27th Pharmaceutical and Medical Device Ethics and Compliance Congress

GHC LIFE SCIENCES
Global Health Care, LLC

October 13 – 16, 2026
Washington Hilton • Washington, DC

Sponsored by the Pharmaceutical Compliance Forum (PCF)

A Hybrid Event — Onsite or Virtual Online Event Live and Archived

Subject to change • Current as of October 14, 2026

C-SUITE CONGRESS VIDEO WELCOME:



Albert Bourla, DVM, PhD, *Chairman and Chief Executive Officer, Pfizer; Former Chair, Pharmaceutical Research and Manufacturers of America (PhRMA); Former President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)*

GOVERNMENT KEYNOTE SPEAKERS:



Jacob Foster, JD, *Acting Chief, Health Care Fraud Unit, Criminal Division, Fraud Section, US DOJ*



Veronika Peleshchuk Fradlin, MPP, *Director, Open Payments Data Group (OPDG), Office of Enterprise Data and Analytics (OEDA), US HHS*



Brenna Jenny, JD, MPH, *Deputy Assistant Attorney General, Commercial Litigation Branch, Civil Division, US DOJ*



Twyla Mosey, PharmD, RPh, *Director, Office of Prescription Drug Promotion, US FDA*



Mary E. Riordan, JD, *Senior Counsel to the Inspector General, HHS Inspector General*

PCF BOARD:



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Melissa T. Lozner, JD, *Senior Vice President, Chief Compliance Officer, Regeneron*

MEDICAL DEVICE EXECUTIVE STEERING COMMITTEE:



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JJ Kuhn, JD, *Chief Ethics & Compliance Officer, Danaher*



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



Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic*



Daniel Spicehandler, JD, *Vice President Compliance, MSNT and Global Programs, Stryker*

COMPLIMENTARY WIRELESS ACCESS ONSITE

The Congress has arranged for complimentary wi-fi for attendees on the meeting floor. To access the wi-fi, connect to the PharmaCongress26 network. When prompted enter the group code: PHlifesci2026.

DOWNLOAD THE CONFERENCE APP

The conference App is required to participate in polling questions. Scan the QR code for your device. If prompted enter the Event Code 27pc2026.

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Google Play QR code

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AN OVERVIEW OF THE 27TH CONGRESS SCHEDULE

Day 1: Tuesday, October 13, 2026

- Afternoon Half-day Specialty Focused Sessions

Day 2: Wednesday, October 14, 2026

- Networking Breakfast in the Exhibit Hall
- Morning Concurrent Mini Summits
- Networking Luncheon in the Exhibit Hall
- Afternoon Opening Plenary Session
- Networking Reception

Day 3: Thursday, October 15, 2026

- Networking Breakfast in the Exhibit Hall
- Morning PCF CCO Roundtable (Invitation-only, Breakfast Included)
- Morning Concurrent Mini Summits
- Networking Luncheon in the Exhibit Hall
- Afternoon Closing Plenary Session

Day 4: Friday, October 16, 2026

- Networking Breakfast
- Morning PCF Industry-only Think Tank
- Noon: Congress Adjournment

IMPORTANT THINGS TO REMEMBER AS YOU PREPARE TO ATTEND THE CONGRESS

- For the first time, the Congress is offering 5 half-day Focused Sessions on Hot Topics on Tuesday afternoon, October 13.
- Onsite attendees may register onsite as early as 11 am ET on Tuesday, October 13.
- All onsite attendees will have the ability to scan QR codes on badges to exchange contact information.
- For the first time, all Congress attendees (both onsite and online) will be able to text each other via the Congress App.
- All onsite attendees will also have access to the Congress Virtual Video/Audio Archive for at least 9 months following the Congress. This will allow attendees to watch sessions that they missed at the Congress.

Proud Congress Sponsor

The Pharmaceutical Compliance Forum

Who We Are

For over 25+ years, PCF has been exclusively dedicated to the advancement of the pharmaceutical and biotech compliance community through networking, education, and best practice sharing.

Our Meetings

We provide a closed-door forum for members to share knowledge, explore innovative solutions to complex compliance challenges, and network with peers to build long-lasting career relationships.

Why Join PCF?

PCF is proud of its distinguished legacy as a trusted leader in corporate compliance education and knowledge sharing. With an unwavering commitment to excellence, we empower compliance and legal professionals through a robust suite of resources, benchmarking insights, and expert guidance.

Reach out to info@pharmacomplianceforum.org
https://pharmacomplianceforum.org

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AGENDA AT A GLANCE

DAY 1: TUESDAY, OCTOBER 13, 2026 *(Included in standard Congress registration)*

11:00 am	**Registration Opens**
1:00 pm – 5:45 pm	**IN-DEPTH FOCUSED SESSIONS** *(See full agenda for break times)*
Focused Session 1:	**Whistleblower Complaints: From Hotline to Resolution: Managing Internal Investigations, Whistleblower Risk & Escalation Decisions** *(30-minute break not listed)*
1:00 pm	• Chair's Welcome and Introductions & DOJ/ FCA Enforcement Trends: Lessons from Whistleblower Cases
1:15 pm	• A Fireside Chat with Nicholas C. Perros, JD, Senior Trial Counsel, Civil Division, Fraud Section, US DOJ
1:45 pm	• Qui Tam Counsel Roundtable
2:30 pm	• AI, Data, and the Next Generation of FCA Whistleblower Cases
3:45 pm	• Hotline Isn't Enough: Building a Smart Investigations Ecosystem
4:30 pm	• Fostering an Enterprise Level Investigations Program
5:15 pm	• Managing Whistleblower Risk and Internal Escalation
5:45 pm	**Adjournment**
Focused Session 2:	**Pharmaceutical and Medical Device Advanced Privacy and Cybersecurity Updates** *(30-minute break not listed)*
1:00 pm	• Chair's Welcome, Overview and Introductions
1:15 pm	• The Basics of Healthcare Privacy for Compliance Professionals and an Overview of Privacy Issues Unique to Pharmaceutical and Medical Device Enterprises
1:45 pm	• IAPP Presents: Privacy, AI Compliance, and Beyond for the Future of Pharma and Medical Devices
2:30 pm	• The International Pharmaceutical and Medical Device Privacy Consortium Presents Advanced Strategies for Addressing Privacy and Cybersecurity Issues for Life Sciences Companies
3:15 pm	• Healthcare as Critical Infrastructure and the Cybersecurity Public Private Partnership
4:15 pm	• Cybersecurity Best Practices for Pharma and Device
5:00 pm	• Session Faculty Q&A
5:45 pm	**Adjournment**
Focused Session 3:	**Managing Medical — Commercial Interactions: Strategic Collaboration, Evolving Roles & Risk-Based Governance** *(30-minute break not listed)*
1:00 pm	• Co-Chair's Introductions & Session Overview
1:15 pm	• Strategic Planning Together, Tactical Execution Separately: Practical Case Studies in Medical–Commercial Collaboration
2:00 pm	• Beyond Sales Representatives and MSLs: Understanding Emerging Field-Based Roles and Governance Challenges
3:15 pm	• Protecting Medical Independence While Enabling Strategic Cross-Functional Collaboration
4:00 pm	• Medical–Commercial Boundaries: Congresses, Sponsorships & Promotional Risk
4:45 pm	• Have We Become Too Restrictive? Rethinking Medical–Commercial Governance for the Next Era
5:30 pm	**Adjournment**
Focused Session 4:	**AI in Action: Real-World Compliance Case Studies from the Front Lines of AI Use in Life Science Compliance Departments** *(15-minute break not listed)*
1:00 pm	• AI Basics, Life Science Industry Ethics and Compliance Applications
1:30 pm	• A Brief Overview of the Epsilon & qordata Annual AI Use Compliance Survey
2:00 pm	• Facilitated Case Study Discussion: From Transcript to Insights: How Compliance Teams Are Using AI to Transform Investigations
2:30 pm	• Facilitated Case Study Discussion: AI Governing AI: Leveraging Artificial Intelligence to Develop Effective Governance Policies
3:15 pm	• Facilitated Case Study Discussion: AI-Assisted Monitoring and Detection of Potential Policy Violations
3:45 pm	• Facilitated Case Study Discussion: Agentic AI Use for Continuous Risk Assessment (vs Annual)
4:15 pm	• The Unspoken Risk of AI: Moral Outsourcing — and Why "Add Human Judgment" Isn't Enough
5:00 pm	• The Health Care Compliance Association Presents: Advanced Strategies in Using AI to Monitor and Improve Compliance: Lessons from Other Healthcare Sectors
5:45 pm	**Adjournment**
Focused Session 5:	**GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers & The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know** *(30-minute break not listed)*
1:00 pm	• Chair's Introductions & Session Overview
1:15 pm	• GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers
4:00 pm	• The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know
5:30 pm	**Adjournment**

AGENDA AT A GLANCE

DAY 2: WEDNESDAY, OCTOBER 14, 2026

7:00 am Registration Opens & Networking Breakfast in the Exhibit Hall

8:00 am – 8:50 am MORNING MINI SUMMITS: GROUP 1

- MS1: Compliance Independence in the Real World: Governance Models That Work
- MS2: The Agentic Compliance Function of the Future
- MS3: Evolution of Patient Finding Activities
- MS4: First Product Launch: Policy Development Strategies and Techniques
- MS5: Speaker Programs in 2026: Practical Legal and Compliance Considerations for Executing from Beginning to End Amid Ongoing Scrutiny

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

- MS6: From Pronouncements to Practice: Understanding DOJ Enforcement Priorities
- MS7: Boring is Risky! Want Stronger Ethics and Compliance Engagement? Train & Communicate Colorfully
- MS8: Best Practices for Data Analytics
- MS9: On the Front Lines: Navigating Field Force & Sales Compliance Risk
- MS10: Communicating the Story on Integrity: What Compliance Leaders Can Learn from Health Stakeholders
- MS11: Designing HCP Engagement with Transparency Built In

9:50 am – 10:10 am NETWORKING BREAK (in the Exhibit Hall)

10:10 am – 11:00 am MORNING MINI SUMMITS: GROUP 3

- MS12: Compliance and M&A: Why Early Engagement Matters
- MS13: The State of Medical Device Compliance: Annual Industry Roundtable
- MS14: The State We're In: Legal & Enforcement Trends Reshaping Life Science Companies' Compliance
- MS15: External Funding Risks and Mitigation: Latest Trends in Exhibit & Display and Sponsorship Requests
- MS16: Beyond the Questionnaire: Building a Risk-Based Third-Party Management Program That Actually Works
- MS17: Navigating Today's Enforcement Landscape with Culture, Data, and Ethics

11:10 am – 12:00 pm MORNING MINI SUMMITS: GROUP 4

- MS18: Risk Advantage: How Resilient Organizations are Capturing Opportunity through Uncertainty
- MS 19: View from the Top: Practical Advice for Accelerating Your Compliance Career
- MS 20: Direct-to-Consumer (DTC) Models: Emerging Compliance Risks and Governance Considerations
- MS 21: Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks
- MS 22: Navigating the Evolving US Privacy Landscape
- MS 23: Agentic Risk Management: Transforming Compliance Across Key Business Processes

12:00 pm – 1:15 pm NETWORKING LUNCHEON — OR — OPTIONAL LUNCHEON DISCUSSION

ENJOY THE CONGRESS NETWORKING LUNCHEON OR ATTEND THIS OPTIONAL SMALL AND MID-SIZED LIFE SCIENCE COMPANIES LUNCHEON

12:10 pm – 1:10 pm Compliance Risks and Challenges in Small and Emerging Life Sciences Companies

Grab your lunch and join this interactive discussion focused on the unique compliance and ethics challenges facing small life sciences companies, particularly rare disease, and emerging biotech organizations. Unlike established pharmaceutical companies, pre-commercial and growth-stage organizations often operate with limited resources while navigating significant pressures related to launch readiness, investor expectations, business growth and development, and early stakeholder engagement.

This practical lunch session brings together a US Compliance Officer and a former Chief Counsel to the Inspector General to examine the unique compliance and ethics challenges facing smaller and emerging life sciences companies. Attendees will gain insights into unique risks from the pre-commercial stage through commercialization, the evolutionary role of the compliance function following product approval, and perspectives when building and managing effective compliance programs with limited resources and budgets.

