

2022 PCF PHARMA & MEDICAL DEVICE CONGRESS AGENDA-AT-A-GLANCE

(Subject to Change)

MONDAY, OCTOBER 24, 2022

Morning Concurrent Workshops and Mini Summits

Workshops (Two Hours):

- Workshop 1: Overview of ESG and the Role of Ethics & Compliance
- Workshop 2: Breakdown in Ethics and Compliance: Understanding Motivation and Behavior

Mini Summits Group I (One Hour):

- Mini Summit 1: How Does Compliance & Ethics Fit into Diversity, Equity, and Inclusion?
- Mini Summit 2: Compliance & Ethics Considerations for Rare Disease, Genetic Testing
- Mini Summit 3: HCP Engagement - Include in Digitizing Compliance & Ethics

Mini Summits Group II:

- Mini Summit 4: New Product Launch Compliance Playbook
- Mini Summit 5: Social Media – Compliance’s Role – plus Auditing and Monitoring
- Mini Summit 6: Global Considerations for US-Based CCOs

Networking Luncheon

Afternoon Opening Plenary Session

- Co-chair Welcome and Introductions
- Antitrust Admonition
- Pharma C-suite Keynote
- OIG Keynote featuring Mary E. Riordan, JD, OIG Senior Counsel (Invited)
- Recent Federal and State Enforcement Activities for the Pharma and Medical Device Industries
- AdvaMed and PhRMA Updates
- Annual Chief Compliance Officer Fireside Chat

Networking Reception on Congress Exhibit Hall

TUESDAY, OCTOBER 25, 2022

Morning Invitation-Only, Closed-Door Chief Compliance Officer (CCO) Roundtable

- Welcome, Co-Chair Introductions & Antitrust Admonition
- CEOs and CCOs Sign on the Compliance Dotted Line – Now What?
- Board Responsibilities and Role in Cultural Governance
 - Increased focus by DOJ on Board Responsibility
 - Board of Directors Role in Cultural Governance
- Debrief, Questions & Knowledge Sharing

Morning Mini Summits

Mini Summits Group III:

- Mini Summit 7: Current Trends in FMV
- Mini Summit 8: Third Party Risk Management
- Mini Summit 9: Compliance & Ethics in Emerging Companies
- Mini Summit 10: Enterprise Risk Management
- Mini Summit 11: Navigating Telehealth Compliance Considerations for Pharma and Device Companies
- Mini Summit 12: Reimbursement & Product Support: Controls and Best Practices

Mini Summits Group IV:

- Mini Summit 13: Compliance Considerations and Sanctions
- Mini Summit 14: Use of Data Analytics in Digitizing Compliance
- Mini Summit 15: Hospitality Considerations (beyond alcohol) Based on Pharma and ADVAMED Updated Codes
- Mini Summit 16: Best Practices in Managing Investigations
- Mini Summit 17: The Evolving Transparency Reporting Landscape: Changes in 2022 and Preparing for 2023
- Mini Summit 18: New and Emerging Risks for Medical Device Codes - See Biogen Settlement

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(Continued)

Mini Summits Group V:

- Mini Summit 19: Drug Price Transparency
- Mini Summit 20: Compliance Considerations in Digital Health Collaborations
- Mini Summit 21: Compliance Due Diligence in Mergers & Acquisitions
- Mini Summit 22: Modern Day Compliance - Thoughtful Risk Taking
- Mini Summit 23: Clinical Trial Fraud and Innovative Strategies for Tracking and Managing
- Mini Summit 24: Developing and Implementing a Risk-Based Monitoring Program
- Mini Summit 25: Continuous Learning and Case Studies
- Mini Summit 26: Building a Cutting-Edge Compliance Program Coming out of a CIA

Networking Luncheon

Afternoon Closing Plenary Session

- Co-chair Welcome and Introductions
- US DOJ Keynote featuring Glenn Leon, Incoming Fraud Section Chief, USDOJ
- Medical Device C-suite Keynote
- FDA Keynote featuring Catherine (Katie) Gray, PharmD, Acting Director, FDA OPDP
- Annual AUSA Roundtable
- Have Life Sciences Companies Achieved an Ethical Culture?

Adjournment

DAY, OCTOBER 26, 2022

Morning Industry-only Plenary Session

Hosted by Pharmaceutical Compliance Forum (PCF)

(Industry-only session for pharmaceutical and medical device industry ethics and compliance professionals and in-house counsel)

Special Presentation by Howard Root, JD Chairman, Reprise Biomedical Former, CEO & Co-Founder, Vascular Solutions, Excelsior