. Campbell, Senior Consultant, <i>InterPro QRA</i></p> <p>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. It is clear that Industry and the U.S. FDA must continue to be proactive to reduce the cause and effects of drug shortages. This session will provide a brief update on the Drug Shortage Task Force. In addition, this session 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.</p>	<p>Breakfast 5: Data Integrity Moderator: Susan J. Schniepp, BS, Distinguished Fellow, <i>Regulatory Compliance Associates Inc.</i></p> <p>The PDA Data Integrity Task Force has been working on a series of technical reports (TRs) addressing data integrity. The most recent TR is focused on data integrity issues related to manufacturing/shop floor systems and processes. A risk-based approach for identification of appropriate data integrity controls and implementation mitigations are the core concepts described in this report. This session will be the first opportunity for PDA members to get an inside look at some of the information and recommendations contained in this draft TR. This session will also include a panel discussion with members from the team that wrote the technical report and will be a great opportunity for PDA members to ask questions regarding the thought process behind the recommendations contained in the report.</p>
<p>7:15 a.m. David L. Jones, PhD, Director, <i>Rapid Micro Biosystems</i></p>	<p>7:15 a.m. What Can We Learn from Compounding</p>	<p>7:15 a.m. Field Alert Reports</p>	<p>7:15 a.m. U.S. FDA Presentation on Quality Systems</p>	<p>7:15 a.m. Els Poff, Executive Director, Data Integrity Center of</p>

<p>7:45 a.m. Q&A Panel with Additional Panelist Ed C. Tidswell, PhD, BSc, Executive Director QA, <i>Merck & Co., Inc.</i></p>	<p>Pharmacy Producing Small Parenteral Batches? Chris J. Smalley, PhD, Compounding Pharmacist Advisor, <i>ValSource, LLC</i></p> <p>7:45 a.m. Q&A Panel with Additional Panelist Ian F. Deveau, PhD, Division Director (Acting), CDER, <i>U.S. FDA</i></p>	<p>Elise A. Murphy, Supervisory Consumer Safety, CDER, <i>U.S. FDA</i></p> <p>7:35 a.m. Biological Product Deviation Reports Kimberly E. Rains, PharmD, Associate Director for Regulatory Affairs, CDER, <i>U.S. FDA</i></p> <p>7:55 a.m. Q&A Panel</p>	<p>CAPT Christine M. Bina, RPh, MPH, Drug Shortage Staff (DSS) Team Leader, CDER, <i>U.S. FDA</i></p> <p>7:45 a.m. Q&A Panel with Additional Panelist Glenn E. Wright, Quality Head, <i>Exelead BioPharma Inc.</i></p>	<p>Excellence, <i>Merck & Co., Inc. and PDA Data Integrity Technical Report Leader</i></p> <p>7:45 a.m. Q&A Panel with Additional Panelists Maan S. Abduldayerm, Supervisory Consumer Safety, CDER, <i>U.S. FDA</i> John Grealis, PhD, Regional Head Data Integrity, <i>Novartis and PDA Data Integrity Technical Report Team</i> Ronald F. Tetzlaff, Corporate Vice President, <i>PAREXEL Consulting and PDA Data Integrity Technical Report Team</i></p>
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8:30 a.m.-10:00 a.m. | P3: Compliance Updates
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. | **Panel Discussion**
John W. Diehl, MS, Director, Compliance Branch, ORA, *U.S. FDA (INVITED)*
Martine L. Hartogensis, DVM, Deputy Director, Office of Surveillance and Compliance, CVM, *U.S. FDA*
Michael Levy, Deputy Director for Policy and Analysis, Office of Compliance, CDER, *U.S. FDA (INVITED)*
Melissa Mendoza, Deputy Director, Office of Compliance and Biologics Quality, CBER, *U.S. FDA*

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

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

INNOVATION AND TECHNOLOGY	QUALITY AND COMPLIANCE	INSPECTION AND AUDITS
<p>A3: Innovations in Aseptic Processing Moderators: Shane D. Killian, MS, Senior Director, Licensing, Acquisition & Early Development, <i>Janssen R&D Quality & Compliance</i> and Lynnsey A. Renn, PhD, Public Health Analyst, Office of Manufacturing Quality, CDER, <i>U.S. FDA</i></p> <p>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</p>	<p>B3: Quality Systems: Focus on Change Management Program Moderator: Rebecca A. Devine, PhD, Biopharmaceutical Consultant</p> <p>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</p>	<p>C3: The New Inspection Paradigm Moderator: Mai X. Huynh, MS, Supervisory Chemist, CVM, <i>U.S. FDA</i></p> <p>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</p>

