# Twenty-Sixth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

SPONSORED BY PHARMACEUTICAL COMPLIANCE FORUM

**Hybrid Onsite Conference & Internet Event – Live and Archived**

## October 22 – 24, 2025

**Washington, DC • Grand Hyatt Washington**

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All Times are EDT • Agenda Current as of October 10, 2025
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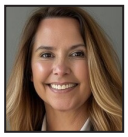

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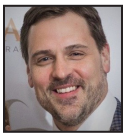

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# Twenty-Sixth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

**The Leading Forum on Pharmaceutical and Medical Device Ethics and Compliance Issues**

**Sponsored by the Pharmaceutical Compliance Forum (PCF)**

**October 22 – 25, 2025 • A HYBRID ONSITE CONFERENCE AND INTERNET EVENT**

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## AGENDA AT A GLANCE

## DAY I: WEDNESDAY, OCTOBER 22, 2025

**7:00 am** — Registration Opens & Continental Breakfast

**8:00 am – 11:50 am** — MORNING MINI SUMMITS (CONCURRENT SESSIONS)

**8:00 am – 8:50 am** — MINI SUMMITS GROUP 1

| | | | | | |
|---|---|---|---|---|---|
| MS1: State Consumer Privacy Laws — Compliance Tips for Pharma and Med Device Companies | MS2: Pharmaceutical Compliance and AI: Government Pricing Compliance Transformation through Intelligent Automation | MS3: Compliance Considerations for Small Companies | MS4: Free ≠ Risk-Free: A Closer Look at the Free Goods Landscape | MS5: Compliance's Role in Digital Information Governance | MS6: Aligning Your Compliance Program Activities with the New Administration's Priorities |

**9:00 am – 9:50 am** — MINI SUMMITS GROUP 2

| | | | | | | |
|---|---|---|---|---|---|---|
| MS7: Optimizing the Compliance Operating Model for the Future | MS8: Navigating Regulatory Uncertainties in Life Sciences | MS9: Fighting Overcriminalization in Federal Regulations | MS10: Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities | MS11: Building Smarter Monitoring Plans: Applying Enhanced Risk Segmentation | MS12: Leveraging Digital Compliance | MS 13: CMS Transparency Update |

**10:00 am – 10:50 am** — MINI SUMMITS GROUP 3

| | | | | | | |
|---|---|---|---|---|---|---|
| MS14: Annual Medical Device Ethics and Compliance Issues Roundtable | MS15: Elevating Compliance: Strategic Risk Leadership in a Global Landscape | MS16: What to Expect from a CMS Open Payments Audit | MS17: Patient Advocacy Organization Relationships —Compliance Considerations for Developing and Maintaining Effective Partnerships | MS18: Navigating Legal and Political Risks in the New DEI Landscape | MS19: External Funding Risks and Mitigation — Latest Trends in Exhibit & Display and Sponsorship Requests | MS20: Integrated Risk Management in Pharma: Building Resilience Across the Value Chain |

**11:00 am – 11:50 am** — MINI SUMMITS GROUP 4

| | | | | | | |
|---|---|---|---|---|---|---|
| MS21: Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI | MS22: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities | MS23: Integrating Compliance into Vendor/Consultant Engagements | MS24: What the Privacy? Live | MS25: Evaluating Compliance Training Effectiveness | MS26: Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success | MS27: Direct to Consumer Commercialization Models: Legal & Market Access Considerations |

**11:50 am – 1:20 pm** — EXHIBIT HALL OPENS & NETWORKING LUNCHEON

**12:20 pm – 1:10 pm** — (LUNCHEON) MINI SUMMITS GROUP 5

| | | | | | | |
|---|---|---|---|---|---|---|
| MS28: Compliance Considerations for Rare Disease | MS29: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future? | MS30: Update on Medical Device Investigations and Prosecutions | MS31: Update on the Status of FCPA Enforcement — Strategic Implications | MS32: Government Pricing: Finding Compliance Zen | MS33: Eyes Wide Open: Navigating the Global Complexities of Third Party Risk | MS34: Vaccines Under the New Administration |

**1:20 pm – 6:00 pm** — OPENING PLENARY SESSION

- **1:20 pm** — PCF Board Welcome and Introductions
- **1:30 pm** — Keynote: OIG Update
- **2:15 pm** — US DOJ Keynote Fireside Chat
- **2:45 pm** — Medical Device C-Suite Keynote Fireside Chat
- **3:15 pm** — Networking Break
- **3:45 pm** — One Size Doesn't Fit All: Tailoring Compliance to Your Product
- **4:30 pm** — New Business Models to Meet Patients Where They Are
- **5:00 pm** — Chief Compliance Officer and Business Leader Roundtable
- **6:00 pm** — Adjournment

**6:00 pm** — NETWORKING RECEPTION IN THE EXHIBIT HALL

*Agenda continued next page*

# AGENDA AT A GLANCE, CONTINUED

## DAY II: THURSDAY, OCTOBER 23, 2025

**7:00 am** — Registration Opens & Continental Breakfast in Exhibit Hall

### CHIEF COMPLIANCE OFFICER (CCO) ROUNDTABLE *(PCF-Sponsored, Exclusive Invitation-Only, Closed-Door Session)*

**7:30 am** — Invitation-only Networking Breakfast

**8:00 am – Noon**

- 8:00 am Welcome, Introductions, and Antitrust Admonition
- 8:15 am Passing the Baton: Reflections from Retiring CCOs
- 8:45 am Fireside Chat with The Honorable Merrick B. Garland
- 9:15 am Perspectives from Former Government Officials
- 10:15 am Executive Breakouts
- 11:30 am Breakout Takeaways & Open Forum
- 11:55 am Wrap Up

**8:00 am – 11:50 am** — MORNING MINI SUMMITS (CONCURRENT SESSIONS)

**8:00 am – 8:50 am** — MINI SUMMITS GROUP 6

| | | | | |
|---|---|---|---|---|
| MS35: Case Studies in AI & Analytics for Monitoring & Investigations | MS36: Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights | MS37: Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success | MS38: Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk | MS39: Use Cases for Leveraging AI in the Transparency Process |

**9:00 am – 9:50 am** — MINI SUMMITS GROUP 7

| | | | | |
|---|---|---|---|---|
| MS40: Telehealth for Life Sciences Companies: New Platforms, Old Risks | MS41: State of Confusion: The Overlooked State Laws in Pharma Compliance | MS42: Making Compliance Cool, Increasing Your Influence | MS43: Compliance Considerations for Mergers and Acquisitions | MS44: How to Build Your Compliance Analytics Programs Efficiently and Effectively |

**9:50 am – 10:20 am** — NETWORKING BREAK IN EXHIBIT HALL

**10:20 am – 11:10 am** — MINI SUMMITS GROUP 8

| | | | | |
|---|---|---|---|---|
| MS45: Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance | MS46: Implementing AI in Life Sciences Compliance: Strategies, Challenges, and Opportunities | MS47: Fair Market Value: Compliant Compensation Strategies | MS48: New Standards for Compliance Learning: What You Need to Know — Rethink's 2025 Benchmarking Report | MS49: What Enforcement May Look Like in Trump 2.0 |

**11:20 am – 12:10 pm** — MINI SUMMITS GROUP 9

| | | | | |
|---|---|---|---|---|
| MS50: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements | MS51: Sanctions — the Enterprise-Wide Risk and Compliance Nexus | MS52: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies | MS53: Strategic Stewardship: Navigating Compliance and Corporate Responsibility in Life Sciences | MS54: Best Practices in Responding to Investigations |

**12:10 pm – 1:20 pm** — NETWORKING LUNCHEON WITH DESSERT AND COFFEE IN THE EXHIBIT HALL

**12:25 pm – 1:15 pm** — SPECIAL LUNCHEON SESSION ON GLOBAL COMPLIANCE (OPTIONAL)

**1:20 pm – 6:00 pm** — CLOSING PLENARY SESSION

- 1:20 pm PCF Board Welcome and Introductions
- 1:30 pm – 2:15 pm Annual AUSA Roundtable
- 2:15 pm – 3:00 pm Investigations, Enforcement and Prosecutions Roundtable
- 3:00 pm – 3:30 pm Networking Break in Exhibit Hall
- 3:30 pm – 4:15 pm Strategies and Techniques for Compliance Conversations with the Business
- 4:15 pm – 5:00 pm Artificial Intelligence in Life Sciences Compliance: Real-World Case Studies
- 5:30 pm – 6:00 pm Updates from AdvaMed, BIO and PhRMA
- 6:00 pm Adjournment

## DAY III: FRIDAY, OCTOBER 24, 2025

**7:00 am** — Registration Opens & Continental Breakfast

**8:00 am – Noon** — INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

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

- 8:00 am Welcome and Antitrust Admonition
- 8:15 am The Gap isn't as Big as You Think — A Collaborative Learning Session: Pharma & Medical Device Focus
- 9:00 am Benchmarking and Q&A Forum
- 10:00 am Can Compliance Predict the Future? Using Data Analytics to Uncover Behavioral Patterns and Early Warning Signals
- 11:00 am Patient Engagement: Interactions & Advocacy Breakouts
- 11:35 am Sharing Insights from Breakout Discussions & Final Q&A
- 11:55 am Wrap Up & Adjournment
- Noon CONGRESS ADJOURNMENT

## MINI SUMMIT TOPICS LISTED BY CATEGORIES

**NOTE:** This is only a guide to help organize and manage topics. Please refer to the brochure for an accurate description of each Mini Summit to facilitate your selections as topics may fall into multiple categories.

| | |
|---|---|
| **AI AND DATA ANALYTICS** | MS 5: Compliance's Role in Digital Information Governance<br>MS 11: Building Smarter Monitoring Plans — Applying Enhanced Risk Segmentation<br>MS 12: Leveraging Digital Compliance<br>MS 21: Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI<br>MS 26: Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success<br>MS 37: Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success<br>MS 46: Implementing AI in LifeSciences Compliance: Strategies, Challenges, and Opportunities<br>MS 51: Sanctions — the Enterprise-Wide Risk and Compliance Nexus |
| **COMPLIANCE FRAMEWORK (SEVEN ELEMENTS)** | MS 3: Compliance Considerations for Small Companies<br>MS 6: Aligning Your Compliance Program Activities with the New Administration's Priorities<br>MS 7: Optimizing the Compliance Operating Model for the Future<br>MS 14: Annual Medical Device Ethics and Compliance Issues Roundtable<br>MS 20: Integrated Risk Management in Pharma: Building Resilience Across the Value Chain<br>MS 25: Evaluating Compliance Training Effectivenes<br>MS 35: Case Studies in AI & Analytics for Monitoring & Investigations<br>MS 42: Making Compliance Cool, Increasing Your Influence<br>MS 48: New Standards for Compliance Learning: What You Need to Know - Rethink's 2025 Benchmarking Report<br>MS 54: Best Practices in Responding to Investigations |
| **DRUG PRICING/ TRANSPARENCY** | MS 2: Pharmaceutical Compliance and AI: Government Pricing Compliance Transformation through Intelligent Automation<br>MS 16: What to Expect from a CMS Open Payments Audit<br>MS 32: Government Pricing: Finding Compliance Zen |
| **HCP ENGAGEMENT** | MS 10; Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities<br>MS 19; External Funding Risks and Mitigation – Latest Trends in Exhibit & Display and Sponsorship Requests<br>MS 36: Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights<br>MS 45: Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance<br>MS 47: Fair Market Value: Compliant Compensation Strategies<br>MS 53: Strategic stewardship: Navigating compliance and corporate responsibility in life sciences |
| **PATIENT INTERACTIONS** | MS 4: Free ≠ Risk-Free: A Closer Look at the Free Goods Landscape<br>MS 17: Patient Advocacy Organization Relationships —Compliance Considerations for Developing and Maintaining Effective Partnerships<br>MS 27: Direct to Consumer Commercialization Models: Legal and Market Access Considerations<br>MS 28: Compliance Considerations for Rare Disease<br>MS 40: Telehealth for Life Sciences Co: New Platorms, Old Risks<br>MS 50: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager Arrangements |
| **REGULATORY ENFORCEMENT UPDATES** | MS 1: State Consumer Privacy Laws – Compliance Tips for Pharma and Med Device Companies<br>MS 8: Navigating Regulatory Uncertainties in Life Sciences<br>MS 9: Fighting Overcriminalization in Federal Regulations<br>MS 13: CMS Transparency Update<br>MS 15: Elevating Compliance: Strategic Risk Leadership in a Global Landscape<br>MS 18: Navigating Legal and Political Risks in the New DEI Landscape<br>MS 22: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities<br>MS 24: What the Privacy?! Live<br>MS 29: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future<br>MS 30: Update on Medical Device Investigations and Prosecutions<br>MS 31: Update on the Status of FCPA Enforcement – Strategic Implications<br>MS 34: Vaccines Under the Trump Administration<br>MS 38: Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk<br>MS 39: Use Cases for Leveraging AI in the Transparency Process<br>MS 41: State of Confusion: The Overlooked State Laws in Pharma Compliance<br>MS 43: Compliance Considerations for Mergers and Acquisitions<br>MS 44: How to Build Your Compliance Analytics Programs Efficiently and Effectively<br>MS 49: What Enforcement May Look Like in Trump 2.0<br>MS 52: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies |
| **THIRD PARTY RISK MANAGEMENT** | MS 23: Integrating Compliance Into Vendor/Consultant Engagements<br>MS 33: Eyes Wide Open: Navigating the Global Complexities of Third-party Risk |

# AGENDA DAY I: WEDNESDAY, OCTOBER 22, 2025

**7:00 am** **Registration Opens**

## MINI SUMMITS GROUP I (8:00 am – 8:50 am)

### Mini Summit 1: State Consumer Privacy Laws — Compliance Tips for Pharma and Med Device Companies

Over the past five years an entirely new landscape of state consumer privacy laws have emerged in the US. These new and emerging laws have created regulatory pressure on pharmaceutical and medical device companies to expand and refine their data compliance programs and processes within the US. In this panel, we will explore the new laws and requirements, discuss a risk-based approach to building and refining data compliance programs, and share practical advice for how to achieve credible compliance within an increasingly complex web of requirements.

