PDA Regulatory Conference 2025 - Archived

Agenda

Sunday, 7 September

EDT Daylight Time (UTC -4:00)

11:30 – 13:00	**Advisory Board Luncheon (River Birch A) (Invite Only)**
13:00 – 17:00	**Advanced Therapy Medicinal Products Advisory Board (MR 14) (Invite Only)** **AB Chair: Friedrich von Wintzingerode PhD**, Director, Microbiology and QC Individualized and Cell Therapy, *Genentech, a Member of the Roche Group* **AB Vice-Chair: Monica Markovski Commerford PhD** Manager, Regulatory Affairs *Thermo Fisher Scientific*
13:00 – 17:00	**Biopharmaceutical Advisory Board (MR 15) (Invite Only)** **AB Chair: Maxwell De Long MS, MechE**, Director and Senior Principal, Individualized Medicines, *Genentech* **AB Vice-Chair: Peter J. Makowenskyj MEng** Senior Director of Design Consulting *G-CON*
13:00 – 17:00	**Regulatory Affairs and Quality Advisory Board (MR 16) (Invite Only)** **AB Chair: Eva M. Urban MSc**, Senior Director, Risk Management, *Bristol Myers Squibb* **AB Vice-Chair: Vinny Browning MS** Executive Director Quality Assurance *Amgen*
13:00 – 17:00	**Science Advisory Board (MR 13) (Invite Only)** **AB Chair: Ivy Louis MPharm, MBA(HRM)**, Founder-Director, *Vienni Training & Consulting LLP* **AB Vice-Chair: Ken Paddock** Director, Global Quality Sterility Assurance *Merz Aesthetics*
14:00 – 19:00	**Registration Open (Rock Creek Ballroom Registration Desk)**
15:00 – 18:00	**Presenter Ready Room Open (Meeting Planner Office B)**
16:00 – 17:30	**PDA Capital Area Chapter Roundtable: FDA Complete Response Letters: A Growing Industry Challenge with Big Impacts (Rock Creek B)** **Moderator: Glenn E. Wright MA**, President and CEO, *PDA*

16:00 – 16:05	**Chapter Welcome and Introductory Remarks** • **Presenter: Martin S. Jenkins PMP**, Senior Project Manager, Qualification and Validation, *Circle MJ Consulting*
16:05 – 16:20	**CRL Recap** • **Presenter: Glenn E. Wright MA**, President and CEO, *PDA*
16:20 – 16:50	**CRL Impacts and Current Issues** • **Presenter: Thomas J Cosgrove JD**, Partner, *Covington & Burling LLP*
	Q&A with Additional Panelists

	16:50 – 17:20	• **Panelist: Ghada N. Haddad PhD**, Head of Global Quality Systems and Quality Processes, *Kite Pharma* • **Panelist: Anil D. Sawant PhD**, Senior Vice President, Global Quality Transformation, *Merck & Co., Inc.* • **Panelist: Stelios C Tsinontides PhD, FAIChE**, Vice President, Global Quality, Quality Management Systems, Transformation & External Advocacy, *Merck & Co., Inc.*
	17:20 – 17:30	**Closing Remarks** • **Presenter: Glenn E. Wright MA**, President and CEO, *PDA*

Monday, 8 September

EDT Daylight Time (UTC -4:00)

07:00 – 08:30	**Continental Breakfast (Ballroom Foyers)**
07:00 – 16:15	**Presenter Ready Room Open (Meeting Planner Office B)**
07:00 – 19:00	**Registration Open (Rock Creek Ballroom Registration Desk)**
08:30 – 10:00	**P1: Quality in Advanced Therapies and Global Collaboration (Potomac Ballroom)** **Moderator: Mary E. Farbman PhD**, Associate Vice President, Global Quality Compliance, *Merck & Co., Inc.*

