# 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**

GHC LIFE SCIENCES
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All Times are EDT • Agenda Current as of September 18, 2025
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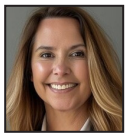

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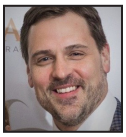

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# Twenty-Sixth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

## 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: Government Pricing: Finding Compliance Zen | 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 |

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

| | | | | | |
|---|---|---|---|---|---|
| MS13: Annual Medical Device Ethics and Compliance Issues Roundtable | MS14: Elevating Compliance: Strategic Risk Leadership in a Global Landscape | MS15: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities | MS16: Patient Advocacy Organization Relationships — Compliance Considerations for Developing and Maintaining Effective Partnerships | MS17: Navigating Legal and Political Risks in the New DEI Landscape | MS18: External Funding Risks and Mitigation — Latest Trends in Exhibit & Display and Sponsorship Requests |

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

| | | | | | | |
|---|---|---|---|---|---|---|
| MS19: Data-Driven Ethics: Transforming Compliance with Embedded Analytics and AI | MS20: What to Expect from a CMS Open Payments Audit | MS21: Integrating Compliance into Vendor/Consultant Engagements | MS22: What the Privacy? Live | MS23: Evaluating Compliance Training Effectiveness | MS24: Agentic AI: Uncovering its Applications and Realities to Elevate Compliance Success | MS25: Patient-Oriented Commercial Models: Legal and 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

| | | | | | |
|---|---|---|---|---|---|
| MS26: Compliance Considerations for Rare Disease | MS27: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future? | MS28: Update on Medical Device Investigations and Prosecutions | MS29: Update on the Status of FCPA Enforcement — Strategic Implications | MS30: Fighting Overcriminalization in Federal Regulations | MS31: Eyes Wide Open: Navigating the Global Complexities of Third Party Risk |

**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

| | | | | |
|---|---|---|---|---|
| MS32: Case Studies in AI & Analytics for Monitoring & Investigations | MS33: Streamlining Bona Fide Service Fee FMV Analysis Through Cost-driver Analytics and Cross-industry Insights | MS34: Turning Risk into Results: Aligning Assessment, Mitigation, and Monitoring for Compliance Success | MS35: Key Recent FDA and Trade Developments for Life Science Supply Chains: Tariffs, Onshoring, and Supply Chain Risk | MS36: Making Compliance Cool, Increasing Your Influence |

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

| | | | | |
|---|---|---|---|---|
| MS37: Telehealth for Life Sciences Companies: New Platforms, Old Risks | MS38: State of Confusion: The Overlooked State Laws in Pharma Compliance | MS39: Vaccines Under the New Administration | MS40: Compliance Considerations for Mergers and Acquisitions | MS41: Strategic Stewardship: Navigating Compliance and Corporate Responsibility in Life Sciences |

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

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

| | | | | |
|---|---|---|---|---|
| MS42: Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance | MS43: Implementing AI in Life Sciences Compliance: Strategies, Challenges, and Opportunities | MS44: Fair Market Value: Compliant Compensation Strategies | MS45: New Standards for Compliance Learning: What You Need to Know — Rethink's 2025 Benchmarking Report | MS46: What Enforcement May Look Like in Trump 2.0 |

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

| | | | | |
|---|---|---|---|---|
| MS47: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements | MS48: Sanctions — the Enterprise-Wide Risk and Compliance Nexus | MS49: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies | MS50: How to Build Your Compliance Analytics Programs Efficiently and Effectively | MS51: 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
5:00 pm – 5:30 pm CMS Transparency Update
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
10:45 am Patient Engagement: Interactions & Advocacy Breakouts
11:45 am Final Q&A, Wrap Up
Noon CONGRESS ADJOURNMENT

# AGENDA DAY I: WEDNESDAY, OCTOBER 22, 2025

**7:00 am Registration Opens**

## PHARMA/DEVICE CONGRESS 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**

**Matt Berkle, JD, LLM,** *Compliance Counsel, Head of US Compliance, Guerbet; Former Vice President, General Counsel, Head of Ethics & Compliance, Breckenridge Pharmaceutical; Former Head of North America Legal and Compliance, ALK-Abelló; Princeton, NJ*