1:15 pm – 5:45 pm PHARMA/DEVICE CONGRESS OPENING PLENARY SESSION

1:15 pm	Welcome and Introduction: PCF Board
1:30 pm	C-Suite Congress Video Welcome
1:40 pm	Keynote Annual OIG Update
2:30 pm	Keynote US DOJ Criminal Division Update Fireside Chat
3:00 pm	Tech & Human-in-the-Loop Compliance (Why Human Judgment Matters More Than Ever)
3:30 pm	Networking Break in the Exhibit Hall
4:00 pm	The Next Generation of Compliance: Leveraging Data to Stay Ahead of Risk
4:30 pm	Integrated Risk Transformation in Pharma/Medical Device: From Compliance Burden to Strategic Advantage
5:00 pm	Annual Chief Compliance Officers Fireside Chat

5:45 pm OPENING PLENARY SESSION ADJOURNMENT AND NETWORKING RECEPTION

AGENDA AT A GLANCE

DAY 3: THURSDAY, OCTOBER 15, 2026

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

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

- **7:00 am** Breakfast Buffet
- **8:00 am** CCO Roundtable Welcome and Introductions
- **8:15 am** Future of the Compliance Profession in an AI Driven Environment
- **9:00 am** Executive Breakout by Company Size — *Leveraging AI to Support Compliance Programs*
- **9:40 am** Networking Break
- **10:00 am** Executive Breakout by Company Size — *Building AI Ready Teams*
- **10:40 am** Board Oversight of Compliance: What Audit Firms Observe and What Regulators Require
- **11:30 am** Open Forum: Opportunities for Benchmarking and Peer-driven Q&A. Bring your questions!
- **11:55 am** Wrap-up
- **12:00 pm** Adjournment

8:00 am – 8:50 am — MORNING MINI SUMMITS: GROUP 5

- **MS24:** Identifying and Managing Risk Associated with AI
- **MS25:** Transparency Reporting: Update on the Centers for Medicare and Medicaid Services Open Payments Program
- **MS26:** From Speak-Up to Proof: Turning DOJ and OIG Expectations into Defensible, AI-Enabled Compliance Operations
- **MS27:** Manufacturer–Specialty Pharmacy Relationships: Managing Compliance Risk in Specialty and Rare-Disease Commercial Models
- **MS28:** The Future of Compliance Monitoring: AI Agents, Risk Intelligence and Practical Adoption

9:00 am – 9:50 am — MORNING MINI SUMMITS: GROUP 6

- **MS29:** Building the Compliance Operating Model for What's Next
- **MS30:** Leveraging AI for More Efficient and Effective Investigations
- **MS31:** Compliance Considerations, Enforcements and Guidelines on Social Media Activities
- **MS32:** Building a Compliance Roadmap: Practical Strategies for Scaling Compliance Programs
- **MS33:** Fair Market Value in Flux: Navigating Complex Fee Arrangements, HCP & Patient Engagement, and Influencer Compensation Risks
- **MS34:** Future Proofing the Compliance Function: Operating Models for an AI-Enabled World

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

10:10 am – 11:00 am — MORNING MINI SUMMITS GROUP 7

- **MS35:** Unstructured Data and Advanced Monitoring Strategies
- **MS36:** Leading Practices for Managing Investigations Panel
- **MS37:** From Makary to Overton: Reflections and Predictions on the FDA's Priorities
- **MS38:** Compliance Considerations for Rare Disease Products
- **MS39:** From Oversight to Partnership: Strengthening Collaboration Between Compliance and the Business
- **MS40:** Digital Ecosystem Considerations for Life Science Companies

11:10 am – 12:00 pm — MORNING MINI SUMMITS GROUP 8

- **MS41:** Enabled Technology can Transform Transactional Testing and Other Components of Your Monitoring Program
- **MS42:** Emerging Commercial & Market Access Risk in Life Sciences: Navigating Innovation, Compliance, and Evolving Access Models
- **MS43:** Effectively Leveraging Post-Investigation Mitigation to Create a Narrative of Continuous Improvement
- **MS44:** Data Analytics & Compliance Monitoring in an AI-Powered World
- **MS45:** Can Learning Data Reduce Risk? Using Measurement to Drive Defensible, Risk-Based Compliance Training
- **MS46:** AI in Clinical Practice: Compliance, Governance & FDA Oversight

12:00 PM – 1:10 PM — NETWORKING LUNCHEON WITH DESSERT AND COFFEE IN THE EXHIBIT HALL

12:10 pm – 1:00 pm — LUNCHEON MINI SUMMITS GROUP 9

- **MS47:** Direct-to-Consumer (DTC) Models in the Pharmaceutical Space
- **MS48:** ROI of AI: Separating Value from Hype
- **MS49:** Lean, Credible, Defensible: Compliance Programs That Work Without Big Budgets
- **MS50:** A Look Under the Hood: Exploring PBM and Payer Arrangement Risks and Emerging Reporting Requirements
- **MS51:** Collaborating to Create Lasting Solutions During and After Monitoring or Investigations
- **MS52:** Annual FDA Office of Prescription Drug Promotion Update

1:10 pm – 5:15 pm — CLOSING PLENARY SESSION

- **1:10 pm** Welcome and Introduction: PCF Board
- **1:15 pm** Keynote Annual DOJ Civil Division Update Fireside Chat
- **1:45 pm** Investigations, Enforcement and Prosecutions Roundtable
- **2:15 pm** Updates from AdvaMed, BIO and PhRMA
- **2:45 pm** Market Access in 2026 and Beyond: A Shifting Compliance Landscape
- **3:15 pm** Networking Break in the Exhibit Hall
- **3:45 pm** Burgeoning Compliance Risks
- **4:15 pm** AI and the Evolving Compliance Function
- **4:45 pm** Managing Risk in Unsettled Times

5:15 pm — **CLOSING PLENARY SESSION ADJOURNMENT**

AGENDA AT A GLANCE

DAY 4: FRIDAY, OCTOBER 16, 2026

7:00 am — **Breakfast Buffet**

8:00 am – 12:00 pm — **PCF 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)

7:00 am	Breakfast Buffet
8:00 am	Welcome and Introductions
8:10 am	Inside the New DOJ Initiative: The Rising Importance of Data Miners
8:45 am	Wins & Losses in the Early Days of AI – Audience Discussion Session
9:15 am	Benchmarking and Q&A Forum
10:00 am	Networking Break
10:20 am	Customer-Centric Complexity: Meeting Customer Needs While Balancing Field Pressures
11:00 am	Breakout by Company Size: "Cross Functional Account Planning & Guardrails"
11:30 am	Last Minute Questions & Benchmarking
12:00 pm	Congress Adjournment

12:00 pm — **CONGRESS ADJOURNMENT**

MINI SUMMIT & FOCUSED SESSION TOPICS LISTED BY CATEGORIES

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

AI AND EMERGING TECHNOLOGIES	MS24	Identifying and Managing Risk Associated with AI
	MS46	AI in Clinical Practice: Compliance, Governance & FDA Oversight
	MS48	ROI of AI: Separating Value from Hype
TECHNOLOGY-ENABLED COMPLIANCE OPERATIONS	FS4	AI in Action: Real-World Compliance Case Studies
	MS2	The Agentic Compliance Function of the Future
	MS23	Agentic Risk Management: Transforming Compliance Across Key Business Processes
	MS26	From Speak-Up to Proof: Turning DOJ and OIG Expectations into Defensible, AI-Enabled Compliance Operations
	MS29	Building the Compliance Operating Model for What's Next
	MS30	Leveraging AI for More Efficient and Effective Investigations
	MS34	Future Proofing the Compliance Function: Operating Models for an AI-Enabled World
COMPLIANCE ANALYTICS & MONITORING	MS8	Best Practices for Data Analytics
	MS28	The Future of Compliance Monitoring: AI Agents, Risk Intelligence and Practical Adoption
	MS35	Unstructured Data and Advanced Monitoring Strategies
	MS41	Enabled Technology Can Transform Transactional Testing and Other Components of Your Monitoring Program
	MS44	Data Analytics & Compliance Monitoring in an AI-Powered World
	MS45	Can Learning Data Reduce Risk? Using Measurement to Drive Defensible, Risk-Based Compliance Training

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SESSION CATEGORIES

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COMPLIANCE PROGRAM & GOVERNANCE	MS1	Compliance Independence in the Real World: Governance Models That Work
	MS4	First Product Launch: Policy Development Strategies and Techniques
	MS7	Boring is Risky! Want Stronger Ethics and Compliance Engagement? Train & Communicate Colorfully
	MS10	Communicating the Story on Integrity: What Compliance Leaders Can Learn from Health Stakeholders
	MS12	Compliance and M&A: Why Early Engagement Matters
	MS13	The State of Medical Device Compliance: Annual Industry Roundtable
	MS18	Risk Advantage: How Resilient Organizations Are Capturing Opportunity through Uncertainty
	MS19	View from the Top: Practical Advice for Accelerating Your Compliance Career
	MS32	Building a Compliance Roadmap: Practical Strategies for Scaling Compliance Programs
	MS39	From Oversight to Partnership: Strengthening Collaboration Between Compliance and the Business
	MS49	Lean, Credible, Defensible: Compliance Programs That Work Without Big Budgets
HCP ENGAGEMENT	FS3	Managing Medical–Commercial Interactions: Strategic Collaboration, Evolving Roles & Risk-Based Governance
	MS5	Speaker Programs in 2026: Practical Legal and Compliance Considerations for Executing from Beginning to End Amid Ongoing Scrutiny
	MS9	On the Front Lines: Navigating Field Force & Sales Compliance Risk
	MS11	Designing HCP Engagement with Transparency Built In
	MS15	External Funding Risks and Mitigation: Latest Trends in Exhibit & Display and Sponsorship Requests
	MS21	Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks
	MS33	Fair Market Value in Flux: HCP, Patient Engagement & Influencer Compensation Risks
PATIENT & CONSUMER ENGAGEMENT	MS3	Evolution of Patient Finding Activities
	MS20	Direct-to-Consumer (DTC) Models: Emerging Compliance Risks and Governance Considerations
	MS27	Manufacturer–Specialty Pharmacy Relationships
	MS38	Compliance Considerations for Rare Disease Products
	MS47	Direct-to-Consumer Models in the Pharmaceutical Space
THIRD-PARTY RISK MANAGEMENT	MS16	Beyond the Questionnaire: Building a Risk-Based Third-Party Management Program That Actually Works
DRUG PRICING, MARKET ACCESS & TRANSPARENCY	FS5	GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers & The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know
	MS25	Transparency Reporting: CMS Open Payments Program
	MS42	Emerging Commercial & Market Access Risk in Life Sciences
	MS50	Exploring PBM and Payer Arrangement Risks and Emerging Reporting Requirements
REGULATORY, ENFORCEMENT & INVESTIGATIONS	FS1	Whistleblower Complaints: From Hotline to Resolution: Managing Internal Investigations, Whistleblower Risk & Escalation Decisions
	MS6	From Pronouncements to Practice: Understanding DOJ Enforcement Priorities
	MS14	The State We're In: Legal & Enforcement Trends Reshaping Life Science Companies' Compliance
	MS17	Navigating Today's Enforcement Landscape with Culture, Data, and Ethics
	MS31	Compliance Considerations, Enforcements and Guidelines on Social Media Activities
	MS36	Leading Practices for Managing Investigations
	MS37	From Makary to Overton: Reflections and Predictions on the FDA's Priorities
	MS43	Effectively Leveraging Post-Investigation Mitigation to Create a Narrative of Continuous Improvement
	MS51	Collaborating to Create Lasting Solutions During and After Monitoring or Investigations
	MS52	Annual FDA Office of Prescription Drug Promotion Update
PRIVACY & CYBERSECURITY	FS2	Pharmaceutical and Medical Device Advanced Privacy and Cybersecurity Updates
	MS22	Navigating the Evolving US Privacy Landscape
	MS40	Digital Ecosystem Considerations for Life Science Companies

DETAILED AGENDA

TUESDAY, OCTOBER 13, 2026

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 1 (Included in standard Congress registration.)

11:00 am Registration Opens/Lunch on Your Own

FEATURING FIVE CONCURRENT IN-DEPTH FOCUSED SESSIONS

Focused Session 1: Whistleblower Complaints: From Hotline to Resolution: Managing Internal Investigations, Whistleblower Risk & Escalation Decisions — GEORGETOWN WEST

1:00 pm **Chair's Welcome and Introductions & DOJ/FCA Enforcement Trends: Lessons from Whistleblower Cases**



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 (Chair)*

1:15 pm **A Fireside Chat with Nicholas C. Perros, JD, Senior Trial Counsel, Civil Division, Fraud Section, US DOJ**

Nicholas C. Perros, JD, *Senior Trial Counsel, Civil Division, Fraud Section, US Department of Justice; Washington, DC*

Interviewed by:
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 (Chair)*

1:45 pm **Qui Tam Counsel Roundtable**

Gregg Shapiro, JD, *Founder, Gregg Shapiro Law; Former Assistant US Attorney and Chief, Affirmative Civil Enforcement Unit, US Attorney's Office, District of Massachusetts, US Department of Justice; Boston, MA*

Robert M. Thomas Jr., *Principal, Whistleblower Law Collaborative; Adjunct Professor; Boston University School of Law; Former Assistant US Attorney, US Attorney's Office for the District of Maryland; Boston, MA*

Mary A. Inman, JD, *Partner, Whistleblower Partners; Founding Member & Board Chair, Psst.org; Member of Advisory Board, Whistleblowing Canada Research Society; San Francisco, CA (Moderator)*

2:30 pm **AI, Data, and the Next Generation of FCA Whistleblower Cases**

Avia M. Dunn, JD, MBA, *Partner, Life Sciences, Skadden; Washington, DC*

Stewart Kameen, JD, *Partner, Davis Wright Tremaine; Former Senior Counsel, Industry Guidance Branch, Office of Counsel to the Inspector General, US Department of Health and Human Services, Washington, DC*

3:15 pm **Networking Break**

3:45 pm **Hotline Isn't Enough: Building a Smart Investigations Ecosystem**

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

Mona Peterson Rosow, JD, MPH, *Former Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Steering Committee)*

Saraswatha Lalitha Putcha, MA, *Chief Operating Officer, Cresen Solutions; Philadelphia, PA (Moderator)*

4:30 pm **Fostering an Enterprise Level Investigations Program**

David J. Derusha, JD, *Assistant General Counsel, Vertex Pharmaceuticals; Former Assistant US Attorney, US Attorney's Offices, District of Massachusetts, US Department of Justice; Boston, MA*

Naveen Ganesh, MA, JD, *Vice President, Global Head of Investigations, Ethics & Compliance, Takeda; Former Head of Investigations & Monitoring, North America & Global Specialty Care, Sanofi; Former Compliance Assurance & Investigations, Lead, Verily; Boston, MA*

Sarah L. Whipple, JD, *Principal, WhipEdge Solutions, Member, Rare Disease Compliance Consortium (RDCC); Former Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Needham, MA*

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

5:15 pm **Managing Whistleblower Risk and Internal Escalation**

Jennifer Beaudoin, CFE, CPA, *Executive Director, Head of Global Compliance Program Strategy, Governance and Transformation, Vertex Pharmaceuticals; Boston, MA*