08:30 – 08:50	**Welcome and Opening Remarks from PDA Leadership and the Conference Co-Chairs** • **Board Chair: Anil D. Sawant PhD**, Senior Vice President, Global Quality Transformation, *Merck & Co., Inc.* • **President & CEO: Glenn E. Wright MA**, President and CEO, *PDA* • **Co-Chair: Janeen Skutnik-Wilkinson** , Director, Regulatory Intelligence and External Engagement, *Moderna* • **Co-Chair: Mary E. Farbman PhD**, Associate Vice President, Global Quality Compliance, *Merck & Co., Inc.*
08:50 – 09:10	**The Power of Quality** • **Presenter: Melissa S. Seymour MBA**, EVP and Chief Quality Officer, *Eli Lilly and Company*
09:10 – 09:30	**The Human Impact** • **Presenter: Jimi Olaghere** , Gene Editing Recipient and Patient Advocate, *Sugarloaf Capital*
09:30 – 10:00	**Q&A**

10:00 – 16:30	**Exhibit Area Open (Ballroom Foyers)**
10:00 – 11:00	**Networking Break in the Exhibit Area (Ballroom Foyers)**
11:00 – 12:30	**P2: Current GMP Compliance Trends and Topics (Potomac Ballroom)** **Moderator: Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.*

11:00 – 11:25	**Drug Compliance Trends and Topics** • **Presenter: Francis R.W. Godwin MBA**, Office Director, OMQ, OC, CDER, *U.S. FDA*

11:00 – 12:30	11:25 – 11:50	**Biologics Compliance Trends and Topics** • **Presenter: Jonathan G Swoboda PhD**, Consumer Safety Officer, OCBQ, CBER, *U.S. FDA*
	11:50 – 12:30	**Q&A with Additional Panelists** • **Panelist: Jeffrey D Meng MSE**, Associate Director, Emerging Technologies and Advanced Manufacturing, Medical Products Inspectorate, OII, *U.S. FDA* • **Panelist: Dillard H. Woody** , Branch Chief, OSC, CVM, *U.S. FDA*
12:30 – 14:00	**Lunch on Your Own**	
14:00 – 15:30	**A1: Competency-Based Training and Digital Learning (Potomac 1)** **Moderator: Susan J. Schniepp** , Distinguished Fellow, *Regulatory Compliance Associates Inc.*	
	14:00 – 14:25	**Training for Performance** • **Presenter: Marc Glogovsky MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*
	14:25 – 14:50	**Digital Tools for Smarter Learning** • **Presenter: Richard Jaenisch MPH**, Senior Director of Education, Outreach and Digital Experience, *Open Biopharma Research and Training Institute*
	14:50 – 15:30	**Q&A with Additional Panelist** • **Panelist: Matthew R. Dionne PharmD, MBA, BCPS**, Regulatory Officer, OC, CDER, *U.S. FDA*
14:00 – 15:30	**B1: Data Integrity (Potomac 2)** **Moderator: Al Kentrup** , Executive Advisor , *NPG*	
	14:00 – 14:25	**DI: The Unbreakable Chain – Is Yours Strong Enough?** • **Presenter: Alicja Wolska MS**, Executive Director, Digital & Data Quality, *Merck & Co., Inc.*
	14:25 – 14:50	**Data Governance to Ensure Regulatory Compliance, Data Protection, and Future Readiness for Advanced Use Cases** • **Presenter: Toni Manzano PhD**, CSO and Compliance Officer, *Aizon*
	14:50 – 15:30	**Q&A** • **Panelist: Shawn Larson PhD**, Development Coordinator, OACII, OII, *U.S. FDA*
14:00 – 15:30	**C1: Beyond Your Facility Walls: Contractor and Supplier Quality Oversight (Potomac 3)** **Moderator: Tara Gooen Bizjak MBS**, Associate Director, GMP and Quality Standards, OC, CDER, *U.S. FDA*	
	14:00 – 14:25	**Building Sustainable Contractor Relationships That Deliver Value** • **Presenter: Jennifer Stone MBA**, SVP, Quality, *PTC Therapeutics*
	14:25 – 14:50	**Selecting Suppliers and Monitoring Lifecycle Signals** • **Presenter: Shaun Crofts** , Executive Director, External Quality Operations, *Gilead*
		Q&A with Additional Panelist

