Twenty-Fourth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

AGENDA-AT-A-GLANCE

As of Thursday, July 20, 2023. This is a draft subject to change. To be updated regularly. **All times listed are EDT.**

WEDNESDAY, OCTOBER 25, 2023

7:00 am **Registration Opens**

PCF CHIEF COMPLIANCE OFFICER (CCO) ROUNDTABLE

(Note: The CCO Roundtable is an independent event organized and sponsored by the PCF which is co-located with the Congress.)

(Closed, Invitation Only)

8:00 am – 12:00 pm; with breakfast

- **PCF Welcome and Introductions**
- **Antitrust Admonition**
- **ESG: Trust in Action: A Leaders Guide to ACT. Right. Now.**
- **The Rising Stakes of Data Governance and What the Government Expects**
- **A Fireside Chat on Whistleblowers with Kirsten Mayer, JD and Gregg Shapiro, JD**
- **Open Forum Q&A**

CONGRESS MORNING SESSIONS

8:30 am – 9:50 am **Workshop: How to Make the Most of Your Time at the 24th Annual Pharma/Device E&C Congress**

8:00 am – 8:50 am **MINI SUMMITS GROUP I**

MS 1: Data Analytic Strategies for Compliance	MS 2: Insights from Medical Device Corporate Integrity Agreements	MS 3: Insights and Actionable Deliverables for Compliance Officers in Response to the DOJ Self-Disclosure Policy	MS 4: The Latest in Social Media Enforcement

9:00 am – 9:50 am **MINI SUMMITS GROUP II**

MS 5: Government Enforcement Actions Piggy-Backing on Product Liability Litigation	MS 6: HCP Engagement: Business Needs Assessment, Contracting, and Activities Management	MS 7: Preparing for Government Intervention in Drug Pricing	MS 8: Alternative Funding Vendors: The Future and Options for Responding to New Challenges to Patient Support Programs

10:00 am – 10:50 am **MINI SUMMITS GROUP III**

MS 9: Proving the Value of Corporate Compliance	MS 10: Assessing Compliance Priorities: Considerations for Conducting an Effective and Collaborative Compliance Risk Assessment	MS 11: Compliance Experts Address Concerns on Emerging Risk Areas	MS 12: Compliance Considerations for Market Access Initiatives	MS 13: Is the "No Patient Left Behind" Approach to Patient Support Programs Viable?

11:00 am – 11:50 am) **MINI SUMMITS GROUP IV**

MS 14: All Things Patients	MS 15: Comedy & Compliance – Shifting Culture & Building Trust with Entertainment	MS 16: Responsibly Harnessing the Power of AI	MS 17: Contemporary Trends in Fair Market Value	MS 18: Third Party Risk Management: Onboarding Diligence, Oversight and Exercising Audit Rights	MS 19: TBD

NETWORKING LUNCHEON

12:00 pm – 12:50 pm **LUNCHEON MINI SUMMITS GROUP V**

MS 20: The Role of Fair Market Value in Pharma and Medical Device Compliance Programs	MS 21: Risk & Ethics Perspective of Artificial Intelligence	MS 22: R&D and Clinical Trials Compliance Update	MS 23: Update on Federal Government Pharmaceutical Price Negotiations

WEDNESDAY, OCTOBER 25, 2023 Continued

1:00 pm – 5:30 pm **OPENING PLENARY SESSION**

- Co-chair Welcome and Introductions
- Keynote Fireside Chat with Geoffrey S. Martha, Chairman and Chief Executive Officer, Medtronic
- Keynote: OIG Update with Robert DeConti, JD, OIG Chief Counsel & Mary Riordan, JD, OIG Senior Counsel
- US DOJ Keynote with Lisa Miller, JD, Deputy Assistant Attorney General, Criminal Division, US DOJ
- Behavioral Compliance: Assessing the Implementation of the DOJ Guidance of Compliance Programs
- Networking Break in the Exhibit Hall
- Prosecutor's Roundtable
- Annual Chief Compliance Officer Fireside Chat
- Adjournment

5:30 pm – 7:00 pm **CONGRESS NETWORKING RECEPTION IN EXHIBIT HALL**

THURSDAY, OCTOBER 26, 2023

7:00 am Registration Opens/Networking Breakfast in Exhibit Hall

MORNING SESSIONS

7:00 am – 7:50 am **BREAKFAST MINI SUMMITS GROUP VI**

MS 24: Sanctions – Compliance Monitoring Approaches and Tools	MS 25: Compliance Monitoring – Operational Insights and Lessons Learned	MS 26: Key Learnings from CMS Audits of Open Payments	MS 27: New Levels of Transparency and Governance Across the Device Ecosystem

8:00 am – 8:50 am **MINI SUMMITS GROUP VII**

MS 28: Practical Guidance for Developing Tomorrow's Compliance Leaders	MS 29: Privacy & Data Privacy and Changes in Laws and the Impact on Our Industry	MS 30: Annual FCPA Update	MS 31: Data Analytics for Prospective Compliance Monitoring	MS 32: Navigating M&A of FDA-Regulated Companies	MS 33: Enterprise Communications Monitoring and the Recent DOJ Guidance	MS 34: DEI Training: Why It Matters and How to Do It?