TAKE-AWAYS:

- Understand landscape of new and emerging state consumer privacy laws;
- Discuss a risk-based approach to building and refining data compliance programs;
- Share practical advice for how to achieve credible compliance.

**8:00 am** **Introductions, Discussions and Q&A**

**Erin Geygan, JD,** *Vice President Law, Patient Services Center/PECS, Johnson & Johnson; New Brunswick, NJ*

**Elizabeth Smith, JD,** *Senior Director, G&A Contracts and Data Privacy, Exelixis; Former Head of Global Privacy, Senior Director & Associate General Counsel, Privacy Law, Seagen; Alameda, CA*

**Christine Moundas, JD, MPH,** *Healthcare and Data Partner, Co-Head, Digital Health Initiative, Ropes & Gray; Former Analyst, Office of Inspector General, US Department of Health and Human Services; New York, NY (Moderator)*

### Mini Summit 2: Pharmaceutical Compliance and AI: Government Pricing Compliance Transformation through Intelligent Automation

Artificial Intelligence (AI) is fundamentally reshaping how pharmaceutical manufacturers uphold compliance, particularly in the complex and high-risk domain of Government Pricing (GP). By automating repetitive tasks, standardizing documentation, and offering granular analytical capabilities, AI is enabling more agile and scalable compliance infrastructures.

Driving Operational Consistency Across Compliance Functions:

AI solutions are streamlining enterprise-wide compliance by eliminating silos and harmonizing cross-functional workflows. In the Government Pricing context, this horizontal integration strengthens foundational compliance elements such as:

- Policy and Procedure Development: AI-assisted document generation and consistency checks ensure all SOPs related to pricing, discounting, and reporting align with regulatory mandates across Medicaid, 340B, and Medicare Part B.
- Customer Class of Trade Assignment: By leveraging machine learning to categorize customers based on transaction level data, AI drastically reduces manual hours and error rates in class of trade determinations—one of the most time-consuming GP activities.

  Deep AI Applications in Government Pricing and GP Operations

  At a domain-specific level, AI enables pharmaceutical companies to build targeted, intelligent systems that enhance compliance accuracy in GP. Specific use cases include:
- Documentation Gap Assessments: AI models assess whether transactional and GP compliance documentation is sufficient to support GP calculations. They identify missing or ambiguous data that could expose manufacturers to audit findings.
- 340B Covered Entity Eligibility Validations: AI engines cross-reference HRSA data, invoice patterns, and chargeback claims to validate whether 340B claims were submitted by truly eligible covered entities—preventing inaccurate reporting due to ineligible purchases.
- GP Calculation Component-Level Validations: AI tools can deconstruct the GP calculation results, such as nominal pricing, free goods, and bundled sales, and validate that each calculation component conforms to policy and regulatory standards. Additionally, AI tools are helpful in comparing GP calculation results to prior periods and detecting the drivers for change through analysis. This deep validation at the component level offers significant assurance prior to submissions to government.

**8:00 am** **Introductions, Discussions and Q&A**

**Matthew Berkle, JD, LLM,** *Member Berkle Consulting LLC; Former Compliance Counsel, Head of US Compliance, Guerbet; Former Vice President, General Counsel, Head of Ethics & Compliance, Breckenridge Pharmaceutical; Princeton, NJ*

**John Shakow, JD,** *Partner, FDA & Life Sciences Practice, King & Spalding; Washington, DC*

**Chris Cobourn, MS,** *Managing Director Government Programs Practice Lead, HELIO; Placida, FL (Moderator)*

### Mini Summit 3: Compliance Considerations for Small Companies

For emerging and small to mid-sized pharmaceutical companies, compliance can feel like a moving target. With limited resources, growing pipelines, and increasing scrutiny from regulators, establishing a practical and effective compliance framework is both challenging and essential.

This panel will explore strategies tailored to smaller organizations, including how to build scalable compliance programs, prioritize limited budgets, manage third-party risks, and foster a culture of integrity from the outset. Panelists will share real-world insights on balancing business objectives with compliance obligations, anticipating regulatory expectations, and preparing for growth or partnerships with larger industry players.

Whether you're building your first compliance program or refining an existing one, this discussion will offer practical guidance to help your company stay agile, compliant, and positioned for long-term success.

**8:00 am** **Introductions, Discussions and Q&A**

**Lori Kagan, MPH,** *Vice President, Chief Compliance Officer, US, Kyowa Kirin; Former Executive Director, Strategy and Operations, Merck Research Labs; Former Director, Compliance, Ironwood Pharmaceuticals; Princeton, NJ*

**Jeffrey Kawalek, MBA,** *Chief Compliance Officer, Zambon US; Former Deputy Chief Compliance Officer US, Jazz Pharmaceuticals, (Former Co-chair, PCF); New York, NY*

**Joseph Zimmerman,** *Senior Vice President, Chief Compliance & Privacy Officer, Head of Quality Assurance, SpringWorks Therapeutics, a healthcare company of Merck KGaA, Darmstadt, Germany; Former Vice President, Chief Compliance & Privacy Officer, US, Head of Government Affairs, Ferring Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Executive Leadership Team Member, Allergan (FKA Actavis, Forest Laboratories), (Former Co-chair, PCF); New York, NY*

**John E. Kelly, JD,** *Partner and Chair, Healthcare Industry Practice, Barnes & Thornburg; Former Assistant Chief for Health Care Fraud, Criminal Division, Fraud Section, US Department of Justice; Washington, DC (Moderator)*

### Mini Summit 4: Free ≠ Risk-Free: A Closer Look at the Free Goods Landscape

Many companies provide free products to physicians and patients through a range of programs, several of which have been addressed in recent OIG Advisory Opinions. This workshop will explore the different types of programs—such as product samples, free trials, demonstration devices, and patient assistance programs (PAPs). We will also examine the regulatory distinctions and associated compliance risks for each program type.

**8:00 am** **Introductions, Discussions and Q&A**

**Steven B. Cohen, MBA,** *Vice President, Chief Ethics and Compliance Officer, North America, Eli Lilly; Fishers, IN*

**Alan G. Minsk, JD,** *Partner and Head, Food and Drug Practice, Arnall Golden Gregory; Atlanta, GA*

**Heather Young, JD,** *Senior Director, Compliance Officer, Global Business Partner, Olympus Corporation of the America s; Former Assistant District Attorney, Philadelphia District Attorney's Office; Philadelphia, PA*

**Brian Van Hoy, RPh,** *Vice President of Compliance, G&M Health; Former Director Compliance & Ethics, Eli Lilly; Somerset, NJ (Moderator)*

### Mini Summit 5: Compliance's Role in Digital Information Governance

- How does Compliance navigate the evolving data risk landscape?
- Compliance officer's role in digital data management and governance
- Artificial Intelligence risks and utilization within the Compliance Department
- Data Governance Risk Assessments — Regulatory Compliance
- Mobile device Compliance
- Third Party Data Governance

**8:00 am** **Introductions, Discussions and Q&A**

**Jennifer L. Joyce, CFE, CIPM,** *Principal, Forensic & Integrity Services, EY; Washington, DC*

**Jeff Lemay, JD,** *Vice President, Chief Compliance Officer, Soleno Therapeutics; Former Executive Director, N.A. Compliance Officer, Jazz; Former Sr. Director, US Compliance Officer, Greenwich Bioscience, Carlsbad, CA*

**Ravi Kumar Monangi, MCA, MBA,** *Founder & Chief Technology Officer, Celito Tech Inc.; Redwood City, CA*

**Jeff Hyre,** *Vice President Sales, Healthcare and Life Sciences, Global Relay; Denver, CO (Moderator)*

### Mini Summit 6: Aligning Your Compliance Program Activities with the New Administration's Priorities

This esteemed panel of Medical Device compliance experts will speak about the compliance challenges posed by current and emerging Administration priorities, what is important to keep a pulse on, and how they are navigating competing company priorities. Topics may include:

- "Healthcare Fraud" is a major enforcement priority for the current Administration. What does it include and how should you prepare?
- Does FDA's DTC and Social Media advertising crackdown apply to device companies? How to risk manage increased enforcement.
- FDA's focus on manufacturing compliance: QMS regulation, surprise foreign plant inspections. Is this in your scope as a CCO? How do you ensure compliance?
- FDA Draft AI Guidance on AI-Enabled Software and Marketing Submissions, and on Support of Regulatory Decisions for product clearance/approval – Just an issue for "Regulatory" or does Compliance have a role here?
- FDA's focus on clinical trial research fraud: what can med device companies do to continue to tighten up their clinical operations?
- Trade Compliance and supply chain issues – Is this in your scope as CCO?
- DOJ's updated FCPA memo – how to prepare.
- DOJ's evolving and amended protocols on "Self-Disclosure" – what role should Compliance have vs. Legal?

**8:00 am** **Introductions, Discussions and Q&A**

**Kate Godfrey, JD, CCEP,** *Senior Vice President, Global Chief Compliance Officer, Karl Storz, US; Former Vice President, Chief Compliance and Privacy Officer, Veracyte; Seattle, WA*

**Robert Mascola, MA, JD,** *Chief Compliance Officer, Juul Labs; Adjunct Professor, Fordham Law School, Program on Corporate Ethics & Compliance; Washington, DC*

**Jenny McVey, MS, PhD,** *Former North America Compliance Officer, bioMérieux; Adjunct Professor, Fordham University School of Law; Salt Lake City, UT*

**Jonathan Turner, MSc,** *Chief Ethics & Compliance Officer, Avanos Medical; Former Chief Compliance & Privacy Officer, ZOLL Medical Corporation; Former Vice President, Ethics & Compliance, Americas Region and Global Ortho, Sports & Wound Franchises, Smith & Nephew; Alpharetta, GA*

**Craig B. Bleifer, JD,** *Partner, McGuire Woods; Former Corporate Vice President, General Counsel North America; Novo Nordisk; Former Senior Vice President, General Counsel & Secretary, Daiichi Sankyo; New York, NY (Moderator)*

**8:50 am** **Transition Break**

## MINI SUMMITS: GROUP 2 9:00 am – 9:50 am

### Mini Summit 7: Optimizing the Compliance Operating Model for the Future

- Explore how organizations of all sizes are reimagining their compliance operating models to drive efficiency, agility, and value.
- Examine strategies for distinguishing core compliance activities from those suitable for outsourcing or automation.
- Discuss the use of lower-cost delivery hubs and shared service centers to optimize resource allocation and reduce costs.
- Highlight approaches for empowering business units through self-service compliance tools and digital enablement.
- Share real-world examples of how leading companies balance risk, cost, and control by leveraging innovative technologies and targeted talent strategies.
- Provide actionable insights for designing a flexible, scalable compliance organization that meets evolving regulatory demands.

**9:00 am** **Introductions, Discussions and Q&A**

**Christian Dingler, MBA,** *Executive Director, Risk Management and Program Effectiveness, Global Compliance, Insmed Incorporated; Richmond, VA*

**Christine Gordon, JD,** *Vice President, Governance, Risk and Compliance (GRC) and Chief Compliance Officer, Olympus Corporation of the Americas; Former Assistant District Attorney, Philadelphia District Attorney's Office; Bethlehem, PA*

**Brooke Nelson, JD,** *Vice President, Ethics & Business Integrity, North America & Global Specialty Care, Sanofi; Former Chief Compliance Officer, Verily; Former Executive Director, Compliance, Amgen; Los Angeles, CA*

**Laura Sorafine, JD,** *Head Strategic Advisor, US and Global Specialty Care, Sanofi, Cambridge, MA*

**Russell Rose, JD,** *Managing Director, Life Sciences Advisory, Deloitte; Dallas, TX (Moderator)*

### Mini Summit 8: Navigating Regulatory Uncertainties in Life Sciences

Navigating a rapidly-evolving regulatory environment is a key challenge for life sciences companies today. This interactive panel will discuss current and anticipated FDA legal and regulatory trends and developments.