	14:50 – 15:30	• **Panelist: Benjamin Mills** , Senior Director, Operations (Joint Audit Program/Quality), *Rx-360*
15:30 – 16:30	**Networking Break in the Exhibit Area (Ballroom Foyers)**	
16:30 – 18:00	**A2: Leveraging AI in Audits (Potomac 1)** **Moderator: Mary E. Farbman PhD**, Associate Vice President, Global Quality Compliance, *Merck & Co., Inc.*	
	16:30 – 16:55	**Enhancing Audit Readiness Through Digital Tools** • **Presenter: Nidia Acevedo PhD**, Senior Vice President, Global Quality Compliance, *Eli Lilly and Company*
	16:55 – 17:20	**Navigating Implementation Challenges for Emerging Technologies** • **Presenter: Vinny Browning MS**, Executive Director Quality Assurance, *Amgen*
	17:20 – 18:00	**Q&A with Additional Panelist** • **Panelist: Hesha J. Duggirala PhD, MPH**, Epidemiologist and AI Center Lead, OSC, CVM, *U.S. FDA*
16:30 – 18:00	**B2: Knowledge Sharing Best Practices (Potomac 2)** **Moderator: Marc Glogovsky MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*	
	16:30 – 16:55	**The Culture We Want to Grow: Collaborating for Consistency in Global Sterility Assurance** • **Presenter: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*
	16:55 – 17:20	**Concept: A Self-Sustaining Sterility Assurance Program is a Journey** • **Presenter: Christopher A. Murdock PhD, CQA**, VP, Sterility Assurance and Microbiology Support, *Eli Lilly and Company*
	17:20 – 18:00	**Q&A with Additional Panelist** • **Panelist: Brooke K. Higgins MS**, Senior Vice President, Regulatory Compliance, *ELIQUENT Life Sciences*
16:30 – 18:00	**C2: From Disruption to Preparedness: Achieving Sustainable Supply Through Crisis Management and Proactive Compliance (Potomac 3)** **Moderator: Janeen Skutnik-Wilkinson** , Director, Regulatory Intelligence and External Engagement, *Moderna*	
	16:30 – 16:55	**Resilient by Design: A Case Study in Rapid Recovery** • **Presenter: Chad Minks MBA**, Sr. Director - Site Quality Head, *Baxter*
	16:55 – 17:20	**Proactive Compliance and Maturity** • **Presenter: Carmen C. Araujo MBA**, Senior Vice President, Head Global Quality Audit and Supplier Quality, *Takeda*
	17:20 – 18:00	**Q&A with Additional Panelist** • **Panelist: Derek S. Smith PhD**, Deputy Director, OPMA, OPQ, CDER, *U.S. FDA* • **Panelist: Ivy E. Sweeney PhD**, Acting Director, Office of Human and Animal Drug Inspectorate,

OII, *U.S. FDA*

18:00 – 20:00	**Networking Reception (Rock Creek Ballroom)**

Tuesday, 9 September

EDT Daylight Time (UTC -4:00)

07:00 – 08:30	**Continental Breakfast (Ballroom Foyers)**
07:00 – 16:45	**Presenter Ready Room Open (Meeting Planner Office B)**
07:00 – 18:00	**Registration Open (Rock Creek Ballroom Registration Desk)**
07:15 – 08:15	**Breakfast 1: Fundamentals of Current Good Manufacturing Practices (Rock Creek A)** **Moderator: Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.* 07:15 – 07:40: **CGMPs Made Practical: A Guide for New and Non-Compliance Professionals** • **Presenter: Maya Davis PhD**, Senior Vice President, Regulatory Compliance, *ELIQUENT Life Sciences* 07:40 – 08:15: **Q&A with Additional Panelists** • **Panelist: Maan Abduldayem MBA**, Supervisor, OC, CDER, *U.S. FDA* • **Panelist: Tamika D Cathey** , Global Principal Program Lead - Pharma Biotech, *National Sanitation Foundation*
07:15 – 08:15	**Breakfast 2: Using Digital Technologies to Assess and Ensure Compliance (Rock Creek B/C)** **Moderator: Lily Y. Koo PhD**, Biomedical Engineer, CBER, *U.S. FDA* 07:15 – 07:40: **Strengthening Compliance with Smarter Systems** • **Presenter: Sarah R. Barkow PhD**, Senior Director Proactive Compliance and Innovation, *AstraZeneca* 07:40 – 08:15: **Q&A with Additional Panelists** • **Panelist: Ekaterina Allen PhD, RAC**, Pharmaceutical Scientist, OPQ, CDER, *U.S. FDA* • **Panelist: Abhinay Gajula MBA**, Manager - Product Marketing & Technology, *ComplianceQuest* • **Panelist: Sebastian Scheler MSc**, Managing Director, *Innerspace*
07:15 – 08:15	**IG2: Regulatory Affairs (Anacostia E)** **Interest Group Leader: Ruhi Ahmed PhD, RAC**, Senior Vice President, *FLAG Therapeutics, Inc.* **Co-Facilitator: Christopher Downey PhD** Director, Division of Pharmaceutical Manufacturing Assessment VI, OPMA, OPQ, CDER *U.S. FDA* **Co-Facilitator: Catherine A Gould** Regulatory Officer, OC, CDER *U.S. FDA*
07:15 – 08:15	**IG1: Quality Systems (Anacostia D)** **Interest Group Leader: Ghada N. Haddad PhD**, Head of Global Quality Systems and Quality Processes, *Kite Pharma* **Interest Group Leader: Vishal Sharma MS** Co-Founder - Director *Vienni Training & Consulting LLP* **Interest Group Leader: Michele Simone PhD** Director, Corporate Quality Compliance, Risk Management, and Continual