Warren T. Allen II, MPP, JD, *Principal, Miles & Stockbridge; Professorial Lecturer in Law (White Collar Crime), The George Washington University Law School; Washington, DC (Co-Moderator)*

David Amendola, *Director, Life Sciences, Resolution Economics; Former Global Compliance Risk, Evaluation & Management, ConvaTec; New York, NY (Co-Moderator)*

5:45 pm **Adjournment**

Focused Session 2: Pharmaceutical and Medical Device Advanced Privacy and Cybersecurity Updates — CABINET

1:00 pm **Chair's Welcome, Overview and Introductions**



Mary Devlin Capizzi, JD, MBA, *Partner, Faegre Drinker; General Counsel, International Pharmaceutical and Medical Device Privacy Consortium; Washington, DC (Chair)*

1:15 pm **The Basics of Healthcare Privacy for Compliance Professionals and an Overview of Privacy Issues Unique to Pharmaceutical and Medical Device Enterprises**

Adam Greene, JD, MPH, *Partner and Co-chair, Health Information & HIPAA Practice, Davis Wright Tremaine; Former Senior Health Information Technology and Privacy Specialist, Office for Civil Rights, US Department of Health & Human Services, Washington, DC*

1:45 pm **IAPP Presents: Privacy, AI Compliance, and Beyond for the Future of Pharma and Medical Devices**

Melissa Bianchi, JD, *Partner and Leader, Firm's Digital Health Initiative, Hogan Lovells Cadwalader; Washington, DC*

Gabe Maldoff, JD, *Partner, Data, Privacy, and Cybersecurity practice, Goodwin Procter; Adjunct Professor, Maine Law School, Washington, DC*

Cobun Zweifel-Keegan, JD, CIPP/US, CIPM, *Managing Director, IAPP; Former Deputy Director, Privacy Initiatives, Better Business Bureau; Washington DC (Moderator)*

2:30 pm **The International Pharmaceutical and Medical Device Privacy Consortium Presents Advanced Strategies for Addressing Privacy and Cybersecurity Issues for Life Sciences Companies**

Tahvia Jenkins, JD, CIPP/US, *US Privacy Officer & Counsel, Sanofi; Former Assistant Counsel, Health Affairs, Privacy, and Data Protection, University of California, Cambridge, MA*

Danielle Manner, JD, *Chief Privacy Officer and Senior Associate General Counsel, Gilead; Former Senior Privacy Counsel, Pfizer; Chicago, IL*

John Tao, JD, AHIP, CIPP/E, FIP, CIPM, *Digital Ethics & Data Privacy Officer, Oncology, Takeda; Cambridge, MA*

Mary Devlin Capizzi, JD, MBA, *Partner, Faegre Drinker; General Counsel, International Pharmaceutical and Medical Device Privacy Consortium; Washington, DC (Moderator)*

3:15 pm **Healthcare as Critical Infrastructure and the Cybersecurity Public Private Partnership**

Gregory T. Garcia, *Executive Director, Cybersecurity Working Group, Health Sector Coordinating Council; Former Assistant Secretary for Cybersecurity, US Department of Homeland Security; Washington, DC*

3:45 pm **Networking Break**

4:15 pm **Cybersecurity Best Practices for Pharma and Medical Device**

David J. Scott, MS, *Managing Director, Forensic & Integrity Services, EY; Former Assistant Director, Counterterrorism, and Head, Operations Branch, Cyber Division, Director, National Cyber Investigative Joint Task Force, Federal Bureau of Investigation; Leesburg, VA*

5:00 pm **Session Faculty Q&A**

Adam Greene, JD, MPH, *Partner and Co-chair, Health Information & HIPAA Practice, Davis Wright Tremaine; Former Senior Health Information Technology and Privacy Specialist, Office for Civil Rights, US Department of Health & Human Services, Washington, DC*

Cobun Zweifel-Keegan, JD, CIPP/US, CIPM, *Managing Director, IAPP; Former Deputy Director, Privacy Initiatives, Better Business Bureau; Washington DC*

Jamie E. Darch, JD, *Partner, HIPAA and State Data Privacy & Cybersecurity Law, Ropes & Gray; Chicago, IL (Moderator)*

5:45 pm **Adjournment**

Focused Session 3: Managing Medical-Commercial Interactions: Strategic Collaboration, Evolving Roles & Risk-Based Governance — INTERNATIONAL EAST

1:00 pm **Co-Chair's Introductions & Session Overview**



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 (Co-Chair)*



Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR, Seagen; Chicago, IL (Co-Chair)*

1:15 pm **Strategic Planning Together, Tactical Execution Separately: Practical Case Studies in Medical–Commercial Collaboration**

Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR, Seagen; Chicago, IL*

Samantha Philis, *Director, E&C Policy, Training, and Business Operations, Jazz Pharmaceuticals; Chicago, IL*

Samantha Sutherland, *Director, Life Sciences Consulting Practice, Baker Tilly; Jersey City, NJ (Moderator)*

2:00 pm **Beyond Sales Representatives and MSLs: Understanding Emerging Field-Based Roles and Governance Challenges**

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

Amy Wilson, MSJ, *Vice President, Chief Compliance Officer, Esperion; Former Head of U.S. Compliance, MorphoSys; Former Director, Enterprise Compliance, Alexion Pharmaceuticals; Boston, MA*

Matt Chandler, JD, *Director, Epsilon Life Sciences; Richmond, VA (Moderator)*

2:45 pm **Networking Break**

Session continued next page

Focused Session 3 *continued*

3:15 pm **Protecting Medical Independence While Enabling Strategic Cross-Functional Collaboration**

Amy Wilson, MSJ, *Vice President, Chief Compliance Officer, Esperion; Former Head of U.S. Compliance, MorphoSys; Former Director, Enterprise Compliance, Alexion Pharmaceuticals; Boston, MA*

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)*

4:00 pm **Medical–Commercial Boundaries: Congresses, Sponsorships & Promotional Risk**

Maureen Cawley, JD, *Senior Director, Corporate Counsel, Incyte; Former Global Agreements Attorney, Merck; Philadelphia, PA*

Akosua Tuffuor, JD, *Corporate Counsel, US General Medicines, Sanofi; Morristown, NJ/Washington, DC*

Achsah Warren, MSJ, *Vice President, Head of Compliance, Sumitomo Pharma America; Former Vice President Compliance, Urovant Sciences; Former Senior Compliance Manager, Allergan, Irvine, CA*

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

4:45 pm **Have We Become Too Restrictive? Rethinking Medical–Commercial Governance for the Next Era**

Giulia Del Cane, MBA; *Ethics & Business Integrity Strategic Advisor, Global and US Specialty Care, Sanofi; Boston, MA*

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

Jillian A. Gillespie, MBA, *Senior Director, Compliance, Medical & Medical Affairs, Pfizer; Former Director, Compliance Business Partner, R&D, Medical Affairs, HEOR, Seagen; Chicago, IL (Co-Chair)*

5:30 pm **Adjournment**

Focused Session 4: AI in Action: Real-World Compliance Case Studies from the Front Lines of AI Use in Life Science Compliance Departments **INTERNATIONAL WEST**

1:00 pm **Chair's Welcome and Introductions and AI Basics, Life Science Industry Ethics and Compliance Applications**



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

1:30 pm **A Brief Overview of the Epsilon & qordata AI Use Compliance Survey**

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

Mohammad Ovais, *Founder & Board Member, qordata; Princeton, NJ*

2:00 pm **Facilitated Case Study Discussion: From Transcript to Insights: How Compliance Teams Are Using AI to Transform Investigations**

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

Alexis Shaw, *Vice President, Head of Healthcare Compliance, Paratek Pharmaceuticals; Former Compliance Officer, Endo Pharmaceuticals; Former Global Compliance Investigations Manager, Boston Scientific; King of Prussia, PA*

Minna Bak, MBA, *Managing Director, HELIO; Boston, MA (Moderator)*

2:30 pm **Facilitated Case Study Discussion: AI Governing AI: Leveraging Artificial Intelligence to Develop Effective Governance Policies**

Marla Izbicky, JD, *Senior Director, Senior Corporate Counsel, Harmony Biosciences; Chicago, IL*

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

3:00 pm **Networking Break**

3:15 pm **Facilitated Case Study Discussion: AI-Assisted Monitoring and Detection of Potential Policy Violations**

Ron Strauss, *Vice President Compliance, MiMedx; Former Sales Leader, Osteo Specialty, Eli Lilly and Company; Marietta, GA*

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

3:45 pm **Facilitated Case Study Discussion: Agentic AI Use for Continuous Risk Assessment (vs Annual)**

Matthew Stasiunas, PMP, CCEP, LPEC, *RAMP & Project Management Lead, Indivior; Former Senior Specialist, Integrity and Compliance, Kaléo; Richmond, VA*

Michael L. Shaw, JD, *Global Head of Compliance, Privacy and Risk, ZS; Former Vice President and Compliance Officer, GSK; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services; Princeton, NJ (Moderator)*

4:15 pm **The Unspoken Risk of AI: Moral Outsourcing — and Why "Add Human Judgment" Isn't Enough**

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

Stacy E. Yeung, JD, *Vice President, General Counsel and Corporate Secretary, SELLAS Life Sciences Group; Former Assistant General Counsel, Arena Pharmaceuticals; Former Deputy General Counsel, DBV Technologies; New York, NY*

L. Stephan Vincze, JD, LLM, MBA, *President and Chief Executive Officer, TRESTLE Compliance; Former Senior Vice President and Chief Compliance Officer, Warner Chilcot; Former Vice President, Ethics and Compliance Officer, TAP Pharmaceutical; Boston, MA (Moderator)*

Session continued next page

Focused Session 4 *continued*

5:00 pm **The Health Care Compliance Association Presents: Advanced Strategies in Using AI to Monitor and Improve Compliance: Lessons from Other Healthcare Sectors**

Joan Podleski, CCEP, CHPC, CHRC, CHC, *Vice President & Chief Privacy Officer, Children's Health System of Texas; Former Director, Institutional Ethics & Compliance Program, Duke University; Dallas, TX*

R. Brett Short, CHC, CHPC, CHRC, *Vice President, Chief Compliance Officer / Chief Privacy Officer and Data Security Compliance Officer, Office of Corporate Compliance, UK Healthcare; Board & Immediate Past Chair, Health Care Compliance Association; Lexington, KY*

Betsy Wade, MPH, CHC, CHPC, CNA, *President, eitic healthcare compliance solutions; Faculty, Health Care Compliance Association (HCCA) Basic Compliance Academy and Privacy Academy, HCCA; Former Chief Compliance & Ethics Officer, Signature Healthcare; Louisville, KY*

5:45 pm **Adjournment**

Focused Session 5: GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers & The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know **GEORGETOWN EAST**

1:00 pm **Chair's Introductions & Session Overview**



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

1:15 pm **GP 101: A Primer on the Fundamentals of Government Pricing for Compliance Officers**

Tracy Mumpower, *Director Managed Services, Life Science Revenue Management, Government Pricing & Commercial Contracting, HELIO; Former Manager, Commercial Contract Administration, King Pharmaceuticals; Bristol, VA*

John Shakow, JD, *Pharmaceutical Government Price Reporting Expert; Partner, FDA & Life Sciences Practice, King & Spalding; Washington, DC*

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

3:30 pm **Networking Break**

4:00 pm **The Evolving Pricing and Contracting Landscape: What Compliance Officers Need to Know**

Kristie Champlin Gurley, JD, *Partner, Covington & Burling; Former Counsel, Office of the General Counsel, CMS Division, US Department of Health and Human Services; Washington, DC*

Kristin M. Hicks, JD, *Partner, Life Sciences & Healthcare Regulatory, Arnold & Porter; Washington, DC*

Tracy Mumpower, *Director Managed Services, Life Science Revenue Management, Government Pricing & Commercial Contracting, HELIO; Former Manager, Commercial Contract Administration, King Pharmaceuticals; Bristol, VA*

Stephanie Trunk, JD, *Partner, Life Science Practice Group, ArentFox Schiff; Former Legal Counsel, Catalyst Health Solutions; Washington, DC*

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

5:30 pm **Adjournment**

2026 CONTINUING EDUCATION CREDITS & CERTIFICATE OF ATTENDANCE

COMPLIANCE CERTIFICATION BOARD (CCB)®

The Compliance Certification Board (CCB)® has approved this event for up to **29.5 Live CCB CEUs and 25.1 Non-Live CEUs,** based on a 50-minute hour, each. Continuing Education Units are awarded based on individual attendance records. Granting of prior approval in no way constitutes endorsement by CCB of this event content or of the event sponsor.

CONTINUING LEGAL EDUCATION (CLE)

The Pharmaceutical and Medical Device Ethics and Compliance Congress is an approved provider of Pennsylvania MCLE Live and Distance Learning courses. The 2026 Congress has been approved for up to 24 Live and 17 Distance Learning CLE credits in Pennsylvania.

Attorneys seeking Pennsylvania CLE credit and a Congress Certificate of Attendance must pay the $100 CLE processing fee and complete the Continuing Legal Education Credit Self-Reporting Attendance and Evaluation Form by December 31, 2026.

For the CLE form, payment instructions, and complete continuing education information, please visit the Congress website or mobile app.

CERTIFICATE OF ATTENDANCE

A self-completed Certificate of Attendance is available on the Congress website and mobile app for attendees seeking documentation for other certifying organizations that accept such certificates.