9:00 am – 9:50 am **MINI SUMMITS GROUP VIII**

MS 35: Outsourced Compliance Programs: How to Make them Work?	MS 36: Fostering a Speak Up Culture at Your Organization	MS 37: AI – Art of the Possible	MS 38: Evolving Risks in Medical Affairs	MS 39: Ex-US Aspects of FCPA/ Compliance Investigations	MS 40: Compliance Considerations for Small and Emerging Markets	MS 41: Legal Risks Around Digital Health Technology

(9:50 am – 10:30 am **NETWORKING BREAK IN EXHIBIT HALL**

10:30 am – 11:20 am **MINI SUMMITS GROUP IX**

MS 42: Global Ethics and Compliance Update Part 1	MS 43: DOJ Agreements, Dual Reporting and the Role of the Compliance Officer	MS 44: Drug Pricing – Price Controls, Negotiation, Antitrust Considerations and Ethical Considerations in Balancing Access with Cost	MS 45: Engaging Your Board Effectively in an Era of Heightened Scrutiny and Enforcement Risk	MS 46: Pixels and Privacy: Navigating the Litigation and Enforcement Landscape of Website and Mobile App Privacy	MS 47: The Modern Investigation: Current Best Practices for Investigations	MS 48: Using Behavioral Compliance to Improve Your Compliance Program – Practical Implementation Suggestions

THURSDAY, OCTOBER 26, 2023 Continued

11:30 am – 12:20 pm MINI SUMMITS GROUP X

MS 49: Global Ethics and Compliance Update Part 2 (Continued)	MS 50: Internal Investigations: Best Practices to Address Compliance Concerns and Reduce Risk	MS 51: Compliance Considerations for Rare Disease	MS 52: What Do Health Equity Initiatives Mean for Compliance?	MS 53: Fireside Chat: Reflections on the Role of the False Claims Act Liability over the past 50 Years into a Major Force in the Regulation of the Pharmaceutical and Medical Device Industries	MS 54: Evolving Board of Directors and Compliance Committees Oversight Obligations	MS 55: Old Concepts New Risks: Trends in Medical Education Support Compliance

12:00 pm – 1:30 pm NETWORKING LUNCHEON

12:00 pm – 12:50 pm LUNCHEON MINI SUMMITS GROUP XI

MS 56: Recent Developments in DOJ and FTC Enforcement Actions	MS 57: Building Fearlessness into Organizations and Cultural Ambassadors	MS 58: A Fireside Chat with Jim Sheehan, JD	MS 59: Med Tech Compliance Bootcamp: Effectively Managing Compliance within a Medical Technology Company

1:30 pm – 5:30 pm CLOSING PLENARY SESSION

- Co-chair Welcome and Introductions
- Keynote Fireside Chat with Richard Simkin, Chief Commercial Officer, Indivior
- The Future Chief Compliance Officer
- Keynote: FDA Update with Katie Gray, PharmD, Acting Director, FDA Office of Prescription Drug Promotion
- Networking Break in the Exhibit Hall
- Updates from AdvaMed, BIO and PhRMA
- How to Ensure Compliance Doesn't Become the Organization's "Kitchen Junk Drawer"?
- What's Next in Pharma: Confronting a Challenging Macroeconomic Environment with Innovation

FRIDAY, OCTOBER 27, 2023

7:00 am Registration Opens/Networking Breakfast

8:00 am – 11:30 am INDUSTRY ONLY COMPLIANCE BEST PRACTICES THINK TANK (Open only to Industry-only attendees)

- PCF Welcome and Introductions
- Antitrust Admonition
- How to be a Wildly Effective Compliance Officer?
- ChatGPT, AI and Machine Learning — What Every Compliance Professional Needs to Know?

WEDNESDAY, NOVEMBER 15, 2023

Virtual Global Pharma and Medical Device Ethics and Compliance Day

A Special Virtual Session of the 24th Pharmaceutical & Medical Device Ethics & Compliance Congress

- Co-chair Intro
- Keynote Address
- Culture, Ethics and Compliance
- EU and CEE Ethics and Compliance Developments Update
- MEA Ethics and Compliance Developments Update
- Asia Pac Ethics and Compliance Developments Update
- LatAm Ethics and Compliance Developments Update
- Strategies to Develop a Coordinated and Consistent Global Compliance Program
- Closing Roundtable