Improvement *Bracco*

Interest Group Leader: Eva M. Urban MSc Senior Director, Risk Management *Bristol Myers Squibb*

Co-Facilitator: Matthew R. Dionne PharmD, MBA, BCPS Regulatory Officer, OC, CDER *U.S. FDA*

P3: Data Integrity at the Next Level (Potomac Ballroom)

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

08:30 – 10:00	08:30 – 08:55	**Advancing DI: New Challenges, Practical Solutions** • **Presenter: Peter Baker MS**, President, *Live Oak Quality Assurance LLC*
	08:55 – 09:20	**Building Resilient Data Systems: Governance and Good Practice** • **Presenter: Dr. Carmelo Rosa** , Division Director, Office of Manufacturing and Product Quality, OC, CDER, *U.S. FDA*
	09:20 – 10:00	**Q&A**
10:00 – 16:30	**Exhibit Area Open (Ballroom Foyers)**	
10:00 – 11:00	**Networking Break in the Exhibit Area (Ballroom Foyers)**	

B3: Quality Indicators and Sustainable Compliance (Potomac 2)

Moderator: Al Kentrup , Executive Advisor , *NPG*

11:00 – 12:30	11:00 – 11:25	**Sustainable Compliance** • **Presenter: Marla A. Phillips PhD**, CEO and President, *Pathway for Patient Health*
	11:25 – 11:50	**Making Metrics Work: A Practical Framework for Compliance Monitoring** • **Presenter: Scott Meikle MS**, SVP Global Technical Organization, *Ecolab*
	11:50 – 12:30	**Q&A**

C3: Quality Oversight in a Modern Supply Chain (Potomac 3)

Moderator: Andrew D. Hopkins PGDip, Senior Director, *Lachman Consultants*

11:00 – 12:30	11:00 – 11:25	**Beyond the Bench: AI-Powered Oversight for Chem and Micro Labs** • **Presenter: Charles Gibbons** , Director, Data Integrity & Data Governance, *Lachman Consultants*
	11:25 – 11:50	**Guardians of Quality: Digital Tools and AI in the Era of Complex Supply Networks** • **Presenter: Michael D. Grischeau** , Director of Data Analytics and Management Review, *AbbVie Inc.*
	11:50 – 12:30	**Q&A with Additional Panelist** • **Panelist: Milind Ganjawala MS, MBA**, Division Director, DDQ, OMQ, OC, CDER, *U.S. FDA*

A3: Effective Validation and Manufacturing Strategies (Potomac 1)