<p>benefits of technological advances in drug manufacturing.</p>	<p>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.</p>	<p>an effective response to U.S. FDA Form 483 Inspectional Observations.</p>
<p>10:45 a.m. Chakradhar Padala, PhD, Director, Process Development, <i>Amgen Inc.</i></p> <p>11:15 a.m. Bryan S. Riley, Supervisory Microbiologist, CDER, <i>U.S. FDA</i></p> <p>11:45 a.m. Q&A Panel with Additional Panelist Hal S. Baseman, Chief Operations Officer, <i>ValSource, LLC</i></p>	<p>10:45 a.m. Kimberly M. Bruhin, Director Pharmaceutical Quality Systems, Metrics & Reporting, <i>Johnson & Johnson</i></p> <p>11:15 a.m. Effective Change Management in the Q12 Paradigm Ileana Barreto-Pettit, RN, MPH, Captain, U.S. Public Health Service, Drug National Expert, ORA, <i>U.S. FDA (INVITED)</i></p> <p>11:45 a.m. Q&A Panel with Additional Panelist Chikako Torigoe, Biologist, CBER, <i>U.S. FDA</i></p>	<p>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), <i>MHRA, UK</i></p> <p>11:05 a.m. Pilot Program: The New Inspection Protocols Project (NIPP) Rosa J. Motta, Supervisory Consumer Safety, CDER, <i>U.S. FDA</i></p> <p>11:25 a.m. Responding to U.S. FDA Form 483 David J. Jaworski, MBA, Senior Policy Advisor, CDER, <i>U.S. FDA</i></p> <p>11:45 a.m. Q&A Panel with Additional Panelists Laura Huffman, MS, Master Microbiology Reviewer, CVM, <i>U.S. FDA</i> Nicholas A. Violand, Consumer Safety Officer, ORA, <i>U.S. FDA (INVITED)</i></p>

12:15 p.m. – 1:45 p.m. | **Portfolio Steering Committee** (*Invitation Only*)

<p>12:30 p.m. – 1:30 p.m. Lunch with the Regulators</p> <p>Back by popular demand and at a new time! 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.</p>	
<p>Review-Based Panel Discussion Moderators: Rebecca A. Devine, PhD, Biopharmaceutical Consultant, Mai X. Huynh, MS, Supervisory Chemist, CVM, <i>U.S. FDA</i>, and Bitia Mirzai-Azarm, MS, Branch Chief, CDER, <i>U.S. FDA</i></p> <p>Panelists Renée S. Blosser, MS, Microbiologist, CVM, <i>U.S. FDA</i> Bing Cai, PhD, Division Director, CDER, <i>U.S. FDA</i> Zhihzo Peter Qiu, PhD, Chief, Biotechnology Manufacturing Assessment Branch, CDER, <i>U.S. FDA (INVITED)</i> Ramesh Raghavachari, Supervisory Chemist, CDER, <i>U.S. FDA (INVITED)</i> Derek S. Smith, Supervisory Chemist, CDER, <i>U.S. FDA</i></p>	<p>Inspection-Based Panel Discussion Moderators: Mary E. Farbman, PhD, Executive Director, Global Quality Compliance, <i>Merck & Co., Inc.</i>, Susan J. Schniepp, BS, Distinguished Fellow, <i>Regulatory Compliance Associates Inc.</i>, and Valerie Whelan, BSc, Vice President, Head of R&D Quality and Compliance, <i>Amgen Inc.</i></p> <p>Panelists David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), <i>MHRA, UK</i> Brooke K. Higgins, MS, Senior Policy Advisor, CDER, <i>U.S. FDA</i> Jose E. Melendez, Drug National Expert, ORA, <i>U.S. FDA (INVITED)</i> Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, <i>U.S. FDA</i></p>

