



**PDA/FDA JOINT REGULATORY
CONFERENCE 2024**
CGMP: Leading with Quality and Integrity

**09-11 SEPTEMBER
WASHINGTON, DC**
#PDAFDA



SCHEDULE-AT-A-GLANCE

SUNDAY, 08 SEPTEMBER

14:00 – 19:00Registration Open
15:00 – 18:00Speaker Ready Room Open

MONDAY, 09 SEPTEMBER

07:00 – 19:00Registration Open
07:00 – 16:15Speaker Ready Room Open
07:00 – 08:30Continental Breakfast
08:00 – 09:15P1: Opening Plenary (**POTOMAC BALLROOM**)
09:15 – 10:15Networking Break in the Exhibit Area
10:15 – 12:00P2: Center Office Updates (**POTOMAC BALLROOM**)
12:00 – 13:30Lunch on Own
13:30 – 15:00Concurrent Sessions
 A1: CAPA Strategy: Moving from Reactive to Proactive (**POTOMAC 1**)
 B1: CGMP Guidance and Policy Updates (**POTOMAC 2**)
 C1: Effective Management and Maintenance of Contract Operations (**POTOMAC 3**)
15:00 – 16:00Networking Break in the Exhibit Area
16:00 – 17:30Concurrent Sessions
 A2: Data Integrity and CGMP: Leveraging Digital Tools (**POTOMAC 1**)
 B2: Quality Risk Management Integration in New Sterile Manufacturing Facilities (**POTOMAC 2**)
 C2: Non-Compliant Inspections and PAI Withhold Decisions: Recent Inspectional Findings
 (**POTOMAC 3**)
17:30 – 20:30Networking Reception

TUESDAY, 10 SEPTEMBER

07:00 – 19:00Registration Open
07:00 – 16:45Speaker Ready Room Open
07:00 – 08:30Continental Breakfast
07:15 – 08:15Concurrent Breakfast Sessions
 Breakfast 1: Sterility Assurance: The Role of Supply Vendors, Contract Irradiators,
 and Laboratories (**ROCK CREEK B/C**)
 Breakfast 2: Anchoring Quality Management Maturity to Business Outcomes (**ROCK CREEK A**)
 Breakfast 3: Platform Technologies Development, Part 1: GMP and CMC
 Considerations for Vaccines (RNA) (**ANACOSTIA D/E**)
 Breakfast 4: Is That a Particle? Dealing with Particulates in Cell and Gene Therapies (ATMPs)
 (**ANACOSTIA F**)
08:30 – 10:15P3: Compliance Office Updates (**POTOMAC BALLROOM**)
10:15 – 11:00Networking Break in the Exhibit Area
11:00 – 12:30Concurrent Sessions
 A3: Aging Facilities: Use of Risk Communication to Address Issues and Ensure Sustainable
 Product Quality (**POTOMAC 1**)
 B3: Quality Enabling Behaviors (**POTOMAC 2**)
 C3: De-Risking Your Quality Control Laboratory (**POTOMAC 3**)
12:30 – 14:00Lunch on Own
14:00 – 15:30Concurrent Sessions
 A4: Independence of the Quality Unit (**POTOMAC 1**)
 B4: Assuring GMPs Through Implementation of Modern Technologies (**POTOMAC 2**)
 C4: Accelerating Robust Manufacturing with Advanced End-To-End Risk Profiling (**POTOMAC 3**)

WI-FI INFORMATION

Network Name: PDAFDA
Password: 2024PDAFDA
(not case sensitive)



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SCHEDULE-AT-A-GLANCE

TUESDAY, 10 SEPTEMBER (CONTINUED)

- 15:30 – 16:15Networking Break and Passport Drawing in the Exhibit Area
- 16:15 – 17:45Concurrent Sessions
 - A5: Engaging the Whole Organization in Quality (*POTOMAC 1*)
 - B5: Innovations in GMP Compliance: Embracing Digital Technologies in GMP Manufacturing (*POTOMAC 2*)
 - C5: Improving Auditing Programs: Going Beyond a Checkbox Approach (*POTOMAC 3*)
- 17:00 – 18:00Concurrent Interest Group (IG) Sessions
 - IG1: Technology Transfer (*ROCK CREEK B/C*)
 - IG2: Quality Systems (*ROCK CREEK A*)
 - IG3: Drug Compounding and Sterile Processing/Parenteral Drug Manufacturing (*POTOMAC 1*)
 - IG4: Data Governance, Management, Integrity, and Digitalization (*POTOMAC 2*)
 - IG5: Quality Risk Management (*POTOMAC 3*)
 - IG6: Regulatory Affairs (*ANACOSTIA D/E*)

WEDNESDAY, 11 SEPTEMBER

- 07:00 – 15:00Registration Open
- 07:00 – 11:00Speaker Ready Room Open
- 07:00 – 08:30Continental Breakfast
- 07:15 – 08:15Concurrent Breakfast Sessions
 - Breakfast 5: Disaster Recovery Planning: Updating Your Contingency Plan (*ROCK CREEK B/C*)
 - Breakfast 6: X-Ray Technology (*ROCK CREEK A*)
 - Breakfast 7: Platform Technologies Development, Part 2: GMP and CMC Considerations for Cell and Gene Therapies (ATMPs) (*ANACOSTIA D/E*)
 - Breakfast 8: Building a Bridge: Leveraging Data Governance Towards the Adoption of Emerging Technologies (*ANACOSTIA F*)
- 08:30 – 10:00P4: Current GMP Compliance Trends and Topics (*POTOMAC BALLROOM*)
- 10:00 – 10:30Networking Break
- 10:30 – 12:00P5: Operationalizing Quality Risk Management and Knowledge Management (*POTOMAC BALLROOM*)
- 12:15 – 13:15Lunch with the Regulators (*ROCK CREEK BALLROOM*)
- 13:30 – 14:30P6: Closing Plenary (*POTOMAC BALLROOM*)

THANK YOU TO OUR SUPPORTERS!

DIAMOND SUPPORTER



PLATINUM SUPPORTER



SILVER SUPPORTER



BRONZE SUPPORTER