Moderator: Nelson E. Rivera JD, Consumer Safety Officer, OC, CDER, *U.S. FDA*

		PV in Motion: Enabling Concurrent Release

	11:00 – 11:25	• **Presenter: Olufemi Rabiu PhD**, SVP, Head of Quality, *Innoviva Specialty Therapeutics*
11:00 – 12:30	11:25 – 11:50	**Phase-Appropriate Approaches for ATMPs: GMP, CMC, and PV** • **Presenter: Markus A. Gruell MSc**, Senior Vice President Head of Quality, *Autolus Ltd.*
	11:50 – 12:30	**Q&A with Additional Panelists** • **Panelist: Tara Gooen Bizjak MBS**, Associate Director, GMP and Quality Standards, OC, CDER, *U.S. FDA* • **Panelist: Laura K. DeMaster PhD**, Gene Therapy CMC Reviewer, OTP, CBER, *U.S. FDA*
12:30 – 14:00	**Lunch on Your Own**	
14:00 – 15:30	**A4: Innovations in Facilities and Technology (Potomac 1)** **Moderator: Shawn Larson PhD**, Development Coordinator, OACII, OII, *U.S. FDA*	
	14:00 – 14:25	**Digitization (Artificial Intelligence) for In-House Operational Excellence** • **Presenter: Vinny Browning MS**, Executive Director Quality Assurance, *Amgen*
	14:25 – 14:50	**Upgraded Facilities to Assure Quality and Compliance** • **Presenter: Ossama Eissa MBA**, Chief Operating Officer, *Cellares*
	14:50 – 15:30	**Q&A with Additional Panelists** • **Panelist: Michael R. Klapal MSc**, Consumer Safety Officer, OC, CDER, *U.S. FDA* • **Panelist: Jeffrey D Meng MSE**, Associate Director, Emerging Technologies and Advanced Manufacturing, Medical Products Inspectorate, OII, *U.S. FDA*
14:00 – 15:30	**C4: Supply Chain Risk and Resilience (Potomac 3)** **Moderator: Andrea K. Kerrigan MS**, Branch Chief, OGAD, CVM, *U.S. FDA*	
	14:00 – 14:25	**Enhancing Supply Chain Resilience Through Quality Risk Management: A Case Study Approach** • **Presenter: Ghada N. Haddad PhD**, Head of Global Quality Systems and Quality Processes, *Kite Pharma*
	14:25 – 14:50	**Weathering the Storm: How Preparation Saved the Supply Chain** • **Presenter: Patrick Gregorowicz** , Sr. Director Operations, *bioMérieux*
	14:50 – 15:30	**Q&A with Additional Panelist** • **Panelist: Jason A. Rossi MS**, Chemist, ONAPE, CVM, *U.S. FDA*
	B4: How to Make Quality Culture Real (Potomac 2) **Moderator: Irving Ford MSc**, , *Quality Leader*	
	14:00 – 14:25	**Operationalizing Quality Culture** • **Presenter: Brad Warsen** , Executive Director, Corporate Quality, *Biogen*

14:00 – 15:30	14:25 – 14:50	**A Sustainable Approach to Compliance** • **Presenter: Elizabeth David MS**, Vice President, IM Supply Chain Quality, Advanced Therapies, *Johnson & Johnson*
	14:50 – 15:30	**Q&A with Additional Panelist** • **Panelist: Nelson E. Rivera JD**, Consumer Safety Officer, OC, CDER, *U.S. FDA*
15:30 – 16:30	**Networking Break in the Exhibit Area (Ballroom Foyers)**	
16:30 – 18:00	**A5: Inspection Ready Facilities: Industry Practices and FDA Expectations (Potomac 1)** **Moderator: Karyn M. Campbell** , Senior Director, QA Audit and Compliance, *AbbVie Inc.*	
	16:30 – 16:55	**Overview of Inspection Readiness Program** • **Presenter: Eric T. Ludewig MBA**, Head, Operational Compliance, Global Quality Audit and Supplier Quality, *Takeda*
	16:55 – 17:20	**FDA PAI/PLI Expectations and Trends** • **Presenter: Ekaterina Allen PhD, RAC**, Pharmaceutical Scientist, OPQ, CDER, *U.S. FDA*
	17:20 – 18:00	**Q&A with Additional Panelists** • **Panelist: Constance Y. Fears JD, PhD**, CEO and Principal Consultant, *Polymath Regulatory Consultants* • **Panelist: Ivy E. Sweeney PhD**, Acting Director, Office of Human and Animal Drug Inspectorate, OII, *U.S. FDA*
16:30 – 18:00	**B5: Decision-Making and Knowledge Transfer (Potomac 2)** **Moderator: Eva M. Urban MSc**, Senior Director, Risk Management, *Bristol Myers Squibb*	
	16:30 – 16:55	**Risk-Based Approach for Learning** • **Presenter: Sara Voit MSPH**, Associate Vice President, Global MQ Learning & Development, *Eli Lilly and Company*
	16:55 – 17:20	**Enhancing Decision Making through Quality Systems in a VUCA World** • **Presenter: Karin Ann Payne MBA, MLS**, Vice President, Corporate Quality, *Bristol Myers Squibb*
	17:20 – 18:00	**Q&A with Additional Panelist** • **Panelist: Kristen L. Anderson PhD**, Microbiologist, ONADE, CVM, *U.S. FDA*
16:30 – 18:00	**C5: Evolving Release Models (Potomac 3)** **Moderator: Paul Z. Balcer** , Consumer Safety Officer, OMQ, OC, CDER, *U.S. FDA*	
	16:30 – 16:55	**Reimagining Lot Release for Vaccines: Balancing Speed, Innovation, and Assurance** • **Presenter: Sabrina Restrepo PhD**, Executive Director - Quality Assurance, *Merck & Co., Inc.*
		Q&A with Additional Panelists • **Panelist: Christina Capacci-Daniel PhD**, Compliance Officer, OMQ, OC, CDER, *U.S. FDA*