WEDNESDAY, OCTOBER 14, 2026

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 2

7:00 am **Registration Opens** **CONCOURSE FOYER**
Networking Breakfast in the Exhibit Hall

MORNING MINI SUMMITS: GROUP 1 (8:00 am - 8:50 am)

Mini Summit 1: Compliance Independence in The Real World: Governance Models That Work — INTERNATIONAL EAST

What does compliance independence look like in day-to-day decisions? This discussion will explore governance models that give Compliance a meaningful voice while supporting effective collaboration with Legal and business teams. Panelists will consider reporting relationships, decision-making authority, escalation paths, and practical ways to address disagreements when priorities compete.

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

Kathy Johnson, JD, *Vice President, Commercial and Development Legal, Vertex Pharmaceuticals; Former US Legal Counsel Consultant, Takeda; Former Senior Director, Legal Counsel, Shire; Boston, MA*

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)*

Mini Summit 2: The Agentic Compliance Function of the Future — CABINET

As life sciences organizations adopt AI, automation, and agentic technologies across the enterprise, compliance must evolve beyond traditional oversight models. This session will explore how an AI-enabled operating model can transform compliance from a reactive control function into a proactive, scalable capability that strengthens trust, accountability, and responsible innovation.

Attendees will gain insights into:

- Embedding "Trust by Design" into AI-enabled processes and digital initiatives
- Translating regulatory expectations into practical guardrails and governance structures
- Using agentic monitoring and AI-native surveillance for continuous oversight and anomaly detection
- Designing scalable human-in-the-loop oversight for AI-assisted and autonomous activities
- Integrating risk intelligence across compliance, operational, cyber, privacy, and strategic risk domains

The session will also address implementation considerations, organizational design, governance challenges, and emerging practices. Participants will leave with actionable perspectives on using agentic technologies and





AI-enabled oversight to make compliance a more strategic enabler of innovation, trust, and enterprise performance.

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

Jennifer Beaudoin, CFE, CPA, *Executive Director, Head of Global Compliance Program Strategy, Governance and Transformation, Vertex Pharmaceuticals; Boston, MA*

Emily Cunningham, *Associate Director, Compliance, Ultragenyx; New York, NY*

Lauren H. Thal, *Vice President, Compliance, Tolmar; Former Compliance Officer, Cerapedics; Former Senior Director of Compliance, Beta Bionics; Chicago, IL*

Emily (Jaffe) Singh, *Partner, Global Spend Transparency Practice Leader, PwC; Chicago, IL (Moderator)*

Mini Summit 3: Evolution of Patient Finding Activities

GEORGETOWN WEST

As therapies become more targeted and bespoke, particularly in the treatment of rare diseases, the accurate identification of appropriate patients has become a growing priority for manufacturers. Sponsored genetic testing programs are among the more widely adopted approaches to support diagnosis and patient identification, but additional patient finding strategies are emerging rapidly. This panel will explore new and evolving patient identification activities and examine the legal, compliance, and privacy considerations they may raise.

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

Betania Glorio, *Former Senior Vice President, Chief Compliance Officer, Avidity Biosciences; Former Chief Compliance Officer and Head of Group Compliance and Data Privacy, EMD Serono; Former Global Head of Compliance, Healthcare, Merck KGaA Boston, MA*

Jesse Siegel, JD, *Head of Business Ethics, Americas, Ipsen; Former Senior Counsel, Neurology & Immunology, EMD Serono; Cambridge, MA*

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

Mini Summit 4: First Product Launch: Policy Development Strategies and Techniques

GEORGETOWN EAST

A forward-looking discussion on how geopolitical developments are influencing enforcement priorities and how compliance programs should be structured today to withstand future DOJ scrutiny (e.g., 2028–2032 outlook). The session would also explore the balance between conduct and cooperation, and the importance of documentation and strategic planning.

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

Michael Morgan, MBA, CCEP, *Global Compliance Officer, Telix Pharmaceuticals (US); Member, Business Ethics Indiana; Former Ethics and Compliance Officer-North America, Corteva; Indianapolis, IN*

Sandra Park, JD, *Senior Vice President, Legal & Chief Compliance Officer, Vera Therapeutics; Former General Counsel & Chief Compliance Officer, IDEOlogy Health; Former Vice President, Commercial Legal, Kite, a Gilead Company; Brisbane, CA*

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

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Hear from our speakers

Yogesh Bahl

First Product Launch: Policy Development Strategies and Techniques
Wednesday, October 14, 2026 | 8:00AM

Burgeoning Compliance Risks
Thursday, Ocober 15, 2026 | 4:15PM

David Amendola

Managing Whistleblower Risk and Internal Escalation
Tuesday, October 13, 2026 | 5:45PM

Leading Practices for Managing Investigations
Thursday, October 15, 2026 | 11:00AM

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Mini Summit 5: Speaker Programs in 2026: Practical Legal and Compliance Considerations for Executing from Beginning to End Amid Ongoing Scrutiny **INTERNATIONAL WEST**

1. What patterns can be observed and lessons learned from continued government scrutiny, enforcement activity, and evolving expectations? What are some key legal and compliance themes?
2. How can compliance, legal, and regulatory teams work with their colleagues to implement compliance standards and strategies?
3. What types of challenges can arise and how can they be addressed?

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

Tracey Hannon, JD, *Director, Compliance Business Partner, Alexion, AstraZeneca Rare Disease; Former Compliance Counsel, Ionis Pharmaceuticals; Boston, MA*

Jennifer A. Romanski, JD, *Principal, Porzio, Bromberg & Newman; Parsippany, NJ*

Noah C. Goldstein, JD, *Counsel, Pharma, Biotech & Medical Device Legal, Regulatory, & Compliance, Porzio Bromberg & Newman; Westborough, MA (Moderator)*

8:50 am **Transition Break**

MORNING MINI SUMMITS: GROUP 2 (9:00 am - 9:50 am)

Mini Summit 6: From Pronouncements to Practice: Understanding DOJ Enforcement Priorities **CABINET**

Join this session for a critical discussion of how DOJ's enforcement priorities are taking shape in practice. We'll share insights on enforcement trends and draw from recent matters (from the sources of these cases to the activities that were scrutinized and how the results aligned with DOJ policy) for an engaging discussion for in-house compliance and legal professionals around the practical considerations and implications of these latest developments for compliance programs.

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

Christina O. Hud, JD, *Senior Counsel, Global Investigations, Pfizer; 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*

Michelle Dineen Jerrett, JD, *Regional Head of Investigations & Monitoring, North America, Sanofi; Former Legal Director, Endoscopy, Boston Scientific; Former Assistant United States Attorney, US Attorney's Office, District of Massachusetts; Cambridge, MA*

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

Jane H. Yoon, JD, *Partner, Litigation Department, Paul Hastings; Former Assistant United States Attorney, Health Care and Government Fraud Unit, US Attorney's Office for the District of New Jersey; New York, NY (Moderator)*

Mini Summit 7: Boring is Risky! Want Stronger Ethics and Compliance Engagement? Train & Communicate Colorfully — GEORGETOWN EAST

Boring is your program's worst enemy. You have so many important things to share, but it all falls apart if employees are tuning you out. People do not speak up to ask questions or report concerns when they're bored, annoyed or afraid.

In this session we'll share creative, practical strategies and success stories and we'll show you real examples inspired by great TV that employees want to binge like Netflix. Tune in to learn how to:

- Change E&C's vibe to create a positive identity and brand
- Get attention and increase E&C awareness all year
- Improve learning engagement while taking up less time
- Generate influence & create E&C influencers

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

Regina Gore Cavaliere, JD, *Chief Ethics and Compliance Officer, Vice President Regulatory and Compliance, Henry Schein; Melville, NY*

Ronnie H. Feldman, *Founder, Chief Executive Officer and Creative Director, Learnings & Entertainment: Comedians Who Improve Compliance; Chicago, IL*

Mini Summit 8: Best Practices for Data Analytics — INTERNATIONAL EAST

Recent enforcement actions have turned manufacturers' own speaker logs, meal records, call notes, and prescribing trends into evidence, putting a pointed question to compliance teams: can they get to the same data, and act on what it shows in time to matter? This panel moves beyond the dashboard. We'll examine how teams set analytics strategy, close the loop from signal to remediation, and govern the use of AI in monitoring and review, including where detection creates its own obligation to act. Panelists will speak to building a credible analytics function at any scale, from a one-person program to a global monitoring team.

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

Bobby Carnathan, *Senior Manager, Ethics and Compliance Business Partner, Novo Nordisk; Plainsboro, NJ*

Christian Malias, MBA, *Associate Director, Compliance Program Development, Insmed; Former Associate Director Compliance Business Partner, Sage Therapeutics; Former Global Corporate Compliance Manager, Adaptimmune; Pittsburgh, PA*

Erica Powers, CHC, *Founder & Chief Executive Officer, Ethical Paths; Former Vice President, Chief Compliance Officer, Sage Therapeutics; Former Director Corporate Compliance, Vertex Pharmaceuticals; Boston, MA (Moderator)*

Mini Summit 9: On the Front Lines: Navigating Field Force and Sales Compliance Risk — INTERNATIONAL WEST

- Compliance risks associated with speaker programs, meals, and HCP interactions
- Sampling controls, documentation risks, and recent enforcement focus areas
- State law developments impacting field activities like disclosures and licensing
- Sales incentive compensation and unintended behavioral risk

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

Ron Strauss, *Vice President Compliance, MiMedx; Former Sales Leader, Osteo Specialty, Eli Lilly and Company; Marietta, GA*

Sarah L. Whipple, JD, *Principal, WhipEdge Solutions; Member, Rare Disease Compliance Consortium (RDCC); Former Vice President, Global Chief Compliance Officer, Apellis; Former Vice President, Legal & Chief Compliance Officer, Akebia; Needham, MA*

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

Mini Summit 10: Communicating the Story on Integrity: What Compliance Leaders Can Learn from Health Stakeholders — GEORGETOWN WEST

Compliance leaders are asked not only to build and sustain effective integrity programs with employees, but to inform business decisions that impact external stakeholder trust. They are also increasingly asked to engage directly with external stakeholders to share and improve their company's practices, from trade associations to collective action initiatives. This session will provide practical insights to help you and your team better communicate the story of integrity when it impacts an external audience, drawing on diverse stakeholder perspectives and experiences from partnerships such as the U.S. Consensus Framework for Ethical Collaboration.

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

Felicia E. Heimer, JD, MPH, *Head of Rare Disease Compliance, Worldwide Compliance & Business Ethics, Amgen; Lecturer in Law, USC Gould School of Law; Former Deputy Chief, Office of Counsel to the Inspector General, United States Department of Health and Human Services; Washington, DC*

Karen Mancera-Cuevas, DrPH, MS, MPH, MCHES, *Senior Director, Research Advancement & Equity, National Health Council; Former Deputy Director, Health Promotion, Illinois Department of Public Health, Washington, DC*

Julie Ritchie Wagner, JD, *Assistant General Counsel, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US Department of Health and Human Services; Washington, DC*

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

Mini Summit 11: Designing HCP Engagement with Transparency Built In — MONROE

As regulatory scrutiny around HCP engagement increases, organizations must ensure transparency is embedded into their processes. This session explores how to design systems that capture required data and leverage AI.

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

Kaoutar Afif, *Manager, Ethics & Compliance, Cardinal Health; Dublin, OH*

Peggy Kruk, HMCC, *Senior Manager, Compliance & Transparency, MIMEDX; Former Director, Compliance, Program Services, Vaniam Group; Marietta, GA*

Jacob Wolf, MBA, *Chief Commercial Officer, Cresen Solutions; Orlando, FL (Moderator)*

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

MORNING MINI SUMMITS: GROUP 3 (10:10 am – 11:00 am)

Mini Summit 12: Compliance and M&A: Why Early Engagement Matters
MONROE

Compliance issues can affect deal value, integration, and post-close risk—yet compliance is often brought in too late. This session explores how early engagement helps teams identify risks sooner, make better decisions, and avoid costly surprises throughout the deal lifecycle.

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

Eliza L. Andonova, JD, *Partner, Global Regulatory, Hogan Lovells Cadwalader; Washington, DC*

Eric Nichols, JD, *Associate Vice President, Ethics & Compliance, R&D and Business Development, Eli Lilly and Company; Indianapolis, IN*

Megan Roberts, CPA, MS, *Head of Integrity & Compliance, Par Health; Former Senior Director, Integrity & Compliance; St. Louis, MO*

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

Russell Rose, JD, *Managing Director, Deloitte Consulting; Dallas, TX (Moderator)*

Mini Summit 13: The State of Medical Device Compliance: Annual Industry Roundtable
CABINET

Medical device compliance is evolving quickly, shaped by changing regulations, heightened enforcement attention, new technologies, and increasingly complex commercial and quality-system risks. This panel brings together experienced compliance leaders and industry experts for a candid discussion of the issues defining today's environment. This discussion will explore:

Enforcement trends: Analyze recent actions involving medical device manufacturers, the underlying compliance breakdowns, and the areas drawing increased regulatory attention.

Compliance strategies: Learn practical approaches for responding to evolving requirements and building durable, risk-based compliance frameworks aligned with industry expectations.

What's next: Hear expert perspectives on upcoming regulatory and enforcement trends so your organization can anticipate change, identify exposure early, and prepare for future compliance demands.