**9:00 am** **Introductions, Discussions and Q&A**

**Dominick P. DiSabatino, JD,** *Partner, Life Sciences, FDA and Healthcare Regulatory Compliance, Sheppard Mullin Richter & Hampton; Washington, DC*

**Scott S. Liebman, JD,** *Partner, Chair of FDA Regulatory & Compliance, Co-Chair of Life Sciences Practice, Sheppard Mullin Richter & Hampton; New York, NY*

### Mini Summit 9: Fighting Overcriminalization in Federal Regulations

Enforcing the MAHA Agenda: What Pharma Needs to Know about the Remade Healthcare Enforcement Landscape

Through executive orders, new priorities, and policy changes, the second Trump administration has given DOJ and HHS-OIG a broad mandate for healthcare related enforcement. This panel will feature a dynamic exchange among DOJ and HHS-OIG enforcement experts as they unpack the administration's key moves and assess the implications for life sciences companies.

Topics may include:

- Executive Orders impacting enforcement, including orders to combat the overcriminalization of regulations and impact prices.
- The DOJ and HHS-OIG False Claims Act Working Group and its priorities, including Medicare Advantage, pricing, barriers to care, kickbacks, and EHR manipulation, among others
- DOJ's continued emphasis on leniency programs and whistleblowers
- Recent corporate resolutions and settlement structures under the new administration

*Session continued next page*

- HHS-OIG Advisory Opinions under the new administration
- DOJ's annual summer enforcement sweep and expansion of its Medicare Strike Force
- Possibility of rising enforcement activity from State Attorneys General and the plaintiffs' bar

**9:00 am** **Introductions, Discussions and Q&A**

**Lee M. Cortes, Jr.,** *Partner, Arnold & Porter; Former Executive AUSA, US Attorneys' Offices, District of NJ; Former AUSA, Chief, Health Care Fraud Unit, and Former Deputy Chief, Special Prosecutions Division, US Attorney's Office, District of New Jersey; Newark, NJ*

**Lisa Re, MS, JD,** *Partner, Arnold & Porter; Retired Assistant Inspector General for Legal Affairs, Office of Inspector General, US Department of Health and Human Services; Chevy Chase, MD*

## Mini Summit 10: Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities

Join us for an engaging panel session exploring the challenges that can emerge when Sales and Medical Affairs teams interact, especially in proactive medical initiatives. This session will address how to maintain clear boundaries, ensure consistent messaging, and stay aligned with regulatory expectations. Panelists will share real-world examples and practical steps companies are using to manage risk – from tightening documentation and oversight to improving training and internal coordination. Whether your team is updating existing practices or putting new safeguards in place, this session will offer concrete strategies to maintain compliance without creating barriers between teams.

**9:00 am** **Introductions, Discussions and Q&A**

**Ethan Davis, JD,** *Chief Compliance Officer, Associate General Counsel, Vericel Corporation; Cambridge, MA*

**David J. Derusha, JD,** *Senior Legal Counsel, Vertex Pharmaceuticals; Former Assistant US Attorney, US Attorney's Office, District of Massachusetts; Boston, MA*

**Joseph E. Keeney, JD,** *Former US Head of Ethics and Compliance. Galderma Laboratories; Former Senior Director/Head, healthcare Compliance, Organogenesis; Dallas, TX*

**James (Jamie) Ravitz, JD,** *Partner and Chair, FDA Practice, McDermott Will & Schulte; Washington, DC (Moderator)*

## Mini Summit 11: Building Smarter Monitoring Plans — Applying Enhanced Risk Segmentation

When designing a monitoring plan, how do you ensure it has the right volume of risk-based samples? In this session, we'll explore how compliance teams can build more strategic, risk-aligned monitoring plans by working through a stepwise evaluation and segmentation of compliance risks.

Using real-world examples from multiple life sciences companies, we'll explain how to:

- Build a comprehensive activity inventory as the foundation for your plan
- Further segment those activities to uncover varying risk levels and control maturity
- Determine best options for evaluating those risks (e.g., aggregate, live, or transactional reviews)
- Evaluate product-specific risks to provide additional clarity on risks/controls
- Use a combination of risk-based and random selection for overall sampling

This session will provide practical tools and proven methodologies to help your compliance program evolve from reactive oversight to proactive, prioritized risk mitigation to yield improved reporting to Compliance Committees and a more effective Compliance Program.

**9:00 am** **Introductions, Discussions and Q&A**

**Evan DaSilva, CPA, CFE, CAMS,** *Associate Director, US Business Ethics, Head of Monitoring & Operations, Ipsen Biopharmaceuticals; Cambridge, MA*

**Mona Peterson Rosow, JD, MPH,** *Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN*

**Monica Schroeter, CPA, CISA,** *Head of Compliance Operations and Risk, LivaNova; Former Head of Compliance, F2G; Former Head of Compliance & Privacy, SK Life Scienc; Goshen, NY*

**Kelly Listro,** *Senior Manager; Potomac River Partners; Chicago, IL (Moderator)*

## Mini Summit 12: Leveraging Digital Compliance

With technology evolving, Compliance departments are digitizing their programs in order to gain scale, efficiency, and effectiveness. Topics for discussion include:

- Where to even start
- How to integrate various Compliance program elements
- How to utilize and leverage AI

**9:00 am** **Introductions, Discussions and Q&A**

**Jonathon L. Kellerman,** *Global Chief Ethics, Compliance and Privacy Officer & Global Head of Business Transformation, Bausch + Lomb; Former Executive Vice President & Global Chief Compliance Officer, Allergan; Bridgewater, NJ*

**Erica Powers,** *Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals; Boston, MA*

**Anna Littman-Quinn, CPA, CFE,** *Senior Manager, Forensic & Integrity Services, EY; Boston, MA (Moderator)*

## Mini Summit 13: CMS Transparency Update

Join Amy and Coles, Centers for Medicare & Medicaid Services, for an update on the Open Payments Program.

**9:00 am** **Introductions, Discussions and Q&A**

**Amy L. Bedsaul,** *Open Payments Communications, Data Analytics & Systems Group, Centers for Medicare & Medicaid Services; Baltimore, MD*

**Coles Mercier, MBA, MS,** *Project Manager, Health Insurance Specialist and Information Technology, Centers for Medicare & Medicaid Services; Baltimore, MD*

**9:50 am** **Networking Break in Exhibit Hall**

# MINI SUMMITS: GROUP 3 10:00 am – 10:50 am

## Mini Summit 14: Annual Medical Device Ethics and Compliance Issues Roundtable

What should currently be top of mind for legal and compliance professionals in the medical device industry? Join us for a roundtable discussion on emerging legal trends and shifting compliance risks affecting medical device manufacturers. This panel of seasoned legal and compliance professionals will explore recent enforcement developments, emerging regulatory challenges, and unique compliance considerations and offer practical insights on how to seize strategic opportunities in today's challenging environment.

**10:00 am** **Introductions, Discussions and Q&A**

**Terra Buckley, JD,** *Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Summit, NJ (Medical Device Executive Committee)*

**Brian Danahy, JD,** *Deputy General Counsel and Chief Compliance Officer, Exactech; Former, Compliance Program Manager, Zimmer; Gainesville, FL*

**Peter Jensen, JD,** *Vice President, Global Chief Compliance Officer, Arthrex; Former Chief Nominations Counsel, US Senate Judiciary Committee; Naples, FL*

**Tara Shewchuk, JD, LLM,** *Senior Vice President, Chief Privacy, Integrity & Compliance Officer Medtronic; Former Senior Director, Ethics and Compliance, AbbVie; Minneapolis, MN (Medical Device Executive Committee)*

**Jonathan Stevens, JD,** *Partner, Litigation Department, Paul Hastings; Former Associate General Counsel, Exactech; Irvine, CA (Moderator)*

## Mini Summit 15: Elevating Compliance: Strategic Risk Leadership in a Global Landscape

Enforcement of the False Claims Act (FCA) and Anti-Kickback Statute regarding healthcare provider (HCP) engagement remains a priority for the DOJ and HHS OIG, bolstered by the recent formation of the DOJ-HHS FCA Working Group. At the same time, novel applications of the FCA are gaining ground and significant policy shifts are expanding enforcement risks affecting domestic and international life sciences companies. This panel will discuss adapting compliance programs to meet the challenges of this complex risk landscape, examining topics such as sanctions and trade compliance, clinical trials, supply chain security, manufacturing and quality, pricing and market access, channel partner arrangements, and the evolving FDA regulatory environment.

**10:00 am** **Introductions, Discussions and Q&A**

**Thomas E. Costa, JD,** *Member, US Board of Directors, Sanofi; Former Vice President, US Compliance & Ethics, Bristol Myers Squibb; Morrisville, PA*

**Sujata Dayal, JD,** *Independent Board Director, Emergent BioSolutions; Senior Advisor, Ethicist International; Former Vice President & Global Chief Compliance Officer, Medline Industries, Inc.; Former Vice President Health Care Compliance & Privacy, Johnson & Johnson; Chicago, IL (Medical Device Executive Committee)*

**Avia M. Dunn, JD, MBA,** *Partner, Life Sciences and Health Care, Skadden, Arps, Slate, Meagher & Flom; Washington, DC*

**Katherine C. Norris, MPA,** *Senior Managing Director, Healthcare & Life Sciences Compliance, Disputes and Economics, Ankura; Washington, DC (Moderator)*

## Mini Summit 16: What to Expect from a CMS Open Payments Audit

Ten years after the federal Sunshine Act was enacted, CMS began auditing companies for compliance with the federal Sunshine Act in 2023. CMS representatives have indicated that the additional companies have been selected for audit this year. The wave of CMS Open Payments audits is expected to continue. In this session, you will:

- Gain practical insight from manufacturers who have navigated CMS audits, including preparation strategies, the audit process, and post-audit takeaways
- Understand the specific audit areas of focus and key lessons on assumptions and process
- Learn actionable steps to prepare your organization for potential audits and identify critical risk areas

**10:00 am** **Introductions, Discussions and Q&A**

**Audrey DeGuarde, MSJ,** *Vice President, Customer Success & Compliance Operations, RLDatix Life Sciences; Morristown, NJ*

**Margaret K. Feltz, MA, JD,** *Vice President, Chief Compliance Officer, Purdue Pharma; (Former Co-chair, PCF); Stamford, CT*

**Sara A. Kimball, JD,** *Assistant General Counsel, Corporate Functions, Legal Affairs, Daiichi Sankyo; Basking Ridge, NJ*

**Nikki Reeves, JD,** *Co-Chair, Government Matters & Regulatory Practice Group; Partner, FDA & Life Sciences Practice, King & Spalding; Washington, DC (Moderator)*

## Mini Summit 17: Patient Advocacy Organization Relationships — Compliance Considerations for Developing and Maintaining Effective Partnerships

- Review legislative activity regarding patient advocacy organization-manufacturer transparency.
- Discuss recent manufacturer news stories regarding such relationships.
- Engage in sharing best practices regarding relationships with patient advocacy organizations.

**10:00 am** **Introductions, Discussions and Q&A**

**M. Cristina "Cris" Barba, MBA, CFE, CEP,** *Director, Compliance, Insmed; Former Associate Director Global and NA Medical Affairs Compliance, Teva Pharmaceuticals; Jamison, PA*

**Brian C. Barry, JD,** *Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Compliance Officer, US & Canada, EMD Serono; Boston, MA*

**Sarah L. Whipple, JD,** *Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Former Vice President, Global Compliance & Privacy Officer, Aegerion; Boston, MA*

**Emily F. Hodge, JD,** *Partner, Choate, Hall & Stewart; Boston, MA (Moderator)*

## Mini Summit 18: Navigating Legal and Political Risks in the New DEI Landscape

Explore how the administration's DEI Executive Orders (and related agency actions) are impacting companies in the pharma/med device space, including how companies are evaluating both internal programs and external health equity efforts. In addition, we'll discuss the DOJ's new Civil Rights Fraud Initiative, and how companies can mitigate risks of DEI-related False Claims Act violations.

**10:00 am** **Introductions, Discussions and Q&A**

**Michael Clarke, JD, CCEP, NACD.DC®,** *Principal, Jaeger-Plymouth Advisors, LLC; Retired Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior Inc., Bridgewater, NJ (Medical Device Executive Committee)*

**Daryl Kreml, JD,** *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Former US Compliance & Global Program Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific; Boston, MA (PCF Board)*

**Richard Perry, M.Ed.,** *Compliance Operations Manager, Incyte; Board Member, William Way LGBT Community Center; Former Corporate Compliance Specialist, Adaptimmune; Wilmington, DE*

**Erin Brown Jones, MA, JD,** *Partner, Latham & Watkins; Washington, DC (Moderator)*

## Mini Summit 19: External Funding Risks and Mitigation — Latest Trends in Exhibit & Display and Sponsorship Requests

There have been recent upticks in the complexity and risks associated with customer-facing colleague external funding submissions requiring heightened diligence, process and analysis before a traditional approval can be provided. For example, there have been an increase in exhibit & display requests that offer a reverse exposition (customer staffed booths), exhibits in restaurant venues, recreational venues (where HCP wellness/retention are motivators, not just education), exhibits at galas & other fund raisers, customer-offered events (where opportunity is only to speak to employees of the entity), funding proceeds being donated to a designated charitable. All of these added considerations raise additional potential scrutiny under the AKS and would be worth exploring at the congress.