	16:55 – 18:00	• **Panelist: Katharine K. Duncan PhD**, Director CMC Policy and Advocacy, *GSK* • **Panelist: Eric A. Levenson PhD**, Biological Reviewer, OTP, CBER, *U.S. FDA* • **Panelist: Swati Verma PhD**, Biologist, OVRR, CBER, *U.S. FDA*
18:00 – 21:00	**PDA Capital Area Chapter: Whiskey State of Mind – Annual Networking Social (Crimson Whiskey Bar) (Ticket Required)**	
19:00 – 21:00	**Lincoln's Last Night Walking Tour (Ticket Required)**	

Wednesday, 10 September

EDT Daylight Time (UTC -4:00)

07:00 – 08:30	**Continental Breakfast (Ballroom Foyers)**	
07:00 – 11:00	**Presenter Ready Room Open (Meeting Planner Office B)**	
07:00 – 15:00	**Registration Open (Rock Creek Ballroom Registration Desk)**	
07:15 – 08:15	**Breakfast 3: Building a Strong Quality Culture (Rock Creek A)** **Moderator: Susan J. Schniepp** , Distinguished Fellow, *Regulatory Compliance Associates Inc.*	
	07:15 – 07:25	**Framing the Conversation** • **Presenter: Susan J. Schniepp** , Distinguished Fellow, *Regulatory Compliance Associates Inc.*
	07:25 – 08:15	**Voices of Experience Roundtable: What Quality Culture Really Takes** • **Panelist: Jeff Broadfoot MBA**, Vice President, Quality Operations, *Emergent BioSolutions Inc.* • **Panelist: Matthew Cushing** , Vice President, Quality and Science, *Nelson Labs* • **Panelist: Shawn Larson PhD**, Development Coordinator, OACII, OII, *U.S. FDA* • **Panelist: Nandini Rakala PhD**, Data Scientist | Visiting Associate, OPQ, CDER, *U.S. FDA*
07:15 – 08:15	**Breakfast 4: Post-Approval Changes and Lifecycle Management (Rock Creek B/C)** **Moderator: Eva M. Urban MSc**, Senior Director, Risk Management, *Bristol Myers Squibb*	
	07:15 – 07:40	**Managing PACs** • **Presenter: Andrea Kurz** , Senior Director External Advocacy Europe and Middle East, *F. Hoffmann-La Roche Ltd.*
	07:40 – 08:15	**Q&A with Additional Panelists** • **Panelist: Anamitro Banerjee PhD**, Director, CMC Regulatory Affairs, *AstraZeneca* • **Panelist: Christina Capacci-Daniel PhD**, Compliance Officer, OMQ, OC, CDER, *U.S. FDA* • **Panelist: J. Paul Kirwan PhD**, Senior Manager, Global Regulatory Affairs CMC, *Amgen*
07:15 – 08:15	**IG3: Data Governance, Management, Integrity, and Digitalization (Anacostia D)** **Interest Group Leader: Kir Henrici** , President, *The Henrici Group* **Interest Group Leader: Ulrich Koellisch PhD** Partner *GxP-CC* **Co-Facilitator: Matthew R. Dionne PharmD, MBA, BCPS** Regulatory Officer, OC, CDER *U.S. FDA*	