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

Kate Godfrey, JD, CCEP, *Senior Vice President, Global Chief Compliance Officer, Karl Storz North America; El Segundo, CA*

JJ Kuhn, JD, *Chief Ethics & Compliance Officer, Danaher; Former Senior Vice President and Chief Ethics & Compliance Officer, Solventum; Former Vice President Chief Counsel, Global Investigations, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

Diane Seol, JD, *Of Counsel, Choate Hall & Stewart; Former Assistant United States Attorney, Affirmative Civil Enforcement Unit, US Attorney's Office, District of Massachusetts; Boston, MA*

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



Mini Summit 14: The State We're In: Legal & Enforcement Trends Reshaping Life Science Companies' Compliance INTERNATIONAL EAST

- Recent and upcoming state law developments affecting life science manufacturers
- Trends in proposed legislation, such as A.I., disclosures, advertising, and more
- Commonly overlooked requirements creating hidden compliance exposure
- Review of recent OIG enforcement actions and Advisory Opinions impacting life sciences organization
- Key themes and patterns emerging from enforcement activity across the industry

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

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

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

Mini Summit 15: External Funding Risks and Mitigation: Latest Trends in Exhibit & Display and Sponsorship Requests GEORGETOWN EAST

Exhibit, display, and sponsorship requests can offer legitimate opportunities for engagement while presenting evolving compliance, legal, and reputational risks. This session will examine current trends and practical approaches for evaluating these requests consistently and appropriately.

Panelists will discuss key considerations, including establishing a legitimate business purpose, assessing value and benefits, applying fair market value principles, maintaining appropriate separation from commercial influence, and documenting funding decisions. The session will also explore common red flags, the role of cross-functional review, and strategies for developing clear, risk-based approval standards. Attendees will gain practical insights to help strengthen oversight while supporting appropriate external engagement.

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

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

Alison J. Page, JD, *Assistant General Counsel, Oncology and US Market Access & Patient Services Compliance Lead, Pfizer; New York, NY*

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

Mini Summit 16: Beyond the Questionnaire: Building a Risk-Based Third-Party Management Program That Actually Works GEORGETOWN WEST

Third party risk management too often calcifies into a check-the-box exercise with a questionnaire at onboarding, then silence until renewal. Meanwhile, real risk emerges dynamically: ownership changes, sanctions designations, sub-distributors operating three tiers beyond visibility. This panel examines how leading life science companies are rebuilding their third-party risk management around how risk actually behaves. Panelists will share practical approaches to meaningful risk-tiering, the shift from point-in-time diligence to continuous monitoring, and where AI-driven screening ends and human intelligence must begin.

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

Ariadna Quesada, MSJ, *Vice President of Compliance - Global Compliance & Privacy lead, Zoll Medical; Former Compliance Director Europe & MEATI, Hillrom; Former Ethics and Compliance Officer, The Netherlands, AbbVie; Madrid, Spain*

Maria Villanueva, MBA, CFE, *Director, Ethics and Compliance, BioTissue; Former Vice President, Compliance Officer and Head of HR, Ra Medical Systems, Manufacturer of DABRA excimer laser system; Former Director, Compliance, Zimmer Biomet; Miami, FL*

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

David Fisher, MS, *President, TDI Solutions; Former Vice President & General Manager, Cyber Innovations, Battelle; Washington, DC (Moderator)*

Mini Summit 17: Navigating Today's Enforcement Landscape with Culture, Data, and Ethics INTERNATIONAL WEST

Participants will explore:

- Are traditional assumptions about enforcement risk still valid?
- When does self-disclosure make strategic sense, and when might it not?
- How can organizations measure whether compliance programs are actually working?
- What data boards and executives are demanding to make better risk decisions?
- How can companies thrive in an environment where certainty is decreasing and scrutiny remains high?

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

Hui Chen, JD, *Co-Founder, Culture. Data. Ethics; Former Compliance Counsel Expert (Consultant), US Department of Justice; Former Assistant General Counsel, Pfizer; Honolulu, HI*

Zachary Coseglia, JD, *Co-Founder, Culture. Data. Ethics; Co-Founder & Former Managing Principal & Head of Innovation R&G Insights Lab, Ropes & Gray; Former Vice President & Assistant General Counsel, Global Compliance Monitoring, Analytics and Digital, Pfizer; Boston, MA*

11:00 am **Transition Break**

MORNING MINI SUMMITS: GROUP 4 (11:10 am – 12:00 pm)

Mini Summit 18: Risk Advantage: How Resilient Organizations are Capturing Opportunity through Uncertainty GEORGETOWN WEST

Compliance mandates in Pharma and MedTech keep growing while headcount stays flat, and geopolitical and regulatory pressure shows no sign of easing. This panel brings together senior compliance leaders to talk candidly about what has worked for them and what hasn't.

Panelists will share how they are resourcing a bigger mandate, including the work they have stopped, automated or handed back to the business, and the data that has persuaded CFOs and Boards to protect headcount. They will also give an honest account of AI in compliance, covering the experiments that fell short as well as the wins, and the cases where a tool simply moved the work elsewhere.

Many compliance leaders are accountable for risks they have no authority to fix, so the conversation will look at how they drive change through credibility and relationships instead. Team structures are shifting too, as more local officers take on compliance alongside other roles and turning data into a clear story becomes a core skill.

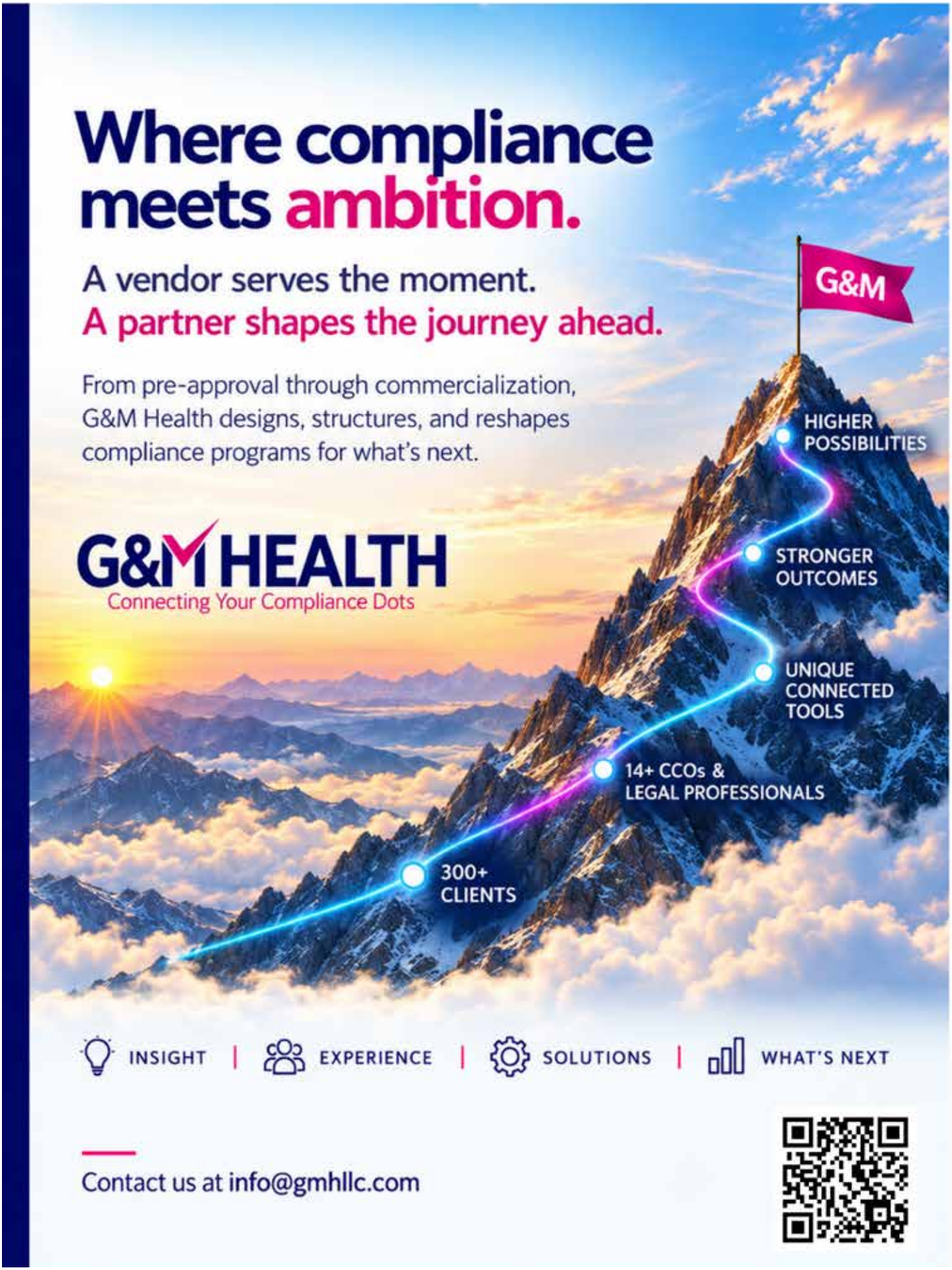
The panel will also consider the longer-term move from a programmatic, yes/no function toward an embedded advisory role and what it takes to get there. Other topics include where Boards are focusing on risk and how leaders keep their teams resilient under sustained pressure, with peer CCO networks as one source of support.

11:10 am **Introductions, Discussions and Q&A**

Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*

Kate Godfrey, JD, CCEP, *Senior Vice President, Global Chief Compliance Officer, Chief Compliance Officer KSNA, Karl Storz North America; El Segundo, CA*

Russell Schaefer, MBA, *Managing Director, BCG; Washington, DC (Moderator)*


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Mini Summit 19: View from the Top: Practical Advice for Accelerating Your Compliance Career GEORGETOWN EAST

What distinguishes a strong compliance professional from a future compliance leader? In this interactive session, accomplished compliance executives will share candid, practical advice on the skills, experiences, and behaviors that can accelerate career growth in today's rapidly evolving environment. Attendees will learn how to increase their visibility, build credibility with business leaders, move from execution to strategy, and identify the next experience needed to advance their careers.

11:10 am **Introductions, Discussions and Q&A**

Terra Buckley, JD, *Senior Vice President, Chief Compliance & Ethics Officer, Bristol Myers Squibb; Former Chief Compliance Officer, LivaNova; Former Executive Director, Head, Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Princeton, NJ*

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

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

Daniel O'Connor, *Senior Vice President, NXLevel Compliance; Lambertville, NJ (Moderator)*

Mini Summit 20: Direct-to-Consumer (DTC) Models: Emerging Compliance Risks and Governance Considerations INTERNATIONAL WEST

As pharmaceutical and medical device companies continue to explore direct-to-consumer models, including telehealth partnerships, online prescribing platforms, patient support services, and direct distribution channels, compliance professionals are facing new and evolving risk areas. The Panel will explore these evolving models, including:

- The growing use of AI in consumer engagement models
- Current trends in patient access and patient support tools and programs
- Best practices in partnerships with healthcare providers

The Panel will also address the compliance risks posed by these models and how to best address them, including:

- Anti-Kickback Statute and False Claims Act considerations
- Patient inducement concerns
- Marketing and promotional oversight
- Data privacy and patient information considerations
- Lessons learned from recent enforcement actions and regulatory scrutiny

11:10 am **Introductions, Discussions and Q&A**

Amy Bentsen, JD, *Head of Investigations for Americas, Ethics & Compliance, Takeda; Cambridge, MA*

Michele Guerino, MS, *Executive Director, Commercial Compliance Office, Human Health Ethics and Compliance, Merck; Former Senior Regional Business Director, Cubist Pharmaceuticals; Hopewell, NJ*

Edward "Ted" B. Diskant, JD, *Partner, McDermott Will & Schulte; Former Assistant US Attorney, Southern District of New York, US Department of Justice; New York, NY (Moderator)*

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Don't miss our panel discussion "Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks" on Wednesday morning!

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Mini Summit 21: Fair Market Value: Practical Strategies and Targeted Insights for Building Defensible FMV Frameworks CABINET

Building and deploying a consistent fair market value (FMV) program remains a cornerstone of compliance programs across the life sciences industry. Designed for professionals at all experience levels, this discussion will cover both foundational concepts and new challenges, including how to assess FMV for non-traditional stakeholders, ensure appropriate valuation for travel and related expenses, navigate some common pitfalls of operating in global markets, leverage data and new technology while maintaining defensibility, and more! Our expert panel of esteemed compliance professionals will share practical insights, lessons learned, and strategies to help organizations build adaptable, risk-based FMV frameworks that keep pace with innovation across the industry.

11:10 am **Introductions, Discussions and Q&A**

Yelena Ferreira, JD, *Head of Compliance and Assistant General Counsel, Pharmacosmos Therapeutics; Former Senior Director, Associate General Counsel, Pacira BioSciences; Morristown, NJ*

Abe Kassis, MBA, PhD, *Global Head Compliance and Legal Operations, Bausch + Lomb; Former Director of Corporate Compliance (Ethics & Compliance); Former Global Compliance, Director of Compliance, Takeda; New York, NY*

Eric Bolesh, *President, Cutting Edge Information; Research Triangle Park, NC (Moderator)*



Mini Summit 22: Navigating the Evolving US Privacy Landscape MONROE

As state privacy laws continue to multiply, understanding the common principles and requirements across these laws has never been more important. In this interactive session, our panelists will provide their insights and concerns regarding risks and compliance demands. Through real-world scenarios, attendees will learn how leading organizations prioritize compliance efforts and navigate the continuously evolving privacy landscape.

11:10 am **Introductions, Discussions and Q&A**

Simonne Brousseau, JD, *Associate, Faegre Drinker; Washington, DC*

Tom Hiney, CIPP/US, CIPM, JD, *Head, Digital Ethics & Compliance, US Business Unit, Takeda; Former Privacy Counsel, Blueprint Medicines; Boston, MA*

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

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

Mini Summit 23: Agentic Risk Management: Transforming Compliance Across Key Business Processes INTERNATIONAL EAST

Agentic AI is redefining the compliance operating model. Compliance teams are managing more signals than ever, often without a clear way to act on them. By the time a violation is confirmed, the moment to prevent it has usually already passed. This panel makes the case for a different model: AI embedded directly into the workflow, flagging and guiding risk in real time, before it becomes a problem. Topics include:

- The hidden risk of over-engineered controls, which create friction that drives workarounds you can't see
- Catching speaker program risk in real time instead of weeks after the event closes
- Why reviewing a monitoring/audit sample can look clean while most of the program goes unseen
- As field tools move toward open, free-text entry, how compliance oversight must evolve to keep pace
- What audit-ready documentation looks like when an AI agent takes the action instead of a person

Panelists will share a practical framework for identifying which compliance processes are ready for agentic transformation, along with what should be in place before that shift begins.