**10:00 am** **Introductions, Discussions and Q&A**

**Edgar H. Donohoe, JD,** *Vice President & Lead Compliance Counsel, Pfizer US; New York, NY*

**Asha Green, JD,** *Director, US Compliance, Ferring; Former Global Head, I&C Risk Assessment and Mitigation Planning and Senior Business Advisor, Indivior; Parsippany, NJ*

**Samantha Barrett Badlam, JD,** *Partner, Litigation & Enforcement Group, Ropes & Gray; Washington, DC (Moderator)*

## Mini Summit 20: Beyond Silos: The Future is Integrated Risk Transformation

Pharmaceutical and Medical Device companies have long managed risk in silos — with ethics & compliance, privacy, quality, cyber, internal audit, and internal controls predominantly operating independently. But as regulations evolve, AI-driven risks emerge, and risk technologies mature, it's time for a more connected approach.

Join us to explore how Integrated Risk Transformation (IRT) can help the industry break down silos and transform the way risk is mitigated across healthcare compliance, privacy, cyber, third parties, and internal audit to enhance trust in the market and enable strategic growth.

- Demystify what IRT means and how it applies across key risk domains.
- Discuss the benefits and roadblocks of an integrated approach.
- Highlight real-world case studies and practical starting points.
- Examine emerging trends and technologies shaping the next era of IRT in pharma and medical devices.

*Session continued next page*

**10:00 am** **Introductions, Discussions and Q&A**

**Brian Riewerts,** *Partner, Pharmaceutical and Life Sciences Risk and Regulatory Leader, PwC, Washington, DC (Moderator)*

**10:50 am** **Transition Break**

# MINI SUMMITS: GROUP 4 11:00 am – 11:50 am

## Mini Summit 21: Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI

In this session, we'll explore how Ethics & Compliance professionals in the pharmaceutical and medical device industries can empower their teams and enhance operations by embedding AI and analytics into their compliance ecosystems. We'll examine how these technologies help identify emerging risks, improve responsiveness, and support a more proactive compliance culture.

Through real-world case studies, we'll demonstrate how organizations are using embedded intelligence to transform their compliance programs—enhancing claims monitoring, metrics tracking, investigative efforts, financial analysis, coding compliance, sales force monitoring, and more.

Participants will leave with a deeper understanding of how to integrate intelligent analytics into their workflows to drive smarter decisions, faster investigations, and a stronger culture of ethics and accountability.

**11:00 am** **Introductions, Discussions and Q&A**

**Michael Curran, CPA, CFE,** *Manager, Forensics, KPMG US; New York, NY*

**Ron Strauss, CIPM,** *Vice President, Compliance, MIMEDX; Marrietta, GA*

**Joseph Zimmerman,** *Senior Vice President, Chief Compliance & Privacy Officer, Head of Quality Assurance, SpringWorks Therapeutics, a healthcare company of Merck KGaA, Darmstadt, Germany; Former Vice President, Chief Compliance & Privacy Officer, US, Head of Government Affairs, Ferring Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Executive Leadership Team Member, Allergan (FKA Actavis, Forest Laboratories), (Former Co-chair, PCF); New York, NY*

**John Gitas, MBA,** *Principal, US Advisory, Healthcare and Life Sciences, KPMG; New York, NY (Moderator)*

## Mini Summit 22: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities

- Understand the Regulatory Landscape: Overview of key laws and guidelines (FDA, EMA, FTC, HIPAA) impacting social media use in life sciences by employees and/or social media influencers, including DTC advertising
- Identify and Manage High-Risk Areas: Explore common pitfalls like off-label promotion, privacy breaches, adverse event reporting on social platforms, and reputational impacts
- Monitor, Train, and Respond: As part of the governance framework, establish monitoring protocols, employee training programs, and response plans for misinformation or compliance breaches

**11:00 am** **Introductions, Discussions and Q&A**

**Wendy Goldstein, JD, MPH,** *Of Counsel, Litigation Department, Paul Hastings; Former Special Counsel to the Commissioner of Health; New York State Department of Health; New York, NY*

**Jill Mason, JD,** *Chief Compliance and Risk Officer, Orthofix; Former Senior Global Compliance Director, St. Jude Medical; Dallas, TX*

**Chad Morin, MBA,** *Senior Vice President, Chief Compliance Officer, Viridian Therapeutics; Former Senior Vice President, Chief Compliance Officer, Kiniksa Pharmaceuticals; Former Vice President, Chief Compliance Officer, bluebird bio; Waltham, MA*

**Laura A. Skinner, MBA,** *Managing Director, Life Sciences Consulting Group, Paul Hastings; New York, NY (Moderator)*

## Mini Summit 23: Integrating Compliance into Vendor/ Consultant Engagements

Using the McKinsey settlement as a reference, the panel will discuss practical approaches to incorporate compliance controls into your business partners' engagements with vendors and consultants. The panel will review the various inflection points where Compliance and Legal oversight may be useful in risk assessment, engagement, implementation, and monitoring.

**11:00 am** **Introductions, Discussions and Q&A**

**Kimberly Ford, MBA, JD,** *Vice President, Chief Ethics & Compliance Officer Americas, Medtronic; Former Vice President Compliance, Americas, Smith+Nephew; Memphis, TN*

**Sam Pietropaolo, JD,** *Lead Counsel US Commercial, Takeda; Former Senior Legal Counsel, Shire Pharmaceuticals; Former Senior Corporate Counsel, Smith & Nephew; Lexington, MA*

**Erica Powers,** *Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals; Boston, MA*

**Sara K. Frank, JD,** *Principal, Choate, Hall & Stewart; Boston, MA (Moderator)*

## Mini Summit 24: What the Privacy? Live

Join the Dovetail Consulting team and special guest panelists for an interactive, informative session spotlighting a few of the industry's current "hot topics" in Privacy. We'll combine late-night game show-styled segments and audience participation (along with a little humor!) to deliver insights, practical tips, and tested strategies to tackle real-world privacy and data protection challenges, including:

- Consent, Cookies and Campaigns: Compliant marketing in the age of complex consent and transparency requirements
- New Dogs; Old Tricks: Managing compliance with the US DOJ's Bulk Sensitive Data Rule
- Outsourced—Not Out of Scope: Managing third-party privacy risk

**11:00 am** **Introductions, Discussions and Q&A**

**Liz Fortier, JD,** *Chief Privacy & Data Governance Officer, LivaNova, Minneapolis, MN*

**Tom Hiney, JD, CIPP/US, CIPM,** *Privacy Counsel and Senior Director, Blueprint Medicines; Boston, MA*

**Patrick Santiago, MBA, CIPM,** *Director, Global Data Privacy, Genmab; Former Associate Director, US Data Privacy Operations, Boehringer Ingelheim; Plainsboro, NJ*

**Courtney Lyles,** *Manager, Privacy and Data Protection, Dovetail Consulting Group, Atlanta, GA*

**Erin Wagenberg, CIPP/US, CIPP/E, CIPT, and FIP,** *Director, Dovetail Consulting Group; Former Deputy Privacy Officer, Deloitte Global; Atlanta, GA*

**Kris Hall, JD, CIPP/CIPM,** *Managing Director, Dovetail; Former Vice President, Chief Privacy Officer, Celgene; Former Vice President, Head of Privacy, Shire; Former Senior Director of Privacy, Philips; Bridgton, ME (Moderator)*

## Mini Summit 25: Evaluating Compliance Training Effectiveness

In this session, the panelists and moderator offer practical guidance and examples for measuring the effectiveness of your ethics and compliance training. Whether you're developing new compliance training or looking to improve your existing training, this session will equip you with ideas to help prove the value of your training and drive continuous improvement.

**11:00 am** **Introductions, Discussions and Q&A**

**Rachel Batykefer, CCEP,** *Vice President, CIA & Compliance Operations, Mallinckrodt Pharmaceuticals; Former Senior Director, Global Compliance & Ethics Training, Policy & Operations, Teva Pharmaceuticals; Bridgewater, NJ*

**Kelley Medeiros, MPP,** *Compliance Officer, Neuromodulation, LivaNova; Former Global & US Oncology Compliance Officer, EMD Serono; Former BU Ethics & Compliance Advisory Operations, Takeda Oncology; Houston, TX*

**Suki Wiltman,** *Vice President, Global Ethics & Compliance, Ipsen Biopharmaceuticals; Former Business Partner, Governance, Ethics & Compliance, GSK; Former Senior Corporate Compliance Manager, Allergan Canada; Toronto, Canada*

**Daniel O'Connor,** *Senior Vice President, NXLevel Compliance; Former Vice President, Learning & Development, Morgan Stanley; New York, NY (Moderator)*

### Mini Summit 26: Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success

Compliance and Legal functions perform many repeating and common activities, making those functions as ripe as any in the organization for the application of appropriate AI solutions. Whether you are on the leading edge of implementing your own AI chassis toward transformation goals associated with efficiency gains and improved effectiveness, or you feel you are on the other end of the adoption curve and are not quite sure how to kickstart your company's efforts to leverage AI enablement (e.g., "what is Agentic AI?"), this panel will provide a little something for everyone, with a focus on critical success factors observed with successful early adopters.

**11:00 am** **Introductions, Discussions and Q&A**

**Fred Gibbons,** *Principal, Life Sciences AI, Deloitte; New York, NY*

**George Mina, CPA,** *Senior Director, International Compliance Monitoring, Pfizer, New York, NY*

**Kelly J. Tope, JD, MBA,** *Head of Ethics and Business Integrity Governance, Operations & Risk MGMT-NA & Global Specialty Care, Sanofi; Former Head of UBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Former Global Director, Compliance Transparency, Monitoring, Systems, Data Analytics & Process Improvement, Zimmer Biomet; Boston, MA*

**Jack Tanselle, MBA,** *Managing Director, Deloitte; Indianapolis, IN (Moderator)*

### Mini Summit 27: Direct to Consumer Commercialization Models: Legal and Market Access Considerations

Pharmaceutical manufacturers and third-parties (e.g., GoodRx) are increasingly adopting consumer-directed health care initiatives. These initiatives, which focus on giving patients enhanced choices and access to health care, may offer consumers "one stop" access to prescription drugs through cash-pay discount drug programs (that operate outside of insurance), telehealth prescribing, and/or online pharmacies. The market for these types of offerings is rapidly developing, presenting alternative channels to commercialize drugs, with a wide range of related legal considerations for pharmaceutical companies to consider. This session will:

- Identify trends in consumer-directed health care initiatives, taking a detailed look at common structures
- Provide an overview of potential legal considerations and concerns
- Examine recent government scrutiny and enforcement actions
- Highlight key "watch outs" in implementing initiatives and options to mitigate risk

**11:00 am** **Introductions, Discussions and Q&A**

**Tess Carey, PharmD,** *Senior Pharmacist, Amazon Pharmacy; Philadelphia, PA*

**Eve M. Brunts, JD, LLM,** *Partner, Ropes & Gray; Boston, MA*

**Alison Fethke, JD,** *Counsel, Ropes & Gray; Former Division Counsel, Legal Regulatory & Compliance, AbbVie; Chicago, IL*

**Margaux J. Hall, JD,** *Partner, Ropes & Gray; Washington, DC*

**11:50 pm** **Transition to Networking Luncheon**

## EXHIBIT HALL OPENS, NETWORKING LUNCHEON AND LUNCHEON MINI SUMMITS

**11:50 am** **Networking Luncheon with Dessert and Coffee in the Exhibit Hall**

## MINI SUMMITS: GROUP 5 12:20 pm – 1:10 pm

### Mini Summit 28: Compliance Considerations for Rare Disease

Manufacturers of treatments for rare diseases face evolving compliance challenges due to the deep relationships with patients, close collaborations with influential advocacy organizations and gaps in health care professional education. This panel will explore recent developments and practical strategies for navigating these complexities, including:

- Compliance considerations for patient educators and other patient-facing field roles;
- Best practices for engaging with patient advocacy groups and organizations; and
- Leveraging electronic health record initiatives to identify appropriate patients.

Join us for a dynamic discussion on balancing meaningful patient engagement with compliance in the rare disease space.