Co-Facilitator: Michael R. Klapal MSc Consumer Safety Officer, OC, CDER *U.S. FDA*

07:15 – 08:15

IG4: Quality Risk Management (Anacostia E)

Interest Group Leader: Amanda McFarland MS, Senior Consultant, *ValSource, Inc.*

Interest Group Leader: Malav Parikh ME Director, Quality Risk Management, Global Quality Compliance and Systems *Takeda*

Co-Facilitator: Nelson E. Rivera JD Consumer Safety Officer, OC, CDER *U.S. FDA*

08:30 – 10:30

P4: Agency Updates: Regulatory Priorities and Enforcement Outlook (Potomac Ballroom)

Moderator: Karyn M. Campbell , Senior Director, QA Audit and Compliance, *AbbVie Inc.*

08:30 – 08:50	**CBER Updates** • **Presenter: Melissa J. Mendoza JD**, Director, OCBQ, CBER, *U.S. FDA*
08:50 – 09:10	**CDER Updates** • **Presenter: Jill Furman JD**, Director, OC, CDER, *U.S. FDA*
09:10 – 09:30	**CVM Updates** • **Presenter: Cindy L. Burnsteel DVM**, Deputy Director for Drugs and Devices, OSC, CVM, *U.S. FDA*
09:30 – 09:50	**OII Updates** • **Presenter: Ivy E. Sweeney PhD**, Acting Director, Office of Human and Animal Drug Inspectorate, OII, *U.S. FDA*
09:50 – 10:30	**Q&A**

10:30 – 11:00 **Networking Break (Ballroom Foyers)**

11:00 – 12:15

P5: Sustainable CGMP Remediation Plans and Communication: FDA Updates (Potomac Ballroom)

Moderator: Paul Z. Balcer , Consumer Safety Officer, OMQ, OC, CDER, *U.S. FDA*

11:00 – 11:25	**From Warning Letter to Meeting: Understanding FDA's Final Guidance Under GDUFA** • **Presenter: Milind Ganjawala MS, MBA**, Division Director, DDQ, OMQ, OC, CDER, *U.S. FDA*
11:25 – 11:50	**Responding to Inspection Findings with Effective CAPA Strategy** • **Presenter: Tara Gooen Bizjak MBS**, Associate Director, GMP and Quality Standards, OC, CDER, *U.S. FDA*
11:50 – 12:15	**Q&A with Additional Panelist** • **Panelist: Rebecca Frey-Cooper PhD**, Associate Director for Regulatory Programs, OC, CDER, *U.S. FDA*

12:30 – 13:45

Lunch with the Regulators (Rock Creek Ballroom)

Moderator: Janeen Skutnik-Wilkinson , Director, Regulatory Intelligence and External Engagement, *Moderna*

Panelist: Donald B. Ertel MS, MT (ASCP) Branch Chief / Program Manager, OCBQ, CBER *U.S. FDA*

Panelist: Juan Jimenez JD Consumer Safety Officer *U.S. Food and Drug Administration, CVM, CGMP Compliance*

	Panelist: Jeffrey D Meng MSE Associate Director, Emerging Technologies and Advanced Manufacturing, Medical Products Inspectorate, OII *U.S. FDA* **Panelist: Dr. Carmelo Rosa** Division Director, Office of Manufacturing and Product Quality, OC, CDER *U.S. FDA*
14:00 – 15:30	**P6: The "Q" Also Applies to "U" (Potomac Ballroom)** **Moderator: Irving Ford MSc**, , *Quality Leader* 14:00 – 14:25: **Driving Quality from the Top: Leadership That Sets the Standard** • **Presenter: Sanat Chattopadhyay** , Executive Vice President & President, Merck Manufacturing Division, *Merck & Co., Inc.* 14:25 – 15:25: **Culture Starts at the Top: A Conversation with Quality Leaders** • **Panelist: Lothar Halmer PhD**, Chief Quality Officer, *Boehringer Ingelheim* • **Panelist: Paul Houri MS, MBA**, Senior Vice President, Chief Quality Officer, *Bristol Myers Squibb* • **Panelist: Maja H. Pedersen MSc**, Chief Technology Officer, EVP, *FUJIFILM Biotechnologies* • **Panelist: Adrian (Ad) Rawcliffe** , Chief Executive Officer, *Adaptimmune* 15:25 – 15:30: **Closing Remarks from the Conference Co-Chairs** • **Co-Chair: Janeen Skutnik-Wilkinson** , Director, Regulatory Intelligence and External Engagement, *Moderna* • **Co-Chair: Mary E. Farbman PhD**, Associate Vice President, Global Quality Compliance, *Merck & Co., Inc.*
16:00 – 18:30	**PDA/PQRI Advancing Artificial Intelligence in the Pharmaceutical Industry Workshop 2025 (Rock Creek B/C) (Day 1 of 2 - Separate Registration Required)**