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

INNOVATION AND TECHNOLOGY	QUALITY AND COMPLIANCE	INSPECTION AND AUDITS
<p>A4: Continuous Manufacturing Update Moderator: Clarice Hutchens, PhD, MA, DM, Senior Director, <i>Pfizer</i></p> <p>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.</p>	<p>B4: Investigations: Quality Risk Management and Structured Investigational Approaches Moderator: Rebecca E. Dombrowski, MS, Senior Policy Advisor, CDER, <i>U.S. FDA</i></p> <p>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.</p>	<p>C4: How Effective Is Your Audit Program? Moderators: Susan J. Schniepp, BS, Distinguished Fellow, <i>Regulatory Compliance Associates Inc</i></p> <p>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.</p>
<p>1:45 p.m. ICH Update Ganapathy Mohan, PhD, Executive Director, <i>Merck & Co., Inc.</i></p> <p>2:05 p.m. Sau L. Lee, Director, Office of Testing, CDER, <i>U.S. FDA</i></p> <p>2:25 p.m. David Pappa, Director of Technical Services/Manufacturing Science, <i>Eli Lilly and Company</i></p> <p>2:45 p.m. Q&A Panel</p>	<p>1:45 p.m. Tia Bush, Senior Vice President, Quality, <i>Amgen</i></p> <p>2:05 p.m. Kevin M. Jenkins, BS, MBA, Vice President, Sterile Injectables Quality, <i>Pfizer</i></p> <p>2:25 p.m. Binh T. Nguyen, PharmD, Consumer Safety Officer, CDER, <i>U.S. FDA</i></p> <p>2:45 p.m. Q&A Panel</p>	<p>1:45 p.m. Ghada N. Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, <i>Merck & Co., Inc.</i></p> <p>2:15 p.m. Guy Villax, CEO, <i>Hovione</i></p> <p>2:45 p.m. Q&A Panel with Additional Panelist David L. Chesney, MSJ, Principal and General Manager, <i>DL Chesney Consulting, LLC</i></p>

3:15 p.m. – 4:00 p.m. | **Refreshment Break and Passport Drawing in Exhibit Area**

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

INNOVATION AND TECHNOLOGY	QUALITY AND COMPLIANCE	INSPECTION AND AUDITS
<p>A5: Cell and Gene Therapy: CMC Considerations Moderator: Carol L. Rehkopf, Chief, Review Management Business Operations Staff, CBER, <i>U.S. FDA</i></p> <p>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. A case study will be</p>	<p>B5: OOS and Effective Remediation: Chemical and Microbiological Moderator: Renée D. Kyro, MBA, Director, <i>AbbVie</i></p> <p>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</p>	<p>C5: The Value of Selecting the Right Consultant Moderators: Rebecca A. Devine, PhD, Biopharmaceutical Consultant and Susan J. Schniepp, BS, Distinguished Fellow, <i>Regulatory Compliance Associates Inc</i></p> <p>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</p>

<p>provided that outlines one company's journey in this space.</p>	<p>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.</p>	<p>prevalent reason companies hire consultants is to help them avoid serious regulatory actions because they behaved in an un-compliant or questionable manner.</p> <p>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.</p>
<p>4:00 p.m. Lilia L. Bi, PhD, CMC Reviewer, CBER, <i>U.S. FDA</i></p> <p>4:30 p.m. Paul J. Gil, PhD, Executive Director, Regulatory Affairs CMC Gene Therapy, <i>Amicus Therapeutics, Inc.</i></p> <p>5:00 p.m. Q&A Panel</p>	<p>4:00 p.m. Inspection Observations Brooke K. Higgins, MS, Senior Policy Advisor, CDER, <i>U.S. FDA</i></p> <p>4:30 p.m. Investigation Case Studies Sean McEwan, Vice President, Quality Assurance, Abbvie Operations, <i>Abbvie</i></p> <p>5:00 p.m. Q&A Panel with Additional Panelist Rick L. Friedman, MS, Deputy Director, OMQ, CDER, <i>U.S. FDA</i></p>	<p>4:00 p.m. Tamara L. Ely, Consumer Safety Officer, CDER, <i>U.S. FDA</i></p> <p>4:30 p.m. Anil Sawant, PhD, MSc, Senior Vice President, Global Quality Compliance, <i>Merck & Co., Inc.</i></p> <p>5:00 p.m. Q&A Panel with Additional Panelist Douglas A. Campbell, Senior Consultant, <i>InterPro QRA</i> John G. Shabushnig, PhD, Principal Consultant, <i>Insight Pharma Consulting, LLC</i></p>