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

**Chris Cobourn, MS,** *Managing Director GP 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, Kyowa Kirin; Former Executive Director, Strategy and Operations, Quality Assurance, Merck; 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, Inc. (Acquired by 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, Food and Drug Practice, Arnall Golden Gregory; Atlanta, GA*

**Heather Young, JD,** *Compliance Officer - Executive Director, Olympus Corporation of the Americas; 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,** *Regional Vice President, Global Relay; Denver, CO (Moderator)*

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

**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**

## PHARMA/DEVICE CONGRESS 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,** *Chief Compliance Officer & Head of GRC, Privacy, and Information Security, 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: Government Pricing: Finding Compliance Zen

**9:00 am** **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 10: Compliance Risks and Challenges Between Joint Sales and Medical Affairs Interactions and Proactive Medical Activities

**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,** *Compliance Director, 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)*

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

## PHARMA/DEVICE CONGRESS
## MINI SUMMITS: GROUP 3 10:00 am – 10:50 am

### Mini Summit 13: Annual Medical Device Ethics and Compliance Issues Roundtable

**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 14: Elevating Compliance: Strategic Risk Leadership in a Global Landscape

**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; Honolulu, HI (Moderator)*

### Mini Summit 15: Compliance Considerations, Enforcements, and Guidelines on Social Media Activities

**10:00 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 16: 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 17: 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 R. Clarke, JD, CCEP, NACD.DC®,** *Former 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 18: 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)*

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

## PHARMA/DEVICE CONGRESS MINI SUMMITS: GROUP 4 11:00 am – 11:50 am

### Mini Summit 19: 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*

**Ronald Strauss,** *Vice President Compliance, MIMedx; Former Executive Sales Representative, Osteo Specialty, Eli Lilly and Company; Marietta GA*

**Joseph Zimmerman,** *Senior Vice President, Chief Compliance & Privacy Officer, Head of Quality Assurance, SpringWorks Therapeutics, Inc. (Acquired by 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 20: What to Expect from a CMS Open Payments Audit

**11:00 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 21: 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 22: 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, 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 23: 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 24: 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*

**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 25: Patient-Oriented Commercial Models: Legal and Market Access Considerations

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

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

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

**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**

# PHARMA/DEVICE CONGRESS MINI SUMMITS: GROUP 5 12:20 pm – 1:10 pm

## Mini Summit 26: Compliance Considerations for Rare Disease

**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 27: AI Enforcement Trends in Pharma and Med Device: What is Happening Now and What to Expect in the Future?

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

**Aurélie Ercoli, LLM, PhD,** *Partner, Life Sciences Practice Group, DLA Piper; 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 28: 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 29: 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 30: Fighting Overcriminalization in Federal Regulations

**12:20 pm** **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 31: 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*

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

**David Fisher, MS,** *President, TDI; 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 General Counsel, Accord BioPharma; Raleigh, NC*

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

**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, MPH, JD,** *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:**

**Seth H. Lundy, JD,** *Partner, 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®,** *Former 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®,** *Former 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 U.S. 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 U.S. 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)*

**11:30 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®,** *Former 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 PHARMA/DEVICE CONGRESS MINI SUMMITS GROUP 6 8:00 am – 8:50 am

## Mini Summit 32: 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 and Ethics 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 33: 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 34: 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 Operations, Monitoring & Systems, Sage Therapeutics; Former Global Corporate Compliance Manager, Investor Relations & Corporate Communications, Adaptimmune; Cambridge, MA*

**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 35: 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**

**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,** *Director of Global Trade Legal & 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 36: 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.