Thursday, 11 September

EDT Daylight Time (UTC -4:00)

07:00 – 16:00	**Registration Open | PDA/PQRI Advancing Artificial Intelligence in the Pharmaceutical Industry Workshop (Rock Creek Ballroom Registration Desk)**
08:00 – 16:00	**PDA/PQRI Advancing Artificial Intelligence in the Pharmaceutical Industry Workshop 2025 (Rock Creek B/C) (Day 2 of 2 - Separate Registration Required)**
08:30 – 16:00	**Aseptic Processing Essentials Workshop (MR 13) (Separate Registration Required)** **Instructor: Hal Baseman MBA**, Vice President, *ValSource, Inc.*
08:30 – 16:00	**CMC Regulatory Compliance Strategy for Biopharmaceutical Manufacturing Training Course (MR 13) (Day 1 of 2, Separate Registration Required)** **Instructor: John Geigert PhD**, President, *BioPharmaceutical Quality Solutions*
08:30 – 16:00	**Contamination Control Strategy Essentials Workshop (MR 12) (Separate Registration Required)** **Instructor: Frederic B. Ayers** , Senior Consultant - Microbiology, *ValSource, Inc.*
08:30 – 16:00	**Fundamentals of Quality Risk Management Training Course (MR 15) (Separate Registration Required)** **Instructor: Virginia Andreotti-Jones** , Consultant, Quality Risk Management, *ValSource, Inc.*

	Instructor: Tiffany A. Baker MBA Senior Consultant *ValSource, Inc.*
08:30 – 16:00	**GxP Auditing Logistics and Inspection Readiness Training Course (Including Mock Activity) (MR 16) (Day 1 of 2, Separate Registration Required)** **Instructor: Iris J Lugo Irizzary** , Principal Corporate Compliance, *Amgen* **Instructor: Jeaneen C. Wallis MBA, PhD** CEO and Principal Consultant *J. Wallis Consulting*
08:30 – 16:00	**Measuring Quality Culture using PDA's Assessment Tool Training Course (MR 10) (Separate Registration Required)** **Instructor: Danielle Duran MA**, Director, GxP Compliance and Training, *Nestlé Health Science* **Instructor: Amanda McFarland MS** Senior Consultant *ValSource, Inc.*
08:30 – 16:00	**Quality and Compliance Management for Virtual Companies Training Course (MR 15) (Day 1 of 2, Separate Registration Required)** **Instructor: Kevin J Slatkavitz PhD**, President & Founder, *ThinkQuality, LLC*

Friday, 12 September

EDT Daylight Time (UTC -4:00)

08:30 – 16:00	**CMC Regulatory Compliance Strategy for Biopharmaceutical Manufacturing Training Course (MR 14) (Day 2 of 2, Separate Registration Required)** **Instructor: John Geigert PhD**, President, *BioPharmaceutical Quality Solutions*
08:30 – 16:00	**GxP Auditing Logistics and Inspection Readiness Training Course (Including Mock Activity) (MR 16) (Day 2 of 2, Separate Registration Required)** **Instructor: Iris J Lugo Irizzary** , Principal Corporate Compliance, *Amgen* **Instructor: Jeaneen C. Wallis MBA, PhD** CEO and Principal Consultant *J. Wallis Consulting*
08:30 – 16:00	**Quality and Compliance Management for Virtual Companies Training Course (MR 15) (Day 1 of 2, Separate Registration Required)** **Instructor: Kevin J Slatkavitz PhD**, President & Founder, *ThinkQuality, LLC*