

AGENDA AT A GLANCE

MONDAY, OCTOBER 28, 2024 DAY I CONGRESS MINI SUMMITS

MINI SUMMITS GROUP 1

9:00 – 9:50 am

Mini Summit 1: Interactions Between Sales and Medical Affairs

Mini Summit 2: Benchmarking and Brainstorming regarding Evolving Regulator Expectations relating to Off-Channel Communication

Mini Summit 3: OIG New General Compliance Program Guidance

Mini Summit 4: Update on Medical Device Regulatory and Enforcement Actions

Mini Summit 5: Compliance Governance and Board of Directors

Mini Summit 6: Health Equity Initiatives—Compliance Considerations

MINI SUMMITS GROUP 2

10:00 – 10:50 am

Mini Summit 7: Targeted, Tailored, True-to-Life: How DOJ Guidance Should Shape Your Compliance Training

Mini Summit 8: Responsible AI at the Cusp of Scale

Mini Summit 9: Hot Topics and Compliance Oversight in the Research and Development Area

Mini Summit 10: Recent Developments in Enforcement Actions

Mini Summit 11: Balancing Compliance and Legal Roles and Responsibilities

Mini Summit 12: Risk-Based Compliance Audits: Prioritizing What Matters Most

MINI SUMMITS GROUP 3

11:00 – 11:50 am

Mini Summit 13: Fair Market Value: Navigating the Ongoing Changes in HCP Compensation Compliance

Mini Summit 14: Compliance Training on the Digital Frontier

Mini Summit 15: Substance over Form: Practical Approaches to Enterprise Risk Management (ERM)

Mini Summit 16: Patient Support Programs and Patient Access Programs—A Look at the Evolution, Risks, and Enforcement Activity

Mini Summit 17: AI and Compliance Analytics: Real Case Studies for Managing HCP, HCO and Third-Party Risk

Mini Summit 18: Beyond Sales Representatives and MSLs: Considerations for Other Field-Based Roles

Mini Summit 19: ESG Overload – A CCO's Guide to a Balanced Program Implementation

MINI SUMMITS GROUP 4

12:00 – 12:50 pm

Mini Summit 20: Is Bigger Always Bad? Assessing Developing FTC Antitrust Enforcement Trends in Life Sciences

Mini Summit 21: Compliance Considerations for Rare Disease

Mini Summit 22: Enhancing Compliance and Overcoming Challenges under Corporate Integrity Agreements (CIA) through AI and Automation

Mini Summit 23: Fostering a Speak Up Culture

Mini Summit 24: Change Management for Compliance Program Transformation

Mini Summit 25: Presenting to Senior Executives Effectively

DAY I CONGRESS OPENING PLENARY SESSION 1:00 pm – 5:30 pm

- Co-chair Welcome and Introduction
- Keynote Address
- Keynote Annual OIG Update
- Keynote Annual FDA Update
- Keynote Fireside Chat
- The Implications of AI for Lifesciences Operations and Business Models
- The Implications of AI for Lifesciences Ethics and Compliance Programs
- Chief Compliance Officer Fireside Chat

5:30 pm ADJOURNMENT AND NETWORKING RECEPTION

6:45 pm PHARMA-MEDICAL DEVICE CONGRESS ANNIVERSARY BANQUET

AGENDA AT A GLANCE

TUESDAY, OCTOBER 29, 2024

DAY II CHIEF COMPLIANCE OFFICER ROUNDTABLE 7:30 – 9:45 am

(PCF Sponsored Special Closed Morning Session, Invitation-only)

- CCO Roundtable Welcome and Introductions and Antitrust Admonition
- Behind the Scenes: Evaluating and Presenting Compliance Program Effectiveness to Judges, Juries and Regulators
- Measuring & Presenting Compliance Effectiveness to Company Leadership — Moderated Best Practice Session
- How Do you Optimize your Resources to Enhance your Compliance Program?

DAY II CONGRESS MINI SUMMITS

MINI SUMMITS GROUP 5

8:00 – 8:50 am

Mini Summit 26: Service Fees: Hidden Compliance Risks and Downstream Market Access and Government Price Reporting Implications

Mini Summit 29: Attention Please! Elevating E&C Learning & Engagement in the Age of Distraction

Mini Summit 27: Government Programs and Compliance Office Oversight

Mini Summit 30: Key Learnings from CMS Audits

Mini Summit 28: Advancing Risk Management: A call to action for Integrated Risk Management (IRM) in Pharma

Mini Summit 31: Exploring Risks and Enforcement Trends for Buy-and-Bill Drugs

MINI SUMMITS GROUP 6

9:00 – 9:50 am

Mini Summit 32: Global Compliance Considerations for Designing Patient Support Programs

Mini Summit 35: Hot Topics in State Law Compliance

Mini Summit 33: Qui Tam Declinations—Analysis and Trends When DOJ Declines to Intervene

Mini Summit 36: The Latest and Greatest in Enforcement and Guidelines for Social Media and Influencers

Mini Summit 34: Privacy Top-Ten: Strategies and Tactics to Address Operational Impacts of the Evolving Privacy Landscape

Mini Summit 37: Compliance Considerations for Genetic Testing

MINI SUMMITS GROUP 7

10:00 – 10:50 am

Mini Summit 38: The Role of Technology and Process Enhancements for Effective ABAC Third Party Vendor Diligence

Mini Summit 41: Detecting Bias in your AI Tools

Mini Summit 39: Intersecting Reforms Affecting Drug Pricing

Mini Summit 42: Evolving Risks in Medical Affairs

Mini Summit 40: Best Practices in Investigations

Mini Summit 43: Regulatory Landscape of Transparency US and OUS

MINI SUMMITS GROUP 8

11:00 – 11:50 am

Mini Summit 44: HCP Expense Auditing and Monitoring

Mini Summit 47: Addressing Nuances in Third-Party Risk Management for Medical Devices

Mini Summit 50: Negotiating DOJ expectations and business challenges while creating a “Culture of Compliance”

Mini Summit 45: Lessons from Spend Transparency and Their Direct Application to Pricing Transparency

Mini Summit 48: Market Access—Compliance Considerations When Resolving Disputes

Mini Summit 46: State Law Updates—2024 Recap and 2025

Mini Summit 49: Analytics and Monitoring: Understanding the Risks and Underlying Complexity of Today’s Copay Program Landscape

DAY II CONGRESS CLOSING PLENARY SESSION

 1:00 – 5:30 pm

- Welcome and Introduction: PCF Co-Chairs
- DOJ Keynote Fireside Chat
- Reflections on the 25-Year Congress Anniversary
- Updates from AdvaMed, BIO and PhRMA
- Investigations, Enforcement and Prosecutions Roundtable
- Perspectives from DOJ, HHS-OIG, and the Relators Bar on How Compliance Departments Can Effectively Prevent and Help Respond To Qui Tam Whistleblower Suits
- The Art of Storytelling—Effectively Conveying the Value of Compliance Beyond Activities and Data

WEDNESDAY, OCTOBER 30, 2024

DAY III PCF INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

8:00 – 12:00 pm

(Industry-only Session for Pharmaceutical and Medical Device Company Ethics and Compliance Professionals and In-house Counsel only. Hosted by PCF)

- Welcome and Introductions
- Antitrust Admonition
- Responsible AI in Action: Real Business Strategies and Mitigation Examples
- Benchmarking, Polling & Q&A Open Forum
- Compliance Breakdowns & Lessons Learned: Unpacking Boeing and Other Company Downfalls
- Hot Topic Table Discussions
- Final Open Forum and Wrap Up