11:10 am **Introductions, Discussions and Q&A**

Kevin Espinoza, *Chief Integrity & Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo; Former Senior Vice President, Corporate Compliance, Boston Scientific; Richmond, VA*

Jeanille Gatta, MA, *Director, Compliance Business Partner, AstraZeneca, North America; Philadelphia, PA*

Stephanie Santana, MPH, PMP, *Associate Principal, ZS; New York, NY (Co-Moderator)*

Michael L. Shaw, JD, *Global Head of Compliance, Privacy and Risk, ZS; Former Vice President and Compliance Officer, GSK; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services; Princeton, NJ (Co-Moderator)*

12:00 pm **Luncheon Activities**

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LUNCHEON ACTIVITIES

Choose between two lunch activities:

12:00 pm – 1:15 pm **Networking Lunch in the Exhibit Hall**
(Pick up your box lunch in the exhibit hall.)

—— OR ——

12:10 pm – 1:10 pm **Optional Luncheon Discussion:**

Compliance Risks and Challenges in Small and Emerging Life Sciences Companies — INTERNATIONAL EAST

Grab your lunch and join this interactive discussion focused on the unique compliance and ethics challenges facing small life sciences companies, particularly rare disease, and emerging biotech organizations. Unlike established pharmaceutical companies, pre-commercial and growth-stage organizations often operate with limited resources while navigating significant pressures related to launch readiness, investor expectations, business growth and development, and early stakeholder engagement.

This practical lunch session brings together a US Compliance Officer and a former Chief Counsel to the Inspector General to examine the unique compliance and ethics challenges facing smaller and emerging life sciences companies. Attendees will gain insights into unique risks from the pre-commercial stage through commercialization, the evolutionary role of the compliance function following product approval, and perspectives when building and managing effective compliance programs with limited resources and budgets.





Discussion Facilitators:

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

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

PHARMACEUTICAL AND MEDICAL DEVICE CONGRESS OPENING PLENARY SESSION

INTERNATIONAL CENTER

1:15 pm **Welcome and Introduction: PCF Board**



Donna White, CCEP, *Vice President, Compliance Officer, Americas Region, Chiesi USA; Cary, NC (PCF Board Chair)*

1:30 pm **C-Suite Congress Video Welcome**



Albert Bourla, DVM, PhD, *Chairman and Chief Executive Officer, Pfizer; Co-Chair, Partnership for New York City; Former Chair, Pharmaceutical Research and Manufacturers of America (PhRMA); Former President, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); New York, NY*

1:40 pm **Keynote Annual OIG Update**



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

2:30 pm **Keynote US DOJ Criminal Division Update Fireside Chat**



Jacob Foster, JD, *Acting Chief, Health Care Fraud (HCF) Unit, Criminal Division, Fraud Section, US Department of Justice (DOJ); Former Trial Advocacy Project Deputy District Attorney, Los Angeles County District Attorney's Office; Washington, DC*



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

3:00 pm **Tech & Human-in-the-Loop Compliance (Why Human Judgment Matters More Than Ever)**



Jason DiPietro, *Associate Director, Compliance Innovation & Analytics, Lundbeck; Deerfield, IL*



Rawan Fusisi, *Director, Integrity & Compliance, Indivior; Former Transparency and Analytics Manager, Stryker; Washington, DC*



Rajiv Mehrotra, MS, *Senior Vice President, Data Science, HELIO; New York, NY*



Marci Juneau, MBA, *A Founding Partner, HELIO, Atlanta, GA (Moderator)*

3:30 pm **Networking Break in the Exhibit Hall** **JEFFERSON-LINCOLN**

4:00 pm **The Next Generation of Compliance: Leveraging Data to Stay Ahead of Risk**



Lindsey LaMoria Gavin, *Senior Director, Deputy Compliance Officer, Lundbeck; Former Compliance Director, Meetings & Events International; Deerfield, IL*



Asha Natarajan, MPH, JD, *Of Counsel, Arnall Golden Gregory; Former Trial Attorney, Civil Fraud Section, US Department of Justice; Former Assistant US Attorney, Criminal Division, Health Care Fraud, US Attorney's Office for the Southern District of Texas; Washington, DC - Atlanta, GA*



Al Park, *Senior Compliance Officer, Global Monitoring, Auditing and Third-Party Risk Management, Global Ethics and Compliance, Jazz Pharmaceuticals; Former Global Program Effectiveness & Insights Leader, Worldwide Compliance & Business Ethics, Amgen; Phoenix, AZ*



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

4:30 pm **Integrated Risk Transformation in Pharma/Medical Device: From Compliance Burden to Strategic Advantage**



Jonathon L. Kellerman, *Chief Compliance & Business Transformation Officer, Chief Privacy Officer Bausch + Lomb; Former Executive Vice President, Global Chief Ethics & Compliance Officer, Allergan; Former BCG Health Industries Partner; Former PwC Advisory Partner; Bridgewater, NJ*



Michael Reyes, *Director, Risk & Regulatory Consulting, PwC; Former Analyst, Compliance Analytics, Edwards Lifesciences; Dallas, TX*



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

5:00 pm **Annual Chief Compliance Officers Fireside Chat**



Terra Buckley, JD, *Senior Vice President, Chief Compliance & Ethics Officer, Bristol Myers Squibb; Former Chief Compliance Officer, LivaNova; Former Executive Director, Head, Business Advisory Center of Excellence, US Healthcare Compliance, Celgene; Princeton, NJ*



Christine Gordon, JD, *Vice President, Risk, Assurance, & Compliance and Chief Compliance Officer, RAC Business Partner, Global SIS Division, Olympus Corporation of the Americas; Former Assistant District Attorney, Philadelphia District Attorney's Office; Bethlehem, PA*



Melissa T. Lozner, JD, *Senior Vice President, Chief Compliance Officer, Regeneron; Former Chief Compliance & Ethics Officer and Special Counsel, Rafael Holdings; Former Vice President, Head of Ethics, Risk & Compliance, Novartis; Tarrytown, NY (PCF Board Member)*



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

5:45 pm **ADJOURNMENT**



Melissa T. Lozner, JD, *Senior Vice President, Chief Compliance Officer, Regeneron; Former Chief Compliance & Ethics Officer and Special Counsel, Rafael Holdings; Former Vice President, Head of Ethics, Risk & Compliance, Novartis; Tarrytown, NY (PCF Board Member)*

5:45 pm **NETWORKING RECEPTION In the Exhibit Hall**

PHARMACEUTICAL AND MEDICAL DEVICE ETHICS AND COMPLIANCE CONGRESS DAY 3

7:00 am **Registration Opens** **CONCOURSE FOYER**

Breakfast Buffet in Exhibit Hall **JEFFERSON-LINCOLN**

CHIEF COMPLIANCE OFFICER ROUNDTABLE

INTERNATIONAL WEST

PCF-Sponsored, Exclusive Invitation-Only, Closed-Door Session

7:00 am **Breakfast will be served in the CCO Roundtable Meeting room**

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



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 Member)*



Antitrust Admonition
Benjamin B. Correa, JD, *Partner, Food, Drug & Medical Device, Sidley Austin; Washington, DC*

8:15 am **Future of the Compliance Profession in an AI-Driven Environment**

AI is reshaping how compliance functions operate, how teams are structured, and what skills tomorrow's leaders must bring to the table. This panel brings together organizations of varying sizes to explore how AI is changing expectations, budgets, staffing models, and the competencies required for the next generation of compliance leadership.

The conversation will focus on practical realities: what companies are doing, where pressures are emerging, and how to prepare talent for a future where AI is embedded in every workflow.



Kevin Espinoza, *Chief Integrity & Compliance Officer, Indivior; Former Chief Integrity & Compliance Officer, Kaléo; Former Senior Vice President, Corporate Compliance, Boston Scientific; Richmond, VA*



Jim Gibney, *Vice President, Global Compliance Operations, Corporate Compliance, Regeneron; Former Director, Worldwide Programs and US Investigations, Pfizer; Ridgewood, NJ*



Rebekah Latchis, JD, *Vice President, Risk Intelligence & Investigations, Office of Privacy, Integrity & Compliance, Medtronic; Former Corporate Responsibility Director, Bon Secours; Washington, DC*



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*



Joy Dowdle, JD, *Partner, Litigation Department, Paul Hastings and Co-Chair of the Houston Office; Houston, TX (Moderator)*

9:00 am **Executive Breakout by Company Size - Leveraging AI to Support Compliance Programs**

Participants will dig into practical, real-world AI implementation, sharing how AI is actually being used inside their organizations—what's working, what's stalled, and where the biggest opportunities and risks are beginning to emerge.



Daniel Spicehandler, JD, *Vice President Compliance, MSNT and Global Programs, Stryker; New York, NY (Pharma Congress Medical Device Executive Steering Committee)*

9:40 am **Networking Break**

10:00 am **Executive Breakout by Company Size - Building AI Ready Teams**

Participants will share how they are upskilling their team to effectively leverage AI. Sharing how they're training current staff, recruiting future compliance talent, and building AI-ready skill sets across their programs.



Mona Peterson Rosow, JD, MPH, *Former Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Steering Committee)*

10:40 am **Board Oversight of Compliance: What Audit Firms Observe and What Regulators Require**

As regulatory expectations intensify and AI accelerates business risk, Boards are reexamining what "good" compliance looks like—and whether their organizations are structured to deliver it. Yet many Boards still misunderstand the purpose, scope, and value of Compliance, creating gaps in oversight and weakening independence.

This session offers an inside look at what audit firms are seeing in board governance and cultural attitudes toward compliance. We will also explore the government's perspective on why robust compliance programs matter, and the oversight behaviors regulators expect Boards to demonstrate in the boardroom.



Katherine Buckley, MBA, *Partner, Pharmaceutical and Life Sciences Risk & Regulatory Consulting Solutions, PwC; Philadelphia, PA*



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



Tony Jordan, *Partner, EY; Former Accounting Branch Chief - Boston District Office, US Securities and Exchange Commission; Boston, MA*



Kenneth A. Polite, Jr, JD, *Partner & Global Co-leader, White Collar Defense, Sidley Austin; Former Assistant Attorney General, Criminal Division, US Department of Justice; Washington, DC*



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

11:30 am **Open Forum: Opportunities for Benchmarking and Peer-driven Q&A. Bring your questions!**



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 Member)*



Mona Peterson Rosow, JD, MPH, *Former Vice President, Chief Risk, Ethics & Compliance Officer, Mozarc Medical; Former Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Steering Committee)*



Daniel Spicehandler, JD, *Vice President Compliance, MSNT and Global Programs, Stryker; New York, NY (Pharma Congress Medical Device Executive Steering Committee)*

11:55 am **Wrap-up**



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 Member)*

Noon **Chief Compliance Officer Roundtable Adjournment**

MORNING MINI SUMMITS: GROUP 5 (8:00 am - 8:50 am)

Mini Summit 24: Identifying and Managing Risk Associated with AI

GEORGETOWN WEST

As AI use expands across life sciences organizations, compliance teams must identify and manage risks without unnecessarily slowing responsible innovation. This session will explore practical approaches for:

- Evaluating and prioritizing AI use cases based on risk
- Establishing appropriate governance, accountability, and human oversight
- Addressing privacy, security, bias, accuracy, and transparency concerns
- Assessing third-party AI tools and vendors
- Monitoring AI systems as their use and capabilities evolve

Panelists will share perspectives on building a risk-based framework that supports innovation while maintaining effective compliance oversight.

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

Kershwin Singh, Esq. *Compliance & Legal Executive, formerly with Pfizer, ZOLL Medical, Boehringer Ingelheim and Aetna (CVS); Avon, CT*

Jerel Smith, MSJ, *Chief Compliance Officer-Director Integrity & Compliance, Upsher-Smith; Former Director, Compliance Operations, Karyopharm Therapeutics; Former, Director, Biopharma Compliance, Pfizer; Bridgewater, NJ*

Mohammad Ovais, *Founder & Board Member, qordata; Princeton, NJ (Moderator)*



Mini Summit 25: Transparency Reporting: Update on the Centers for Medicare and Medicaid Services Open Payments Program

INTERNATIONAL CENTER

- What's changed this year: Priorities for the Trump Administration, the Open Payments realignment under the Transparency & Data Group within CMS's Office of Healthcare Experience & Interoperability — including what the structural change means for industry.
- Where the process still strains: the issues that persist after the system upgrade, with a focus on covered recipient matching, and what CMS and reporting entities can each do to improve it.
- Audits, analytics, and enforcement posture: how CMS is applying data analytics, what an Open Payments audit involves, and the practical difference between an educational letter and an investigation — including how a company should respond to each.
- Compliance best practices: documentation and internal auditing expectations, what to do when routine auditing surfaces errors, and the preventable mistakes CMS sees most often.
- Getting interpretation right: where reporting requirements are most often misread — including ownership and investment interests — and how to resolve issues when they arise.