**12:20 pm** **Introductions, Discussions and Q&A**

**Tracy Berns, JD,** *Senior Vice President, Chief Compliance & Quality Assurance Officer, Ionis Pharmaceuticals; Former Chief Compliance Officer, Akcea Therapeutics; Former Vice President, Chief Compliance Officer & Legal Affairs, AMAG Pharmaceuticals; Boston, MA*

**Tara D'Orsi, JD,** *Executive Vice President, General Counsel, Kyowa Kirin North America; Princeton, NJ*

**Laura Hunter, JD,** *Senior Associate, Healthcare Regulatory, Hogan Lovells; Washington, DC*

**Eliza L. Andonova, JD,** *Partner, Life Sciences Global Regulatory, Hogan Lovells; Washington, DC (Moderator)*

### Mini Summit 29: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future?

The use of AI in the Pharma and Medical Device industries continues to expand in areas such as initial scientific research, clinical development, patient support, and sales and marketing. This panel will explore recent enforcement trends in the AI space with an eye towards these use cases in the Pharma and Med Device industries, trends that include actions by federal prosecutors and state attorneys general, the failed attempt to curtail state laws under the OBB, the potential impact of the White House AI Plan, and the impact of FDA's recent spate of marketing related warning letters. Our panelists will provide their insights into the governance and controls companies are considering mitigating against the evolving enforcement risk in this area.

**12:20 pm** **Introductions, Discussions and Q&A**

**Aurélie Ercoli, LLM, PhD,** *Partner, Life Sciences Practice Group, DLA Piper, US; Washington, DC*

**Lucy Muzzy, JD,** *Vice President Enterprise Lead Responsible AI, Digital and Privacy Compliance Counsel, Pfizer; Former Assistant US Attorney, US Attorney's Office, New Jersey; New York, NY*

**Natasha Trifun, JD,** *Head of Enterprise Compliance & Risk and Privacy, AstraZeneca; Former Head of Ethics and Compliance for EUCAN/International, R&D, and Operations for Alexion AstraZeneca Rare Disease; Former Corporate Counsel, Brazil Compliance Officer, Pfizer; Boston, MA*

**Kim Tyrrell-Knott, JD,** *Senior Vice President, Chief Compliance Officer, Enovis; Former Associate General Counsel, GE HealthCare; San Diego, CA*

**Jeffrey Scott, JD,** *Of Counsel, Life Sciences Practice Group, DLA Piper; Former Lead Compliance Counsel, Digital, Reporting, and Analytics, Pfizer; Philadelphia, PA (Moderator)*

## Mini Summit 30: Update on Medical Device Investigations and Prosecutions

Join us for an insightful panel discussion exploring the rapidly changing landscape of medical device regulations and recent enforcement actions. This session will provide up-to-date information on the latest regulatory developments, equipping you with industry best practices and valuable insights drawn from recent cases that have shaped compliance strategies.

Key topics include:

- Enforcement Trends: Examine recent enforcement actions affecting medical device manufacturers, with a focus on key lessons learned and areas under increased regulatory scrutiny.
- Compliance Insights: Explore effective approaches for adapting to changing regulatory requirements and establishing robust compliance frameworks that meet industry standards.
- Regulatory Forecast: Gain insights from experts on upcoming regulatory trends and how they may impact the medical device industry, enabling you to anticipate and address future compliance requirement.

**12:20 pm** **Introductions, Discussions and Q&A**

**Terra Buckley, JD,** *Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast; Former Executive Director, Head, Business Advisory, Center of Excellence, US Healthcare Compliance, Celgene; Summit, NJ (Medical Device Executive Committee)*

**Kate Godfrey, JD, CCEP,** *Senior Vice President, Global Chief Compliance Officer, Karl Storz, US; Former Vice President, Chief Compliance and Privacy Officer, Veracyte; Seattle, WA*

**Mark McPherson, JD,** *Principal, Choate, Hall & Stewart, Boston, MA*

**Casey J. Horton, CFE,** *Managing Director, Epsilon Life Sciences; Former Director, Compliance Operations, AbbVie; Chicago, IL (Moderator)*

## Mini Summit 31: Update on the Status of FCPA Enforcement — Strategic Implications

**12:20 pm** **Introductions, Discussions and Q&A**

**Adam Falkowitz,** *Head of Legal, North America, Getinge; Former Deputy General Counsel, Olympus Corporation of the Americas; New York, NY*

**Christina O. Hud, JD,** *Global Investigations Senior Counsel, Pfizer Inc.; Former Health Care Fraud Acting Unit Chief and Senior Trial Counsel at US Department of Justice, US Attorney's Office for the District of New Jersey; New York, NY*

**Alexandria (Alex) Lav,** *Director Risk & Compliance, Dow Jones; New York, NY*

**Allan Medina, JD,** *Partner, Goodwin Procter; Former Senior Deputy Chief, Criminal Division, US Department of Justice; Washington, DC (Moderator)*

## Mini Summit 32: Government Pricing: Finding Compliance Zen

Discuss the role of the Compliance Department in Government Pricing, including oversight, collaboration with the Legal Department, investigations, and normalizing discussion with ELT and the Board around pricing and market access related topics from a compliance perspective.

**12:20 pm** **Introductions, Discussions and Q&A**

**Beth Krewson, JD,** *Vice President, Head of US Legal and Compliance, PharmaEssentia; Former General Counsel, Formation Bio; Former Senior Vice President, BlueRock Therapeutics; Philadelphia, PA*

**Meena Datta, JD,** *Partner and Global Co-leader, Healthcare Practice, Sidley Austin; Chicago, IL (Moderator)*

## Mini Summit 33: Eyes Wide Open: Navigating the Global Complexities of Third Party Risk

Compliance leaders will share their approaches to managing third-party risks in today's complex global environment. Discussions will cover innovative due diligence processes, continuous monitoring techniques, and strategies for adapting to geopolitical shifts.

**12:20 pm** **Introductions, Discussions and Q&A**

**Sri Burra, MBA,** *Director, US Ethics and Compliance, Organon; Former Ethics & Compliance Lead, North America, Haleon; Former Transformation Lead, Ethics & Compliance Workstream, GSK; Malvern, PA*

**Terri C. Segura, JD,** *Vice President, Compliance Officer, Americas, Zimmer Biomet; Chevy Chase MD*

**Mara Senn, JD,** *Former Global Executive Compliance Leader, GE Health-Care; Former Director & Senior Counsel, Global Compliance Investigations, Zimmer Biomet; Former Special Assistant US Attorney, US Attorney's Office District of Maryland, US Department of Justice; Washington, DC*

**David Fisher, MS,** *President, TDI; Washington, DC (Moderator)*

## Mini Summit 34: Vaccines Under the New Administration

This talk will explore the current administration's actions related to vaccines and its impact on the vaccines industry.

**12:20 pm** **Introductions, Discussions and Q&A**

**Richard H. Hughes IV, JD, MPH,** *Partner, Epstein Becker & Green; Lecturer, George Washington University Law School; Member, Board of Directors, Vaccinate Your Family; Former Vice President, Moderna; Washington, DC (Moderator)*

**1:10 pm** **Transition Break**

# PHARMA/DEVICE CONGRESS OPENING PLENARY SESSION

**1:20 pm** **PCF Board Welcome and Introduction**

**Christie Camelio,** *Senior Vice President and Chief Compliance Officer, Insmed; Former Vice President & Deputy Global CCO, Celgene; Florham Park, NJ (PCF Board)*

**1:30 pm** **Keynote: OIG Update**

**Mary E. Riordan, JD,** *Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, US Department of Health and Human Services; Washington, DC*

**2:15 pm** **US DOJ Keynote Fireside Chat**

**Matthew R. Galeotti, JD,** *Head, Criminal Division, US Department of Justice; Former Acting Deputy Chief, Business& Securities Fraud Section, US Attorney's Office, Eastern District of New York; Washington, DC*

**Interviewed by: Gary F. Giampetruzzi, JD,** *Partner & Global Chair Life Sciences Department, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer; New York, NY*

**2:45 pm** **Medical Device C-Suite Keynote Fireside Chat**

**Spencer Stiles, MBA,** *Group President, Orthopaedics, Stryker; Director, Chart Industries (GTLS); Director, Medical Device Manufacturers Association (MDMA); Director, Business Leaders for Michigan (BLM); Kalamazoo, MI*

**Interviewed by: Daniel Spicehandler, JD,** *Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Medical Device Executive Committee)*

**3:15 pm** **Networking Break**

**3:45 pm** **One Size Doesn't Fit All: Tailoring Compliance to Your Product**

**David M. Blank, JD,** *Partner, Arnall, Golden, Gregory; Former Senior Counsel, US Department of Health and Human Services (HHS); Former Special Assistant US Attorney, Southern District of Mississippi, US Attorney's Office; Washington, DC*

**Reanna Carver, JD,** *Assistant Vice President, Deputy General Counsel, Accord BioPharma; Raleigh, NC*

**Kristin Comer, JD,** *General Counsel, RVL Pharmaceuticals; Former General Counsel and Chief Compliance Officer, RedHill Biopharma, Inc; Former Vice President and Assistant General Counsel, Syneos Health; Bridgewater, NJ*

**Robert Melillo, JD,** *Co-founder and Managing Director, G&M Health; Cocoa Beach, FL (Moderator)*

**4:30 pm** **New Business Models to Meet Patients Where They Are**

**Peter Brensilver, JD, MPH,** *Senior Vice President, Chief Global Commercial Compliance, and Risk Counsel, Pfizer; New York, NY*

**David Dopf, JD,** *Executive Director & Executive Counsel, US Human Pharma Business Law, Boehringer Ingelheim; Ridgefield, CT*

**Stefanie A. Doebler, JD,** *Partner and Co-Chair, Health Care Practice Group, Covington & Burling; Washington, DC (Co-moderator)*

**Sarah A. Franklin, JD,** *Partner and Vice-Chair, Life Sciences Investigations Practice, Covington & Burling; Former Attorney, US Federal Trade Commission; Washington, DC (Co-moderator)*

**5:00 pm** **Chief Compliance Officer and Business Leader Roundtable**

**Brent Boucher,** *Senior Vice President, Americas, Solventum; Former Executive Vice President, Global Commercial, NuVasiv, St. Paul, MN*

**Anisa Dhalla,** *Vice President, Global Head, Ethics and Business Integrity, UCB; (PCF Board); Acworth, GA*

**JJ Kuhn, JD,** *Senior Vice President, Chief Ethics & Compliance Officer, Solventum; Former Vice President Chief Counsel, Global Investigations, Medtronic; St. Paul, MN*

**Colleen Kempf,** *Head of Ethics & Compliance, US Biopharmaceuticals, AstraZeneca; Wilmington, DE*

**Meredith Odell,** *Executive Director Marketing, AstraZeneca; Former Specialty Sales Representative, GSK; Wilmington, DE*

**Jeffrey Stark, MD,** *Vice President & Head of Medical Immunology, UCB; Smyrna, GA*

**Paul J. Silver,** *Principal, Life Sciences Regulatory, Legal, & Compliance Leader, Deloitte, Atlanta; GA (Moderator)*

**6:00 pm** **ADJOURNMENT AND NETWORKING RECEPTION**

# AGENDA DAY II: THURSDAY, OCTOBER 23, 2025

**7:00 am** **Registration Opens: Continental Breakfast in Exhibit Hall**

## CHIEF COMPLIANCE OFFICER ROUNDTABLE

*(PCF-Sponsored, Exclusive Invitation-Only, Closed-Door Session)*

**7:30 am** **Invitation-only Networking Breakfast**

**8:00 am** **Welcome and Introductions**

**Daryl Kreml, JD,** *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Former US Compliance & Global Program Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific; Boston, MA (PCF Board)*

**Antitrust Admonition:**

**Brian A. Bohnenkamp, MHA, JD, P***artner, FDA and Life Sciences, King & Spalding, Washington, DC*

**8:15 am** **Passing the Baton: Reflections from Retiring CCOs**

Retiring Chief Compliance Officers will reflect on the pivotal challenges they've faced and the enduring lessons they've learned, illuminating opportunities for those stepping into leadership roles.

**Cindy Cetani, LPEC, NACD.DC®,** *Retired Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia, Glen Allen, VA (PCF Board)*

**Michael Clarke, JD, CCEP, NACD.DC®,** *Principal, Jaeger-Plymouth Advisors, LLC; Retired Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior Inc., Bridgewater, NJ (Medical Device Executive Committee)*

**8:45 am** **Fireside Chat with The Honorable Merrick B. Garland**

In this exclusive spotlight, former US Attorney General Merrick Garland will reflect on his decades of public service and the evolving landscape of justice, civil liberties, and regulatory enforcement. Judge Garland will offer timely insights into the shifting expectations facing Chief Compliance Officers, including heightened scrutiny around corporate ethics, emerging enforcement priorities, and the expanding role of compliance in safeguarding institutional integrity.

**Merrick B. Garland, JD,** *Partner, Arnold & Porter; Former 86th US Attorney General, Chief Judge of the US Court of Appeals, DC Circuit and Chair, Executive Committee, US Judicial Conference, US Department of Justice; Washington, DC*

**Interviewed by: Mahnu Davar, JD,** *Partner and Co-chair Life Sciences & Healthcare Regulatory Practice, Arnold & Porter; Washington, DC*

**9:15 am** **Perspectives from Former Government Officials**

This expert panel convenes distinguished former leaders from the DOJ, HHS OIG, and the US Attorney's Office to share candid insights into enforcement trends, shifting regulatory priorities, and the evolving role of compliance across public and private sectors. With firsthand experience across key regulatory agencies, panelists will further drill down to deliver strategic foresight and practical guidance, equipping Chief Compliance Officers to navigate today's increasingly complex enforcement landscape.