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

**Virginia MacSuibhne, JD, CCEP,** *The Compliance Fairy Godmother; Executive Director, Legal Compliance, Alumis; Former Vice President, Global Chief Compliance & Privacy Officer, Agilent Technologies; Santa Clara, CA*

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

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

# PHARMA/DEVICE CONGRESS MINI SUMMITS GROUP 7 9:00 am – 9:50 am

## Mini Summit 37: 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, Fraud Investigation and Dispute 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 38: 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 39: Vaccines Under the New Administration

**9:00 am** **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)*

## Mini Summit 40: Compliance Considerations for Mergers and Acquisitions

**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 41: 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.

**9:00 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*

**Suj Patel,** *Director, Digital, Healthcare Strategy and Transformation Practice, Baker Tilly; Tampa, FL*

**Perri Pomper, JD,** *Vice President, Global Compliance Program Management, Stryker; Former Vice President, Compliance & Legal Affairs, Clinical Genomics; Former Director, Ethics and Compliance Strategy & Education, Novo Nordisk; New York, NY*

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

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

# PHARMA/DEVICE CONGRESS MINI SUMMITS GROUP 8 10:20 am – 11:10 am

## Mini Summit 42: 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 43: 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 44: 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 45: 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, Global Head of Governance, Risk and Compliance Strategy and Planning, 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 46: 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**

## PHARMA/DEVICE CONGRESS MINI SUMMITS GROUP 9 11:20 am – 12:10 pm

### Mini Summit 47: Examining Business Relationships and Compliance Risks with Pharmacy Benefit Manager (PBM) Arrangements

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

**Jamie E. Darch, JD,** *Partner, Life Sciences Practice Group, 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 48: 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*

**Jamiee Reid,** *Chief Compliance Officer, Intercept Pharmaceuticals; Morristown, NJ*

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

### Mini Summit 49: SIUU in Practice: Lessons Learned, Compliance Pitfalls & Evolving Strategies

**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 and Head of Compliance, Astria Therapeutics; Former Vice President, General Counsel, Vaccines Business Unit, Takeda; Member, Board of Directors, Executive Committee and Personnel and Governance Committee, Massachusetts Technology Collaborative; Former Deputy General Counsel and Chief Compliance Officer, Stealth BioTherapeutics; 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 50: How to Build Your Compliance Analytics Programs Efficiently and Effectively

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

**Peter Agnoletto, CPA,** *Compliance Officer, General Medicines and Consumer Health Care, Sanofi; Former Senior Director, Chief Compliance Officer & Chief Audit Executive & ERM Leader, Par Pharmaceutical Companies; Bridgewater, NJ*

**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; Landsdale, PA (Co-moderator)*

### Mini Summit 51: Best Practices in Responding to Investigations

**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)*

**11:50 am** **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, U.S. ethics and compliance officers in life sciences can no longer afford to think locally. This dynamic panel invites you to step outside the U.S. 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 U.S. 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 Ebel, MBA,** *Principal, Forensic & Integrity Services, 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** **CMS Transparency Update**

**Veronika Peleshchuk Fradlin, MA,** *Director of Division of Transparency Projects, Centers for Medicare and Medicaid Services; Baltimore, MD*

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

**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®,** *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, MBS,** *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)*

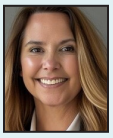
**Terra Buckley, JD,** *Chief Compliance Officer, LivaNova; Former Vice President, Head of Compliance, Mesoblast Limited; Former Executive Director, Head of the Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Summit, NJ (Medical Device Executive Committee/ Moderator)*

**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®,** *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)*

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

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

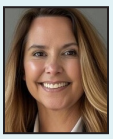
**10:00 am** **Can Compliance Predict the Future? Using Data Analytics to Uncover Behavioral Patterns and Early Warning Signals**

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*

**10:45 am** **Patient Engagement: Interactions & Advocacy Breakouts**

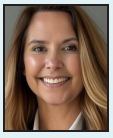
We'll kick things off with an overview to tee up the key patient engagement themes, then shift into breakout discussions to surface insights from diverse perspectives. Finally, we'll reconvene to share collective learnings and actionable takeaways.



**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)*

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

**11:45 am** **Final Q&A, 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**