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

Veronika Peleshchuk Fradlin, MPP, *Director, Open Payments Data Group (OPDG), Office of Enterprise Data and Analytics (OEDA), Centers for Medicare & Medicaid Services, US Department of Health and Human Services; Washington, DC*

Lisa M. Re, JD, *Partner, Life Sciences/Healthcare Regulatory Practice Group, Arnold & Porter; Former Assistant Inspector General for Legal Affairs, Office of Inspector General, US Department of Health and Human Services; Washington, DC (Moderator)*

Mini Summit 26: From Speak-Up to Proof: Turning DOJ and OIG Expectations into Defensible, AI-Enabled Compliance Operations

GEORGETOWN EAST

Regulators no longer view an effective compliance program as a set of policies on paper. They expect organizations to demonstrate, with evidence, that risks are being detected, escalated, investigated, and remediated in a consistent, measurable way. Recent DOJ guidance emphasizes the role of data, analytics, AI, and strong speak-up programs in supporting continuous risk detection.

The session will focus on practical, regulator-aligned approaches for moving from reactive case handling to proactive, evidence-based compliance management. Attendees will see how data, analytics, and AI can strengthen continuous risk detection, surface meaningful trends, and create the audit-ready records needed to demonstrate program effectiveness over time.

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

Allison Benkert, MBA, *Senior Director, Compliance Policies, Training & Investigations, Jazz Pharmaceuticals; Former Senior Director, Global Investigations, Pfizer; Former Head of Global Compliance Investigations, Seagen; Doylestown, PA*

Aaron Lewis, MBA, *Director, Legal and Compliance Operations, Cordis; Former Director, Compliance Insights and Technologies, Cardinal Health; Miami Lakes, FL*

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

Shannon Walker, *Executive Vice President, Thought Leadership & Strategy, Case IQ; Founder and President, WhistleBlower Security; Ontario, Canada (Co-Moderator)*

Mini Summit 27: Manufacturer–Specialty Pharmacy Relationships: Managing Compliance Risk in Specialty and Rare Disease Commercial Models — CABINET

Relationships between manufacturers and specialty pharmacies are foundational to modern specialty and rare disease commercial models, supporting patient access, adherence, and complex therapy management. At the same time, these arrangements operate in a legally sensitive space, raising recurring fraud and abuse questions around financial support, data sharing, service arrangements, and the degree of manufacturer involvement in pharmacy operations.

As manufacturers increasingly rely on specialty pharmacies to execute patient support and distribution strategies, compliance and legal teams are frequently asked to help define the appropriate level of collaboration with specialty pharmacies. This panel will examine the core compliance considerations that arise in manufacturer–specialty pharmacy relationships, focusing on practical risk identification, program design, and oversight approaches that reflect how these models function in the real world. Panelists will share perspectives on common friction points, recurring questions from internal stakeholders, and strategies for supporting patient access while maintaining appropriate compliance guardrails.

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

Elizabeth Conti, JD, *Senior Legal Counsel, Nestlé Health Science; Arlington, VA*

Rakan F. Ghubej, JD, *Senior Director, Senior Corporate Counsel & Assistant Corporate Secretary, Kyowa Kirin; New York, NY*

Aaron P. Maskery, CPA, CIA, *Senior Director, Compliance Operations, Mighty Therapeutics; Former Senior Director, Compliance, Karuna Therapeutics; Former Director, Compliance Auditing & Monitoring, Idorsia; Wilmington, DE*

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

Mini Summit 28: The Future of Compliance Monitoring: AI Agents, Risk Intelligence and Practical Adoption — INTERNATIONAL EAST

With AI capabilities maturing rapidly, compliance leaders are evaluating how these technologies can move beyond experimentation and create measurable value within monitoring programs. Join us for a discussion on where AI is delivering value today within compliance monitoring programs, including a live demonstration of AI-enabled capabilities and practical examples. We will explore the evolving role of agentic AI relative to traditional analytics approaches, key cost considerations, governance implications, and lessons learned from organizations developing and deploying AI-enabled monitoring programs.

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

Kristiana Bankova, MS, *Senior Manager, Forensics, EY; New York, NY*

Rachael Hu, MS, MPP CIPM, CISP, CIPP/E, CIPP/US, *Data Privacy Senior Compliance Program Manager, Medtronic; Santa Clara, CA*

Libby M. Rosenberry, *Senior Manager, Forensic & Integrity Services, EY; Boston, MA*

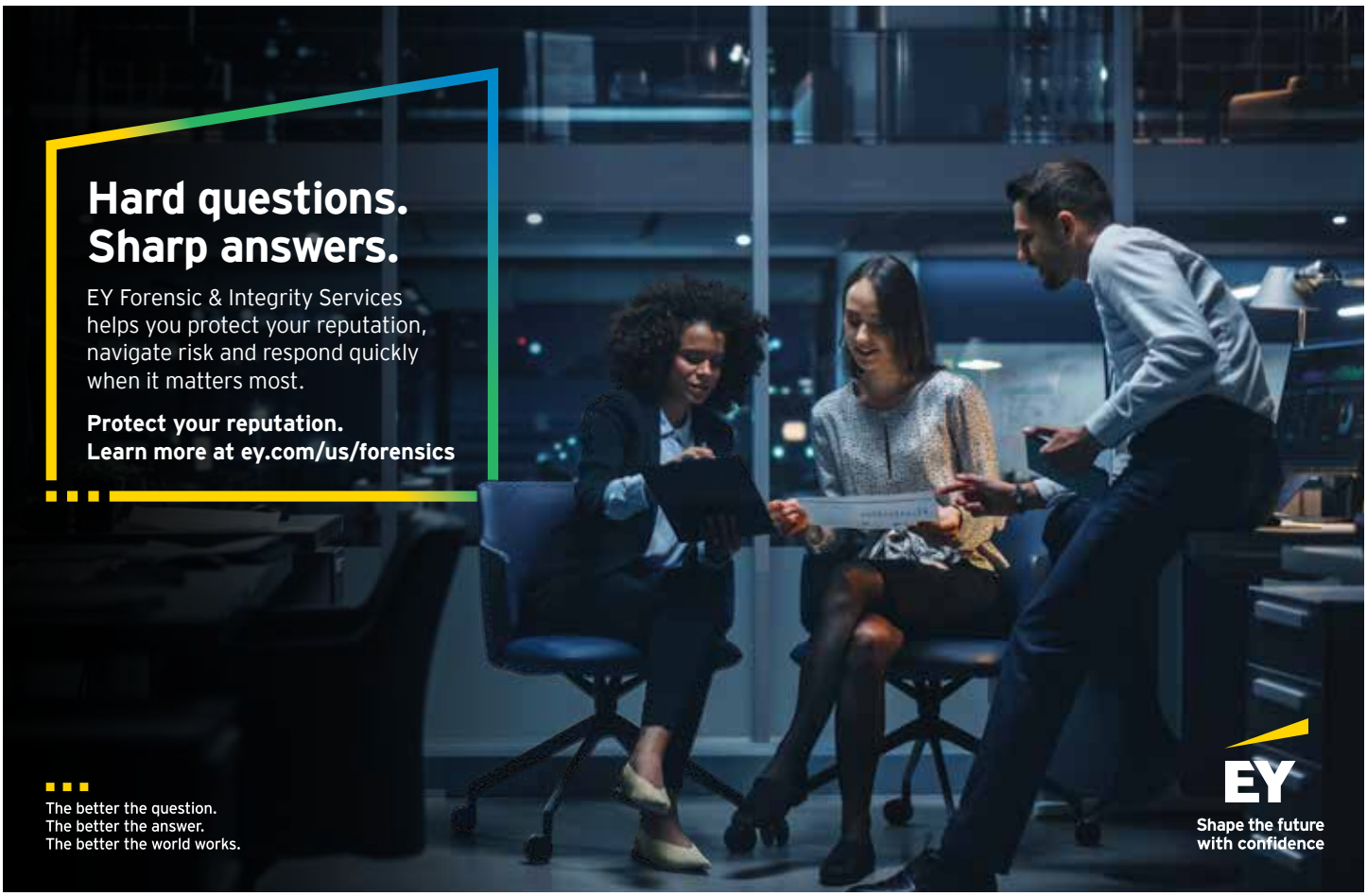
8:50 am **Transition Break**

MORNING MINI SUMMITS: GROUP 6 (9:00 am - 9:50 am)

Mini Summit 29: Building the Compliance Operating Model for What's Next — INTERNATIONAL CENTER

As AI, automation, and advanced technologies reshape work, compliance can no longer rely on traditional operating models. This session explores how leading organizations are redesigning governance, talent, and

Session continued next page



oversight to manage new risks, enable innovation, and build a more connected, data-driven compliance function.

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

Christopher Corallo, *Chief Compliance Officer, KARL STORZ; Former Interim Global Chief Compliance Officer, Convatec; Former Senior Manager, Global Compliance Training, Intercept Pharmaceuticals; Stanhope, NJ*

Carly Greenberg, JD, *Vice President, Risk Assessment, Monitoring, Governance & Legal Operations, Pfizer, New York, NY*

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

Clarissa Crain, *Managing Director, Life Sciences Regulatory, Compliance, and Legal Leader, Deloitte Consulting; Phoenixville, PA (Moderator)*

Mini Summit 30: Leveraging AI for More Efficient and Effective Investigations — INTERNATIONAL EAST

Legal, compliance, and investigations professionals are increasingly leveraging AI throughout the lifecycle of investigations. Not only do these tools drive cost and time efficiencies, but they also can help investigators get to the truth faster and with less business disruption. But at the same, deploying this technology can create risks if not done with appropriate care and planning. During this session we will:

- Offer practical and creative AI use cases (beyond the basics) throughout the investigation lifecycle, from intake to interviews to investigative output;
- Dig into legal issues presented by the use of AI in investigations, including how to avoid foot faults with respect to the attorney client privilege and attorney work product;
- Provide "watch-outs" or common mis-steps to avoid when leveraging AI tools in this context; and
- Consider how to leverage AI to not only respond to individual allegations, but also to use broader investigations data to identify trends

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

Mike D'Alessandro, CFE, CHC, CPA, *Senior Manager, Forensics & Integrity Services, EY; Former Chief Ethics and Compliance Officer, ahma Rx; Iselin, NJ*

Susana Franco, MBA, *Director, Field Compliance and Investigations, Lundbeck; Former Director of Compliance Operations, Orthofix; Dallas, TX*

Tracey Tran, CFE, RCA, *Senior Manager, Forensic and Integrity Services, EY; New York, NY*

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

Mini Summit 31: Compliance Considerations, Enforcements and Guidelines on Social Media Activities — GEORGETOWN EAST

As companies use social media to engage with patients, healthcare professionals and the public, legal and compliance teams must navigate evolving promotional rules and enforcement expectations. This discussion will explore practical considerations for reviewing social media content, managing employee and third-party activity, and responding when a post raises regulatory concerns.

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

Rosemary McKenna, JD, *Executive Director, Regulatory Legal, Organon; Former Director, Regulatory-Legal, Merck; Philadelphia, PA*

Joseph Philipose, JD, *Former Vice President, Chief Ethics and Compliance Officer, Emergent BioSolutions; Former Vice President, U.S. and Enterprise Compliance, Alexion Pharmaceuticals; Former U.S. Compliance Officer, Salix Pharmaceuticals; Boston, MA*

Gillian M. Russell, JD, *Counsel, Government Matters & Regulation; Washington, DC (Moderator)*

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Day 3 – 9:00 AM – 9:50 AM

Mini Summit 30: *Leveraging AI for More Efficient and Effective Investigations*

Featuring Latham Partner: **Erin Brown Jones**

Day 3 – 1:45 PM – 2:15 PM

Investigations, Enforcement and Prosecutions Roundtable

Featuring Latham Partner: **Jennifer Bragg**

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Mini Summit 32: Building a Compliance Roadmap: Practical Strategies for Scaling Compliance Programs — GEORGETOWN WEST

Building a compliance program is not a one-size-fits-all exercise. For life sciences companies navigating clinical/pre-commercial, commercialization, and growth stages, leaders must determine which risks require immediate attention, what elements are needed to address them, and how to build a roadmap that aligns compliance priorities with business objectives.

In this panel discussion, experienced compliance leaders from companies at different maturity stages will share practical approaches to developing and implementing compliance roadmaps that appropriately address the risk at your organization, including:

- Identifying and prioritizing risks across different stages of organizational growth
- Determining what and when program components are needed and how they should evolve over time
- Leveraging existing resources, AI, and cross-functional partnerships to enhance compliance effectiveness
- Balancing competing priorities and resource constraints while maintaining a risk-based approach
- Real-world examples and lessons learned from building and maturing compliance programs

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

Geeta Kaveti, MHA, JD, *Chief Compliance Officer & US General Counsel, Nyxoah; Former Vice President, Chief Compliance & Privacy Officer, Nevro; Former Division Counsel - Legal Regulatory & Compliance, Abbott; Vernon Hills, IL*

Fabiana Morette-Lattea, LLM, LLB, *Global Compliance Program Lead, Telix Pharmaceuticals; Former Associate Director, Compliance, Merck; Former Compliance Officer Europe and North America, Roche; Fishers, IN*

Meghan Naas, MA, *Senior Director, Head of Compliance, Innoviva Specialty Therapeutics; Former Head of Corporate Compliance, Adaptimmune; Former Senior Director, Global Operations and US Compliance Officer, Zai Lab; Waltham, MA*

Eric Ortman, MBA, *Senior Director, Legal Operations & Healthcare Compliance, 4D Molecular Therapeutics; Former Senior Director, Legal Operations, BeiGene; Former Director, Legal Operations, Ultragenyx Pharmaceutical; Walnut Creek, CA*

Adam T. Oakley, *Senior Director, Potomac River Partners; Washington, DC (Moderator)*

Mini Summit 33: Fair Market Value in Flux: Navigating Complex Fee Arrangements, HCP & Patient Engagement, and Influencer Compensation Risks — MONROE

Explore the evolving fair market value (FMV) landscape for healthcare professionals (HCPs), patients, and social media influencers with a focus on the unique market, regulatory, and compliance considerations that influence engagement strategies.