**Robert K. DeConti, JD,** *Partner, King & Spalding; Former Chief Counsel, Inspector General, Office of Inspector General, US Department of Health and Human Services; Washington, DC*

**Joshua S. Levy, JD,** *Partner, Ropes & Gray; Former US Attorney for the District of Massachusetts, US Department of Justice; Boston, MA*

**Lisa H. Miller, JD,** *Partner, Sidley Austin LLP; Former Deputy Assistant Attorney General, Fraud and Appellate Sections, Criminal Division, US Department of Justice; Washington, DC*

**Tara Shewchuk, JD, LLM,** *Senior Vice President, Chief Privacy, Integrity & Compliance Officer Medtronic; Former Senior Director, Ethics and Compliance, AbbVie, Minneapolis, MN (Medical Device Executive Committee) (Moderator)*

**10:00 am** **Break**

**10:15 am** **Executive Breakouts**

Attendees will choose two topics of interest and engage in facilitated breakout discussions designed for active collaboration and shared learning.

**Breakout Topics:**

**1. Strengthening Board Effectiveness Through Impactful Engagement**

Exchange of ideas and strategies for enhancing Board engagement, oversight, and governance.

**2. Navigating the Crossroads: Legal & Compliance Collaboration**

Explore how organizations are redefining roles, streamlining leadership structures—particularly in relation to CCO reporting—and addressing friction points to foster stronger cross-functional collaboration.

**3. Empowering Leadership: Growth Strategies for You and Your Team**

Share practical strategies for advancing your own professional growth or building a strong bench of future leaders, intentional development is essential to long-term success.

**Christie Camelio,** *Senior Vice President and Chief Compliance Officer, Insmed; Former VP & Deputy Global CCO, Celgene; Florham Park, NJ (PCF Board)*

**11:40 am** **Breakout Takeaways & Open Forum**

Key insights from executive breakout sessions, followed by interactive opportunities for benchmarking and peer-driven Q&A.

**Christie Camelio,** *Senior Vice President and Chief Compliance Officer, Insmed; Former VP & Deputy Global CCO, Celgene; Florham Park, NJ (PCF Board)*

**Michael Clarke, JD, CCEP, NACD.DC®,** *Principal, Jaeger-Plymouth Advisors, LLC; Retired Vice President, Deputy General Counsel & Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior Inc., Bridgewater, NJ (Medical Device Executive Committee)*

**11:55 am** **Wrap Up**

**Daryl Kreml, JD,** *Head, Ethics & Compliance, Global Oncology, Takeda; Former Senior Vice President, Chief Enterprise Risk & Compliance Officer, Sage Therapeutics; Former US Compliance & Global Program Management, Biogen; Former Senior Managing Counsel, FCPA Officer, and Director, International Compliance, Boston Scientific; Boston, MA (PCF Board)*

**Noon** **Adjournment**

# MORNING MINI SUMMITS

# MINI SUMMITS GROUP 6 8:00 am – 8:50 am

## Mini Summit 35: Case Studies in AI & Analytics for Monitoring & Investigations

This panel will deep-dive into practical operationalized case studies of how life sciences companies are leveraging artificial intelligence and real-time data analytics to improve their monitoring and investigations work. Learn how analytics and AI can better monitor HCP/HCO spend, distributor transactions, and other third party transactions, to move from sample-based and periodic monitoring to real-time comprehensive monitoring. Learn how AI is also accelerating the intake and completion of investigations and how investigation teams are leveraging AI and analytics to make their investigations and mitigation more effective and targeted. The panel will cover:

- The Role of Analytics & AI in Monitoring HCP/HCO and Third-Party Spend
- The Interplay of Analytics & AI between Investigations & Monitoring teams
- Leveraging AI in the Investigations Process

**8:00 am** **Introductions, Discussions and Q&A**

**Angelique Lee, JD,** *Former Vice President, Chief Compliance and Ethics Officer, Jazz; Former Vice President, Global CCO, R&D Legal Lead, Greenwich Biosciences & GW Pharmaceuticals; Orange County, CA*

**Aaron Lewis, MBA,** *Director, Legal and Compliance Operations, Cordis; Former Director, Compliance Insights and Technologies, Cardinal Health; Columbus, OH*

**Jon Tan, LLB, MSC(Fin),** *Director, Compliance, Ethics and Investigations, Bristol Myers Squibb; Singapore*

**Emily Treanor, JD,** *Head of Global Investigations & Enterprise Risk Management, Alnylam; Washington, DC*

**Brook Mishler, RN, MSN,** *Global Director of Compliance Solutions - Life Sciences, Case IQ; Former Compliance Officer for the Americas, Cordis; Grand Rapids, MI (Moderator)*

## Mini Summit 36: Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights

As scrutiny of payments to healthcare professionals and organizations continues to grow, life sciences companies must ensure their bona fide service arrangements are supported by robust, defensible fair market value (FMV) assessments. This session will explore how organizations can enhance the consistency and efficiency of FMV determinations by leveraging cost-driver analytics, benchmarking and insights drawn from both within and outside the industry. Attendees will gain practical strategies for: - Identifying and applying relevant cost drivers to service fee evaluations - Using cross-industry data to inform and strengthen FMV positions - Streamlining review processes while maintaining compliance integrity - Improving documentation and decision-making transparency Participants will walk away with actionable approaches to strengthen FMV support, improve consistency and reduce compliance risk across their third-party vendor engagements.

**8:00 am** **Introductions, Discussions and Q&A**

**Ayushman Hazarika, CA, MBA, CFE,** *Managed Markets Finance, Novartis; Former US SEC and Management Reporting, Merck and Schering-Plough; Berkeley Heights, NJ*

**Samantha Sutherland,** *Director, Digital Health and Transformation Practice, Baker Tilly; Jersey City, NJ*

**Natasha Thoren, JD, LLM,** *Chief Legal and Compliance Officer, X4 Pharmaceuticals; Former Associate General Counsel & Chief Compliance and Privacy Officer, Albireo Pharma, Inc; Former Executive Director, Brand Attorney | Interim General Counsel | Senior Director, Legal Affairs, Intercept Pharmaceuticals; Boston, MA*

**Darren R. Jones, CIA,** *Principal, Life Science Industry Leader, Baker Tilly; New York, NY (Moderator)*

## Mini Summit 37: Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success

Achieving an effective and efficient compliance program requires more than identifying risks, it takes a coordinated strategy that links assessment, mitigation, and monitoring. In this panel compliance leaders will share how compliance programs are evolving their programs to better manage risk and improve oversight.

The discussion will focus on practical, risk-based approaches to pinpoint high-priority areas, design targeted mitigation plans, and implement monitoring strategies that drive accountability and program improvement. Panelists will also explore how analytics and automation are enhancing transparency, reducing manual burden, and demonstrating compliance program effectiveness.

Attendees will leave with clear insights on how to integrate these core elements to strengthen risk management and improve both operational efficiency and regulatory outcomes.

**8:00 am** **Introductions, Discussions and Q&A**

**Casey J. Horton, CFE,** *Managing Director, Epsilon Life Sciences; Former Director, Compliance Operations, AbbVie; Chicago, IL*

**Christian Malias, MBA,** *Associate Director, Compliance Program Effectiveness, Insmed; Former Associate Director, Compliance Operations, Monitoring & Systems, Sage Therapeutics; Former Global Corporate Compliance Manager, Investor Relations & Corporate Communications; Pittsburgh, PA*

**Adam Price, JD,** *Vice President, US Chief Compliance & Integrity Officer, Boehringer Ingelheim; Ridgefield, CT*

**Michael T. O'Connor, MS,** *Chief Executive Officer, qordata; Former Global Head Compliance and Ethics Operations, Alexion Pharmaceuticals; Former Executive Director, Global Head, IS Business Consulting, Boehringer Ingelheim; New York, NY (Moderator)*

## Mini Summit 38: Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk

**8:00 am** **Introductions, Discussions and Q&A**

**Aaron M. Applebaum, MBA, JD,** *Counsel, Sidley Austin; Washington, DC*

**Monica Schroeter, CPA, CISA,** *Head of Compliance Operations and Risk, LivaNova; Former Head of Compliance, F2G; Former Head of Compliance & Privacy, SK Life Science; Goshen, NY*

**Rita K. Warfield, JD,** *Senior Director, Global Trade Legal and Compliance, Medtronic; Former Associate General Counsel, Regulatory Law Group, BD; Former Assistant General Counsel, Ferring Pharmaceuticals; Livingston, NJ*

**Benjamin Correa, JD,** *Partner Food, Drug & Medical Device, Sidley Austin; Washington, DC (Moderator)*

## Mini Summit 39: Use Cases for Leveraging AI in the Transparency Process

As global regulatory demands around transparency reporting continue to escalate, life sciences organizations are under increasing pressure to manage vast volumes of data with greater precision, speed, and compliance. This session explores how AI is reshaping the transparency reporting lifecycle — streamlining data aggregation, enhancing accuracy, and enabling proactive compliance. Join this panel to hear from industry peers as they share real-world AI use cases, from automating data validation to identifying reporting anomalies. The discussion will also address the challenges of balancing innovation with regulatory risk, and automation with accountability, offering practical insights for organizations navigating this evolving landscape.

**9:00 am** **Introductions, Discussions and Q&A**

**Emily Singh,** *Partner, Global Spend Transparency Practice Leader, PwC; Chicago, IL*

**8:50 am** **Transition Break**

# MINI SUMMITS GROUP 7 9:00 am – 9:50 am

## Mini Summit 40: Telehealth for Life Sciences Companies: New Platforms, Old Risks

- Review new and emerging telehealth models
- Analyze potential legal issues for life sciences companies in light of recent enforcement and government inquiries
- Consider strategies that support high-quality, patient-centric care while mitigating risk

**9:00 am** **Introductions, Discussions and Q&A**

**Thomas A. Gregory, CPA, CFA,** *Partner, Forensic & Integrity Services, EY; Atlanta, GA*

**Stefanie A. Doebler, JD,** *Partner and Co-Chair, Health Care Practice Group, Covington & Burling; Washington, DC*

**Sarah A. Franklin, JD,** *Partner and Vice-Chair, Life Sciences Investigations Practice, Covington & Burling; Former Attorney, US Federal Trade Commission; Washington, DC*

## Mini Summit 41: State of Confusion: The Overlooked State Laws in Pharma Compliance

Do you know the unknowns? This session covers some of the lesser talked about compliance requirements, like drug take back programs, PhRMA Code (where it's law!), and disclosures, as well as unique requirements in the pipeline for 2026.

**9:00 am** **Introductions, Discussions and Q&A**

**Thomas Daly, JD,** *Associate Director of Compliance, Biocon Biologics; New York, NY*

**Olivia Krzeminski, JD,** *Director of Compliance & Legal Research, G&M Health; Somerset, NJ*

## Mini Summit 42: Making Compliance Cool, Increasing Your Influence

Compliance can feel pretty uncool. It's tedious and bland. This is a problem because employees aren't listening or learning, and people don't speak up when they're bored, annoyed or afraid. In this session we will share a variety of techniques to help you proactively position and promote your program so that its more interesting and approachable, which helps increase your influence and impact. Compliance is more attainable when the business enjoys hearing from you.

- Compliance Culture: Change the vibe. People won't go to the office of 'No.'
- Learning & Engagement: A spoonful of sugar helps the medicine go down.
- Comms & Awareness: Stand out, remind and reinforce. Nudge-Nudge.
- Engage & Empower Leaders: Provide messaging they'll deploy without an eye-roll.

**9:00 am** **Introductions, Discussions and Q&A**

**Angelique Lee, JD,** *Former Vice President, Chief Compliance and Ethics Officer, Jazz; Former Vice President, Global CCO, R&D Legal Lead, Greenwich Biosciences & GW Pharmaceuticals; Orange County, CA*

**Ronnie Feldman,** *Founder, Chief Executive Officer and Creative Director, L&E: Comedians Who Improve Compliance; Chicago, IL*

## Mini Summit 43: Compliance Considerations for Mergers and Acquisitions

The panel will explore the critical compliance considerations that organizations must address during mergers and acquisitions in the sector. The panel will discuss leading practices, regulatory challenges, and strategies to drive integration success and mitigate risk.

**9:00 am** **Introductions, Discussions and Q&A**

**Sara K. Frank, JD,** *Principal, Choate, Hall & Stewart; Boston, MA*

**Patrick Gibson, JD,** *Former Associate Vice President, Global Compliance Counseling, Organon; Former Special Assignment – Global Compliance Separation Lead, Merck; Villanova, PA*

**Tiffeny Rivard, MBA,** *Senior Director, Compliance and Privacy Operations, Medtronic; Minneapolis, MN*

**Kiley Smith Kelly, MBA,** *Partner/Principal, Forensic & Integrity Services, EY; Philadelphia, PA (Moderator)*

## Mini Summit 44: How to Build Your Compliance Analytics Programs Efficiently and Effectively

OIG and DOJ guidance continues to reinforce a clear expectation: companies must understand their data and leverage analytics to proactively identify and mitigate compliance risks. Yet many organizations struggle to operationalize this guidance. Some don't know where to begin, while others are overwhelmed by the perceived costs, complexity, or lack of internal expertise needed to build a robust analytics program.