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

<p>IG11: Filtration</p>	<p>This session will update participants on the PDA/BPOG SFQRM (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.</p>
<p>IG12: Inspection Trends</p>	<p>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.</p>
<p>IG13: Lyophilization and Packaging Science</p>	<p>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 the beginning of 2018. The IG session will then be an open forum for discussions on these and other current topics in packaging for both liquid products and lyophilized preparations.</p> <p>In this open forum format, topics are identified by participants for discussions by the group. The topics will then be prioritized by participants voting, reflecting the level of interest for discussion by the group.</p>
<p>IG14: Prefilled Syringes</p>	<p>The Prefilled Syringes IG will continue its series on glass alternatives. Alternative materials such as COC or COP 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. In this session one vendor will present their branded syringe and development data. A roundtable discussion of plastic syringe development challenges will follow the presentation.</p>
<p>IG15: Regulatory Affairs</p>	<p>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</p>

	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. PDA's Regulatory Affairs IG will host an interactive panel discussion with representatives from Manufacturing, Regulatory Affairs and a Regulatory Agency, and use 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	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 SQM models (i.e., change control), and 3) supply chain management of cell gene therapies.

Wednesday, September 18

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

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

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

<p>Breakfast 6: Using Statistical Tools and Effective Statistical Control: Introduction to Statistical Process Control Moderator: Jacqueline A. Kunzler, PhD, MBA, Senior Vice President, Chief Quality Officer, <i>Baxter Healthcare Corporation</i></p> <p>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, <i>before</i> 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).</p>	<p>Breakfast 7: Using Emerging Tools to Understand Post-Market Patients'/Consumers' Perspectives on Quality Moderator: Neil A. Stiber, PhD, Associate Director for Science and Communication, Office of Surveillance, CDER, <i>U.S. FDA</i></p> <p>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</p>	<p>Breakfast 8: Quality Culture Moderator: Susan J. Schniepp, BS, Distinguished Fellow, <i>Regulatory Compliance Associates Inc</i></p> <p>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.</p>	<p>Breakfast 9: Aseptic Processing for Cell and Gene Therapy Products Moderator: Laurie P. Norwood, MS, President, <i>Norwood Biologics Consulting LLC</i></p> <p>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. FDA's 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.</p>	<p>Breakfast 10: Smoke Studies Moderator: Lynnsey A. Renn, PhD, Public Health Analyst, Office of Manufacturing Quality, CDER, <i>U.S. FDA</i></p> <p>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.</p>
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	can improve future patient experiences.			
7:15 a.m. Overview of Statistical Process Control Karthik B. Iyer , Supervisory Consumer Safety, 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	7:15 a.m. Christine S. Lee, PhD, PharmD , Scientist, OC, U.S. FDA 7:35 a.m. Hyunwoo Park , Assistant Professor, Department of Management Sciences, The Ohio State University 7:55 a.m. Q&A Panel	7:15 a.m. Quality Culture Role Play Cylia Chen-Ooi, MS , Director Quality External Affairs, Amgen Inc. and Member, PDA Quality Metrics Task Force Steve E. Mendivil, BS , Independent Consultant and Member, PDA Quality Metrics Task Force 7:45 a.m. Q&A Panel	7:15 a.m. Lily Y. Koo, PhD , Consumer Safety Officer, CBER, U.S. FDA 7:45 a.m. Q&A Panel	7:15 a.m. Dave Matsuhiro , Senior Consultant, Cleanroom Compliance, Inc. 7:45 a.m. Q&A Panel with Additional Panelists Tamara L. Ely , Consumer Safety Officer, CDER, U.S. FDA Jose E. Melendez , Drug National Expert, ORA, U.S. FDA (INVITED)

8:30 a.m. – 10:00 a.m. | **P4: Center Updates**
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 senior management officials from various U.S. FDA Centers in this highly interactive session! In a roundtable 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. | **Panel Discussion**
Peter W. Marks, MD, PhD, Director, CBER, U.S. FDA
Ellen F. Morrison, Assistant Commissioner for Medical Products and Tobacco Operations, ORA, U.S. FDA (INVITED)
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**

10:30 a.m. – 12:15 p.m. | **P5: The Evolving Regulatory Landscape**
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 infrastructure upgrades are critical to promote meaningful advancements. Likewise, clear regulatory standards are equally important to ameliorate risk related to the uncertainty inherent in the use of innovative technologies and products. 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 assurance.

10:30 a.m. | **Peter W. Marks, MD, PhD**, Director, CBER, U.S. FDA

11:00 a.m. | **Industry Representative Invited**

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

12:00 p.m. | **Closing Remarks and Introduction of 2020 PDA/FDA Joint Regulatory Conference Co-Chairs**