Whether you're just starting your analytics journey or looking to enhance an existing program, we'll explore how to build compliance analytics programs that are both efficient and effective. Drawing on real-world examples and lessons learned, our experts will share their perspectives regarding any current challenges and practical strategies.

**9:00 am** **Introductions, Discussions and Q&A**

**Peter Agnoletto, CPA,** *Strategic Advisor General Medicines and Gold Bond, Sanofi; Former Senior Director, Chief Compliance Officer & Chief Audit Executive & ERM Leader, Par Pharmaceutical Companies; Bridgewater, NJ*

**Dhara Moro, CPA, CFE,** *Director, Compliance, Disc Medicine; Former Director, Compliance Partnership & Operations, Sage Therapeutics; Watertown, MA*

**Julia Heller,** *Principal, Global Commercial Compliance Consulting - US Leader, IQVIA; Philadelphia, PA (Co-moderator)*

**Johan Holm,** *Principal, Global Analytics and Transparency, IQVIA; Former Director, Global Transparency Operations, EFPIA, AstraZeneca; Lansdale, PA (Co-moderator)*

**9:50 am** **Networking Break in Exhibit Hall**

# MINI SUMMITS GROUP 8 10:20 am – 11:10 am

## Mini Summit 45: Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance

This session will address the legal and compliance challenges presented by Medical Affairs and Commercial interactions in a life sciences organization. Topics will include lines of separation and areas of overlap, including market access, HEOR/HCEI, disease awareness and pre- and post-approval communications and activities. This session will also explore recent opportunities and challenges presented by the SIUU guidance, as well as ongoing risks with communication of off-label information and scientific exchange.

**10:20 am** **Introductions, Discussions and Q&A**

**Michelle D. Axelrod, JD,** *Principal, Porzio, Bromberg & Newman; Former Assistant General Counsel, Sunovion; Westborough, MA*

**Hannah Putnam, MHA, CHC, CHRC,** *Head of Ethics & Compliance Operations, Oncology, Takeda; Former Senior Director, Ethics & Compliance, Veloxis Pharmaceuticals; Former Senior Corporate Ethics & Compliance Officer, Fresenius Medical Care; Cambridge, MA*

**Eddie Underwood, PharmD,** *Medical Science Liaison, argenx; Former Lead Medical Science Liaison (Southeast), NOVAVAX; Former Regional Director of Scientific Affairs, AcelRx Pharmaceuticals; Former Medical Science Liaison, Ironwood Pharmaceuticals; Crestview-Fort Walton Beach-Destin, FL*

**Jennifer A. Romanski, JD,** *Principal, Porzio, Bromberg & Newman; Morristown, NJ (Moderator)*

## Mini Summit 46: Implementing AI in Life Sciences Compliance: Strategies, Challenges, and Opportunities

- Introduction: Overview of AI's evolving role in LifeSciences compliance.
- Strategic Implementation: Aligning AI initiatives with compliance objectives and business goals.
- Key Challenges: Addressing data quality, regulatory requirements, and organizational change management.
- Opportunities: Enhancing efficiency, risk detection, and decision-making through AI.
- Case Studies: Insights from successful AI implementations in the industry.
- Best Practices: Recommendations for effective AI integration in compliance processes.
- Q&A Session: Engaging with the audience to discuss experiences and address queries.

**10:20 am** **Introductions, Discussions and Q&A**

**Rebekah Latchis, JD,** *Vice President, Global Investigations, Data and Governance, Medtronic; Former Corporate Responsibility Director, Bon Secours Health System; Washington, DC*

**Jennifer McGovern, JD,** *Risk, Operations & Data Lead, AstraZeneca, Wilmington, DE*

**Saraswatha Lalitha Putcha, MS,** *Associate Director, Product Delivery & AI Implementations, Cresen Solutions; Exton, PA*

**Neeraj Gupta, MBA,** *President, Chief Technology Officer, Cresen Solutions; Chester Springs, PA (Moderator)*

## Mini Summit 47: Fair Market Value: Compliant Compensation Strategies

Seasoned compliance professionals share their experiences managing HCP and Non-HCP compensation challenges. From HCP rate negotiations to the rise of influencers and increased sensitivities when engaging, tiering, and compensating Non-HCPs, the discussion dives into solutions your organization should consider when tackling these issues. Discover how traditional FMV frameworks are being tested and what your organization can do to address both common and emerging challenges.

**10:20 am** **Introductions, Discussions and Q&A**

**Abe Kassis, PhD,** *Senior Director, Global Head Compliance and Legal Operations, Bausch + Lomb; Former Global Compliance - Director of Compliance, Takeda; Former Associate Director, Ethics and Compliance - CIA Auditing and Monitoring & Risk Management Oversight, Takeda; New York, NY*

**Michael Koether,** *Associate Director, Compliance, Sun Pharmaceutical Industries; Princeton, NJ*

**Matt Zebley,** *Senior Manager, Compliance, Transparency and HCP Engagement, Incyte Corporation; Wilmington, DE*

**Eric Bolesh,** *Chief Executive Officer, Cutting Edge Information; Durham, NC (Moderator)*

## Mini Summit 48: New Standards for Compliance Learning: What You Need to Know — Rethink's 2025 Benchmarking Report

Join us for an exclusive look at Rethink Compliance's most recent compliance and ethics training benchmarking study. Developed by seasoned compliance veterans, this session will unveil key findings and strategic insights, including:

- How top companies leverage training analytics to drive tangible results
- Leading practices for training boards and third parties effectively
- Strategic approaches to managing compliance training deployments
- The growing trend of adopting shorter training formats and microlearning solutions to boost engagement and retention

This session offers a unique opportunity to benchmark your program against the industry's best and discover actionable strategies to enhance your organization's compliance and ethics initiatives.

**10:20 am** **Introductions, Discussions and Q&A**

**Catherine Kanzler, JD,** *Vice President, Governance, Risk, Compliance, Privacy & InfoSec Strategy and Planning, Legal, Risk & Compliance Function, Olympus Corporation; Center Valley, PA*

**Jamie McKillop,** *Vice President for Advisory Services, Rethink Compliance; Reading, MA*

**Kirsten Liston,** *Founder and Chief Executive Officer, Rethink Compliance; Boston, MA (Moderator)*

### Mini Summit 49: What Enforcement May Look Like in Trump 2.0

The first nine months of the second Trump administration have seen significant shifts in announced priorities, approaches, and staffing at both DOJ and FDA. This panel will discuss the flurry of developments since January, the potential impact of announced but not yet implemented priorities and activities, and what it all may mean for life science compliance organizations over the next three years and beyond.

**10:20 am** **Introductions, Discussions and Q&A**

**Allison DeLaurentis, JD,** *Senior Counsel, Litigation and Government Investigations, Bristol Myers Squibb; Philadelphia, PA*

**Perham Gorji, JD,** *Partner, DLA Piper; Former Deputy Chief Counsel for Litigation, US Food and Drug Administration; Former Trial Attorney, Consumer Protection Branch, Department of Justice; Former Assistant US Attorney, US Attorney's Office, District of Columbia; Washington, DC*

**Gabriel Scannapieco, JD,** *Partner; Co-Chair Life Sciences, Arnall Golden Gregory; Former Assistant Director, Consumer Protection Branch, US Department of Justice; Washington, DC*

**Maya P. Florence, JD,** *Partner, Life Sciences and Health Care; FDA Regulatory; Litigation, Skadden, Arps, Slate, Meagher & Flom; Boston, MA (Moderator)*

**11:10 am** **Transition Break**

## MINI SUMMITS GROUP 9 11:20 am – 12:10 pm

### Mini Summit 50: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements

The role of Pharmacy Benefit Managers (PBMs) has gained significant attention recently, with increased regulatory scrutiny and broader discussions about their place in the pharmacy supply chain. This spotlight has prompted questions regarding the relationships between PBMs and manufacturers. As scrutiny intensifies, the Compliance department's proactive involvement becomes crucial to align both parties and address relevant state and (looming) federal mandates. Our panel will explore forward-looking strategies for enhancing your organization's Compliance Program and outline key considerations for partnering effectively with PBMs.

**11:20 am** **Introductions, Discussions and Q&A**

**Jamie E. Darch, JD,** *Health Care Partner, Ropes & Gray; Chicago, IL*

**Kari K. Loeser, JD,** *Vice President, Chief Compliance Officer, CytoKinetics; Former US Healthcare Compliance Officer, Vifor Pharma; Former Senior Counsel, Jazz Pharmaceuticals; Former Investigator, US Department of Health & Human Services; San Francisco, CA*

**Jenny McVey, MS, PhD,** *Former North America Compliance Officer, bioMérieux; Adjunct Professor, Fordham University School of Law; Salt Lake City, UT*

**Jeffrey Low, RPh, MHA,** *Managing Director, Ankura; Former Vice President Clinical Services, Magellan Health; Former Director, Medicare Services, CVS/Caremark; Phoenix, AZ (Moderator)*

### Mini Summit 51: Sanctions — the Enterprise-Wide Risk and Compliance Nexus

Not concerned about Sanctions because primary responsibility for risk management may not typically be managed by Compliance? Given the current administration's focus on sanctions, tariffs, terrorist financing, and cartels, a renewed focus on enterprise-wide sanctions management is needed. This panel will discuss the key elements of a sanctions compliance management program and how to coordinate responsibilities among Compliance, Legal, Operations, Finance, and Human Resources.

**11:20 am** **Introductions, Discussions and Q&A**

**Christopher Corallo**, *Deputy Chief Compliance Officer, Convatec; Bridgewater, NJ*

**Jaimee Reid, JD, LLM,** *Head of Compliance and Privacy Officer, Intercept Pharmaceuticals; Morristown, NJ*

**Nicole Succar, JD,** *Partner, Paul, Weiss, Rifkind, Wharton & Garrison; Former Sanctions Officer, US Treasury Department's Office of Foreign Assets Control (OFAC); New York, NY*

**David Amendola,** *Director, ResEcon Life Sciences & Healthcare; Former Global Compliance Risk Evaluation and Management, ConvaTec; New York, NY (Moderator)*

### Mini Summit 52: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies

This session will discuss the FDA's guidance on scientific information on unapproved uses of approved/cleared medical product communications (SIUU communications), including recent changes to the guidance and FDA's enforcement policies. With both in-house and outside counsel perspectives, the session will address compliance implications for companies, including questions about appropriate changes to compliance structures and procedures to address the new guidance

**11:20 am** **Introductions, Discussions and Q&A**

**Mahnu V. Davar, MA, JD,** *Partner and Co-chair, Life Sciences & Healthcare Regulatory, Arnold & Porter; Washington, DC*

**Saul B. Helman, MD, MBA,** *President, Epsilon Life Sciences; Chicago, IL*

**Rupa Cornell, JD,** *Vice President, Legal Commercialization and Chief Compliance Officer, Astria Therapeutics; Member, Board of Directors, Massachusetts Technology Collaborative; Former Vice President, General Counsel, Vaccines Business Unit, Takeda; Former Deputy General Counsel and Chief Compliance Officer, Stealth BioTherapeutics; Former General Counsel and Chief Compliance Officer, Americas, Stallergenes Greer; Cambridge, MA*

**Jacob T. Elberg, JD,** *Professor & Faculty Director, Center for Health & Pharmaceutical Law, Seton Hall University School of Law; Former AUSA, US Attorney's Office, District of New Jersey; Newark, NJ (Moderator)*

### Mini Summit 53: Strategic Stewardship: Navigating Compliance and Corporate Responsibility in Life Sciences

With evolving regulations and uncertainty around National Institutes of Health (NIH) funding, life sciences companies face increasing pressure to support healthcare advancement through stewardship activities such as educational grants, charitable contributions and research sponsorships, while maintaining rigorous compliance standards. This session explores strategies for achieving a balanced approach to ethical engagement and meaningful impact. Attendees will gain insights into:

- Designing stewardship initiatives that align with both compliance requirements and organizational values
- Navigating complex regulatory frameworks to reduce risk and ensure program integrity
- Leveraging stewardship to build credibility, strengthen community relationships and support the broader healthcare ecosystem
- Learning about the various workflows associated with the different types of activities and the unique compliance controls that can be built in for each Participants will leave with practical approaches for making stewardship a sustainable, value-driven component of their organization's healthcare mission.

**11:20 am** **Introductions, Discussions and Q&A**

**David Cromley, JD,** *Principal, Cromley Consulting, LLC, Adjunct Professor, Villanova University Charles Widger School of Law; Former Associate Vice President, Global Compliance Organization, Merck; Glenside, PA*

**Colleen Snow Rybchuk, JD,** *Director, US & Canada Compliance, Zimmer Biomet; Washington, DC*

**Alexis Wermuth, JD, C***hief Compliance Officer, Marmon Medical; Former Head of Health Care Compliance, Global; Ethics & Compliance Officer, Fresenius Medical Care North America; Heber City, UT*

**Mark C. Scallon, MHA,** *Principal, Life Sciences Consulting, Baker Tilly; Richmond, VA (Moderator)*

### Mini Summit 54: Best Practices in Responding to Investigations

Learn and discuss effective approaches for responding to investigations. Hear from and engage with in-house experts and outside counsel on topics including:

- Practical uses of AI and emerging technologies to enable effective, efficient investigations
- Coordination between legal and compliance
- Best practices for engaging with the business
- Outside counsel perspectives on managing confidentiality and privilege, engaging experts, and conducting effective negotiations

**11:20 am** **Introductions, Discussions and Q&A**

**Briana Cabrera, MS, CFE,** *Senior Director, Global Privacy & Compliance Investigations, Medtronic; Miami, FL*

**Sarah diFrancesca, JD,** *Executive Director, Compliance Lead, Immunology & Dermatology, Incyte; Wilmington, DE*

**David C. Tolley, MA, JD,** *Partner, Chair, Boston Litigation and Trial Department, Latham & Watkins; Boston, MA*

**Brett Barlag, MBA,** *Senior Managing Director, Healthcare Risk Management and Advisory, FTI Consulting; New York, NY (Moderator)*

**12:10 pm** **Transition to Networking Luncheon**

## NETWORKING LUNCHEON

**12:10 pm** **Networking Luncheon with Dessert and Coffee in the Exhibit Hall**

## SPECIAL LUNCHEON SESSION ON GLOBAL COMPLIANCE (OPTIONAL) 12:25 pm – 1:15 pm

In an era where supply chains, clinical trials, digital health platforms, and third-party relationships cross every border, US ethics and compliance officers in life sciences can no longer afford to think locally. This dynamic panel invites you to step outside the US bubble and explore how global developments are reshaping the risk landscape — and creating strategic opportunities — for pharmaceutical and medical device companies. Hear directly from senior leaders spanning industry, government, and civil society as they unpack how emerging global trends in ethics and compliance are influencing the US environment as well as our stakeholders' expectations and operational practices. Expect questions and insightful discussion on topics spanning international anti-corruption shifts, digital and AI governance, health access, and third-party due diligence and risk management. Whether you operate globally or not, these outside-in insights will sharpen your strategy, challenge your assumptions, and equip you to lead ethics and compliance into a more interconnected future.

**12:25 pm** **Special Luncheon Session — Bringing the Outside In: Global Ethics & Compliance Trends and US Implications**

**Aleksej Daineko, MA,** *Vice President, Chief Ethics & Compliance Officer, Lundbeck; Former CCO, Sobi - Swedish Orphan Biovitrum AB; Former Director, Head of Global Compliance & Risk Business Partnering, LEO Pharma; Copenhagen, Denmark*

**Anisa Dhalla,** *Vice President, Global Head, Ethics and Business Integrity, UCB; (PCF Board); Acworth, GA*

**Gary Kalman,** *Executive Director, Transparency International US; Former Executive Director, Financial Accountability and Corporate Transparency (FACT) Coalition; Founder, Americans for Financial Reform; Former Director, Federal Legislative Office, US Public Interest Research Group (PIRG); Washington, DC*

**Mwana Lugogo, JD, MPP,** *Chief Ethics & Compliance Officer and Executive Team, Takeda; Former Senior Counsel, Baxter Healthcare; Zurich, Switzerland*

**Lisa K. Miller, JD, LLM,** *Head, Integrity Compliance, Integrity Vice Presidency, World Bank Group; Washington, DC*

**Andrew Blasi, MBA,** *Chief Executive Officer, Ethicist International; Founding Member, Anti-Corruption Leaders Hub, OECD; Faculty, Intl Anti-Corruption Academy; Washington, DC (Moderator)*

**1:15 pm** **Transition Break**

# CLOSING PLENARY SESSION

**1:20 pm** **Welcome and Introduction: PCF Co-Chairs**

**1:30 pm** **Annual AUSA Roundtable**

**Charlene Keller Fullmer, JD,** *Assistant US Attorney and Deputy Chief Civil Division, US Attorney's Office, Eastern District of Pennsylvania, US Department of Justice; Former Attorney Advisor, Federal Bureau of Investigation; Philadelphia, PA*

**Abraham George, JD,** *Assistant US Attorney and Chief, Civil Division, US Attorney Office, District of Massachusetts; Boston, MA*

**Mackenzie Queenin, JD,** *Assistant US Attorney and Chief, Health Care Fraud, US Attorney Office, District of Massachusetts; Adjunct Professor, Boston College of Law; Boston, MA*

**Gary F. Giampetruzzi, JD,** *Partner & Global Chair Life Sciences Department, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer; New York, NY (Moderator)*

**2:15 pm** **Investigations, Enforcement and Prosecutions Roundtable**

**Jennifer L. Bragg, JD,,** *Partner, Latham and Watkins; Former Associate Chief Counsel for Enforcement, Office of Chief Counsel, US Food and Drug Administration; Washington, DC*

**Greg Demske, JD,** *Partner, Goodwin Procter; Former Chief Counsel, Office of Inspector General, US Department of Health and Human Services; Washington, DC*

**Gejaa T. Gobena, JD,** *Partner, Hogan Lovells; Former Deputy Chief, Fraud Section, Criminal Division, US Department of Justice; Washington, DC*

**Lisa H. Miller, JD,** *Partner, Sidley Austin; Former Deputy Assistant Attorney General, Fraud and Appellate Sections, Criminal Division, US Department of Justice; Washington, DC*

**Kip F. Ebel, MBA,** *Global and Americas Forensic & Integrity Services Life Sciences Sector Leader, EY; New York, NY (Moderator)*

**3:00 pm** **Networking Break in Exhibit Hall**

**3:30 pm** **Strategies and Techniques for Compliance Conversations with the Business**

**Susan Williamson, MBA,** *Senior Vice President & Chief Compliance Officer, Endo; Former Senior Manager, WEBB Finance, Operational Risk Management, Pfizer; Malvern, PA*

**John S. Rah, JD,** *Counsel, Potter & Murdock; Potomac, MD*

**Shoshanna Clark, JD,** *Vice President, Ethics & Compliance, Kailera Therapeutics; Former Vice President, Chief Compliance Officer, Caravel Therapeutics; Former Head of UBU Ethics & Compliance Operations, Takeda; Boston, MA*

**Yogesh Bahl, MBA,** *Partner and Practice Leader, Resolution Life Sciences and Healthcare, Chief Financial Officer and Head of Investor Relations, IACTA Pharmaceuticals; New York, NY (Moderator)*

**4:15 pm** **Artificial Intelligence in Life Sciences Compliance: Real-World Case Studies**

**Rachel Batykefer, CCEP,** *Vice President, CIA & Compliance Operations, Mallinckrodt Pharmaceuticals; Former Senior Director, Global Compliance & Ethics Training, Policy & Operations, Teva; Bridgewater, NJ*

**Omar Richardson, MBA,** *Senior Director of Compliance, Shionogi Inc.; Former Compliance Officer, Grünenthal Group; Former Director, Corporate Compliance; New York, NY*

**Kelly J. Tope, JD, MBA,** *Head of Ethics and Business Integrity Governance, Operations & Risk MGMT-NA & Global Specialty Care, Sanofi; Former Head of UBU Ethics & Compliance Monitoring & Reporting Operations, Takeda; Former Global Director, Compliance Transparency, Monitoring, Systems, Data Analytics & Process Improvement, Zimmer Biomet; Boston, MA*

**John Poulin,** *Chief Technology Officer and Partner, HELIO, Boston, MA (Moderator)*

**5:00 pm** **Annual FDA Update Address**

**Twyla Mosey, PharmD, RPh,** *Director, Division of Advertising & Promotion Review, US Food and Drug Administration, Washington, DC*

**5:30 pm** **Updates from AdvaMed, BIO and PhRMA**

**John Delacourt, JD,** *Deputy General Counsel, Vice President Health, Regulatory & Commercial Operations, Biotechnology Innovation Organization; Former Chief Antitrust Counsel, Office of Policy Planning, Federal Trade Commission; Washington, DC*

**Ida Nassar, JD,** *Vice President, Assistant General Counsel, Ethics & Compliance, AdvaMed; Former Senior Attorney, Office of Chief Counsel, Drug Enforcement Administration; Washington, DC*

**Julie Ritchie Wagner, JD,** *Assistant General Counsel, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US DHHS; Washington, DC*

**Amanda P. Masselam Strachan, JD,** *Partner, WilmerHale; Former Chief, Criminal Division, US Attorney's Office for the District of Massachusetts, US Department of Justice; Boston, MA (Moderator)*

**6:00 pm** **ADJOURNMENT**

# AGENDA DAY III: FRIDAY, OCTOBER 24, 2025

## INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

## PHARMA/DEVICE CONGRESS DAY III

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

**7:00 am** **Continental Breakfast**

**8:00 am** **Welcome**

**Cindy Cetani, LPEC, NACD.DC®,** *Retired Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia; Glen Allen, VA (PCF Board)*

**Antitrust Admonition:**

**Kristin Graham Koehler, JD,** *Office Managing Partner, Washington DC Office, Management Committee, and Executive Committee Member, Sidley Austin LLP; Washington, DC*

**8:15 am** **The Gap isn't as Big as You Think — A Collaborative Learning Session: Pharma & Medical Device Focus**

Discover the nuanced intersections between two dynamic industries—Pharma and Medical Devices. While they operate in distinct regulatory and clinical spaces, they share more common ground than many realize. This session will demystify the medical device landscape and spotlight career pathways that bridge both worlds.

**Tracy Berns, JD,** *Senior Vice President, Chief Compliance & Quality Assurance Officer, Ionis Pharmaceuticals; Former Chief Compliance Officer, Akcea Therapeutics; Former Vice President, Chief Compliance Officer & Legal Affairs, AMAG Pharmaceuticals; Boston, MA*

**Mark P. Graves, JD, MBA,** *Senior Advisor, Integrity & Compliance, Indivior; Former US Compliance Officer, Averitas Pharma; GRT Therapeutics; Fern Health; Former Senior Vice President and Chief Compliance Office MiMedX; Former US Lead-Patient Experience & Value, Neurology; Gainesville, FL*

**Daniel Spicehandler, JD,** *Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Medical Device Executive Committee)*

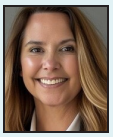
**Terra Buckley, JD,** *Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Summit, NJ (Medical Device Executive Committee/ Moderator)*

**9:00 am** **Benchmarking and Q&A Forum**

Opportunity for polling, ask questions and benchmark against peers for valuable insights-Come prepared with questions!

**Terra Buckley, JD,** *Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Summit, NJ (Medical Device Executive Committee/ Moderator)*

**Cindy Cetani, LPEC, NACD.DC®,** *Retired Chief Integrity and Compliance Officer, Indivior; Former Group Integrity & Compliance, Head, Compliance Operations, Novartis; Former Managed Markets Director of Operations Customer Development Unit, Pharmacia; Glen Allen, VA (PCF Board)*



**Jill Dailey, JD,** *Vice President, Chief Compliance Officer, Oncology, Menarini Stemline; Former Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer; New York, NY (PCF Board)*

**9:45 am** **Break**

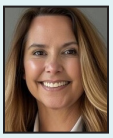
**10:00 am** **Can Compliance Predict the Future? Using Data Analytics to Uncover Behavioral Patterns and Early Warning Signals**

Measuring compliance effectiveness and the practical application of data analytics are major areas of current interest in compliance. Professor Soltes will share both research and practical examples of utilizing data analytics to identify early warning signals to uncover behavioral patterns that effectively predict compliance risks.

**Eugene T. Soltes, MBA, PhD,** *McLean Family Professor of Business Administration & Founder of Integrity Lab, Harvard Business School; Author,* Why They Do It: Inside the Mind of the White-Collar Criminal; *Cambridge MA*

**11:00 am** **Patient Engagement: Interactions & Advocacy Breakouts**

We'll kick things off with an overview to tee up the key patient engagement themes, then shift into breakout discussions to surface insights from diverse perspectives. Finally, we'll reconvene to share collective learnings and actionable takeaways.



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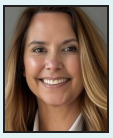
**11:35 am** **Sharing Insights from Breakout Discussions & Final Q&A**



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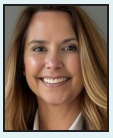
**Daniel Spicehandler, JD,** *Vice President Compliance, Commercial Divisions, Stryker; New York, NY (Medical Device Executive Committee)*

**11:55 am** **Wrap Up & Adjournment**



**Jill Dailey, JD,** *Vice President, Chief Compliance Officer, Oncology, Menarini Stemline; Former Vice President & Chief Compliance Officer, Incyte; Former Assistant General Counsel, Asia Pacific Compliance Lead, Pfizer; New York, NY (PCF Board)*

**Noon** **CONGRESS ADJOURNMENT**