Key Details

- Examine the complexities of establishing FMV for HCPs and patients across markets with varying regulatory requirements, healthcare infrastructure, and economic conditions.
- Discuss challenges created by HCP scarcity, supply-and-demand dynamics, and market-specific restrictions that can affect engagement and compensation.
- Explore FMV considerations for social media influencers/digital opinion leaders, including the lack of standardized compensation benchmarks and platform variability.
- Review emerging compliance risks, including transparency and disclosure expectations, as well as heightened regulatory scrutiny over promotional versus educational content.

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

Sarah diFrancesca, JD, *Head of US Compliance – Immunology/Dermatology, Incyte; Wilmington, DE*

Erin B. Pulice, JD, *Litigation & Investigations Counsel, Medtronic; Minneapolis, MN*

Ravneet Talwar, MBA, *Senior Manager, Life Sciences & Healthcare Consulting Group, Paul Hastings; New York, NY*

Laura A. Skinner, MBA, *Managing Director, Life Sciences & Healthcare Consulting Group, Paul Hastings; Managing Director, Rare Disease Compliance Consortium; New York, NY (Moderator)*

Mini Summit 34: Future Proofing the Compliance Function: Operating Models for an AI-Enabled World — CABINET

As organizations navigate AI adoption, increasing regulatory expectations, and evolving business models, compliance leaders are reevaluating how their functions are structured and staffed. This session could explore emerging operating models, changing skill requirements, the impact of AI on compliance roles, and how organizations can position compliance teams for long-term success.

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

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*

Christian Dingler, CCEP, *Executive Director, Risk Management and Program Effectiveness, Insmed; Richmond, VA*

Christina Morris, *Senior Managing Director, FTI Consulting; Washington DC*

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

9:50 am **Networking Break in the Exhibit Hall** JEFFERSON-LINCOLN

MORNING MINI SUMMITS GROUP 7 (10:10 am – 11:00 am)

Mini Summit 35: Unstructured Data and Advanced Monitoring Strategies — INTERNATIONAL EAST

As communications expand across email, mobile devices, and social media, organizations need more sophisticated strategies for monitoring unstructured data and identifying emerging risks. This session will examine:

- Updating policies and procedures
- Using AI in monitoring programs and establishing appropriate governance
- Identifying common violations and areas for improvement
- Monitoring email, mobile devices, and social media
- Using monitoring results to identify training opportunities

Panelists will share practical approaches for strengthening monitoring programs and translating findings into meaningful compliance improvements.

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

Aaron Lewis, MBA, *Director, Legal and Compliance Operations, Cordis; Former Director, Compliance Insights and Technologies, Cardinal Health; Miami Lakes, FL*

Ron Strauss, *Vice President Compliance, MiMedx; Former Sales Leader, Osteo Specialty, Eli Lilly and Company; Marietta, GA*

Christina Woods, MHA, *Partner, Pharmaceutical and Life Sciences Risk & Regulatory Consulting, PwC; New York, NY*

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

Mini Summit 36: Leading Practices for Managing Investigations Panel — GEORGETOWN EAST

When a report drops, the first 72 hours can define the outcome—this panel will show you how leading organizations respond with speed, rigor, and control. Hear practical, real-world approaches to critical steps in the investigation process, such as preserving evidence and privilege, aligning quickly with counsel and governance teams, reporting out to the organizations, and using various tools and approaches to get to the facts faster. You'll leave with actionable ideas that you can tailor to enhance your investigation practices.

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

Amy Bentsen, JD, *Head of Investigations for Americas, Ethics & Compliance, Takeda; Cambridge, MA*

John S. Rah, JD, *Counsel and Head, Life Sciences Compliance Practice, Potter & Murdock; Potomac, MD*

Olga Zinavenka, CPA, MBA, *Head of Compliance Operations, Keenova; Former Executive Director, Head of Compliance Operations, Endo; Former Compliance Officer – Europe, Middle East and Africa; Paoli, PA*

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

Mini Summit 37: From Makary to Overton: Reflections and Predictions on the FDA's Priorities — MONROE

With a new FDA Commissioner announced in August and "micro" trends at the FDA continuing to shift every two to three months, this presentation tracks recent and rapidly evolving developments from peptides to tariffs. The discussion will evaluate where the agency stands today and what to watch considering the risks and opportunities likely to shape the life sciences industry in the coming months.

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

Dominick P. DiSabatino, JD, *Partner, Mayer Brown; Washington, DC*

Scott S. Liebman, JD, *Partner, Mayer Brown; New York, NY*

Mini Summit 38: Compliance Considerations for Rare Disease Products — INTERNATIONAL CENTER

Rare disease products present distinct compliance questions, from engaging with small patient communities to supporting education about conditions that may be difficult to diagnose. This discussion will explore practical approaches to patient and HCP engagement, interactions with advocacy organizations, and applying compliance principles when the patient population is small and relationships are especially close.

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

Cheryl Lee, MBA, *Head of Compliance, Cycle Pharmaceuticals; Former Vice President, ECG Strategy and Execution; Forner Vice President, Head of Compliance Worldwide Markets; New York, NY*

Daniel S. Murdock, MBA, JD, *Associate General Counsel, Sobi - Swedish Orphan Biovitrum AB (publ); Former Associate General Counsel - Life Sciences, McKinsey & Co; Former Assistant General Counsel, Indivior; Washington, DC*

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)*

Mini Summit 39: From Oversight to Partnership: Strengthening Collaboration Between Compliance and the Business — CABINET

Compliance and business functions share a common goal: enabling organizations to achieve their objectives responsibly and ethically. Yet too often, these functions operate in silos, creating friction, inefficiencies, and missed opportunities for collaboration. This panel discussion will explore how organizations can move from a traditional oversight model to a partnership approach that strengthens both business performance and risk management. Leaders from Compliance, Commercial Excellence, and Business Operations will share practical strategies for building trust, aligning objectives, leveraging data and analytics, and creating governance models that support informed decision-making. Attendees will leave with actionable insights for fostering stronger cross-functional partnerships and positioning Compliance as a strategic business partner that enables growth while maintaining appropriate oversight.

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

Jessica Constant, MS, *Associate Director, Compliance & Business Controls – US Oncology, AstraZeneca; Former Global Compliance Business Partner, QIAGEN; Washington, DC*

Edmund Greenidge JD, LLM, CCEP, *Senior Director, Compliance, Summit Therapeutics; Former R&D Ethics and Compliance Lead, Takeda; Former Vice; President, Corporate Compliance, Aclaris Therapeutics; Menlo Park, CA*

Angela Schwartz, JD, *Senior Principal, Global Commercial Compliance Consulting Leader, IQVIA; Former Special Assistant District Attorney, Montgomery County District Attorney's Office; Philadelphia, PA (Moderator)*

Mini Summit 40: Digital Ecosystem Considerations for Life Science Companies — GEORGETOWN WEST

Life Science Companies have increasingly developed complex digital ecosystems that underly their patient support programs, provider outreach, digital marketing, data analytics, and AI initiatives. This session will review regulatory and practical considerations related to overseeing and safeguarding these digital ecosystems. During this session we will speak specifically regarding state and federal regulatory updates, heightened IT security expectations, and litigation and enforcement trends.

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

Siyka Bozadjieva-Galiova, JD, *Global Data and Privacy Senior Advisor, Medtronic; Minneapolis, MN*

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)*

11:00 am **Transition Break**

MORNING MINI SUMMITS GROUP 8 (11:10 am – 12:00 pm)

Mini Summit 41: Enabled Technology can Transform Transactional Testing and Other Components of Your Monitoring Program — GEORGETOWN EAST

Disparate systems, unstructured and inconsistent data and documentation, lack of resources, geographic variability….all historic and real challenges to your compliance program, and specifically your monitoring program. Once anomalies and risk are identified, further assessment and testing are required. Historically, this is a manual process, conducted by valuable human resources and team members with limited bandwidth that need to focus on higher risk and impact matters. The use of data and technology is an expectation of our industry's regulators and leadership is continuously asking compliance teams to "do more with less." Compliance professionals need to start considering how automation and AI can be leveraged to enhance their programs. This session will discuss these issues and highlight real-world examples of how

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compliance and risk assurance functions are addressing these challenges. In this session, we will discuss:

- Current challenges including resources, organizational structure, and geo market variability
- Regulators' expectations around leveraging data, AI, and automation
- What are the core functions and/or components of your compliance program where automation and AI can play a significant role?
- How can technology modernize your transactional testing program?

11:10 am **Introductions, Discussions and Q&A**

Devin C. Bates, *Global Director, Compliance Operations, Danaher Life Sciences Platform, DH Life Sciences LLC, a Danaher Corporation subsidiary; Former, Director of Compliance, Walgreens; Chicago, IL*

Terri C. Segura, JD, *Global Chief Compliance Officer, LivaNova; Former Vice President, Compliance Officer – Americas; Chevy Chase, MD*

Angela Rodin, MBA, *Principal, Global Ethics, KPMG; Former Vice President, Global Head of Investigations and Monitoring, GSK; Washington, DC (Co-Moderator)*

Jordan Seiferas, MS, *Principal, Life Sciences Data Modernization, KPMG US; Columbus, OH (Co-Moderator)*

Mini Summit 42: Emerging Commercial & Market Access Risk in Life Sciences: Navigating Innovation, Compliance, and Evolving Access Models — MONROE

Review emerging compliance risks, including transparency and disclosure expectations, as well as heightened regulatory scrutiny over promotional versus educational content.

11:10 am **Introductions, Discussions and Q&A**

Stephanie Macholtz, JD, MBA, *Adjunct Faculty, Suffolk University Law School; Former Vice President, Healthcare Compliance, Organogenesis; Former Senior Director Global Compliance and Deputy General Counsel, Clinical Affairs, Apellis Pharmaceuticals; Cambridge, MA*

Juliana Jaccoud Molina, JD, LLM, CCEPI, *Global Compliance & Legal Executive, formerly Global Director, Compliance, Privacy, Governance, Third-Party Risk & Investigations, ZOLL Medical; Miami–Fort Lauderdale, FL*

Maria Villanueva, MBA, CFE, *Director, Ethics and Compliance, BioTissue; Former Vice President, Compliance Officer and Head of HR, Ra Medical Systems, Manufacturer of DABRA excimer laser system; Former Director, Compliance, Zimmer Biomet; Miami, FL*

Anthony S. Greco, MBA, *Managing Director, Pharmaceutical & Life Sciences Advisory Services, PwC; Philadelphia, PA (Moderator)*

Mini Summit 43: Effectively Leveraging Post-Investigation Mitigation to Create a Narrative of Continuous Improvement — INTERNATIONAL CENTER

In many investigations the focus is often on intentional or negligent conduct of individuals. In the long run; however, the ability to draw lessons learned for your compliance program and to make programmatic improvements in areas like policies, controls, training, and communications provides more value. This panel will explore best practices in managing and tracking programmatic mitigation, when to keep outside counsel involved, when to turn to other SMEs, and ultimately how to incorporate this work into a narrative of continuous improvement. The 2024 DOJ Guidance on Compliance programs expects programs to focus on continuous improvement as a measure of effectiveness. Currently, a lot of focus is around the front end, the use of AI and analytics to identify instances of non-compliance or programmatic gaps, but equal attention is required on the back end, the pull through of mitigation efforts, to be able to tell a convincing story of actionable evaluation of effectiveness.

11:10 am **Introductions, Discussions and Q&A**

Perri Pomper, JD, *Vice President, Compliance - Orthopaedics, Strategy & Education, Stryker; Former Vice President, Compliance & Legal Affairs, Clinical Genomics; Former Director, Ethics and Compliance Strategy & Education, Novo Nordisk; Mahwah, NJ*

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

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 44: Data Analytics & Compliance Monitoring in an AI-Powered World — GEORGETOWN WEST

Structured and unstructured data is ubiquitous throughout our organizations, as is the opportunity – and the expectation – for compliance officers to actively engage with company data while using it to assess risk, monitor trends, and identify areas of potential concern.

With so many functions, so much data, so many possibilities, and so little time – where do you even begin? And what does "good" look like? How might the data we are collecting and analyzing be used to advance compliance programs and prevent or reduce revenue leakage, and how might the insights that data brings create concerns in its own right, such as concerns regarding violations of FDA or DEA regulations, or implications of the FCA and AKS? What tools work well, and how can they be used most effectively? What are the implications of this harnessing and monitoring data-driven information in investigations and litigation?

This session will discuss a range of data analytics and monitoring tools and techniques ranging from the simple to the complex, and will examine case studies to illuminate the life cycle of structured and unstructured data capture, analysis and ongoing monitoring – in addition to insights into how this same data can be analyzed in reactive scenarios.

Session continued next page



11:10 am **Introductions, Discussions and Q&A**

Ignatius Grande, JD, *Of Counsel, Winston Taylor; New York, NY*

Omar S. Richardson, MBA, *Executive Director, Compliance, Shionogi; Former Compliance Officer, Grünenthal Group; New York, NY*

Roberta Rima, MS, *Vice President, Global Compliance Audit, Monitoring & Analytics, Zimmer Biomet; Former Senior Director, Head of Third Party & Corporate Compliance Audit, Gilead; San Francisco, CA*

Stephanie M. Lewko, CFE, *Managing Director, Healthcare Risk Management & Advisory, FTI Consulting; Washington, DC (Moderator)*

Mini Summit 45: Can Learning Data Reduce Risk? Using Measurement to Drive Defensible, Risk-Based Compliance Training — CABINET

Regulators and auditors are no longer satisfied with completion rates and pass scores — they want documented evidence that training actually changed behavior and reduced risk. This session focuses specifically on compliance training programs: how to use assessment data, role-based segmentation, and adaptive learning pathways to build defensible proof of competency — not just activity. Attendees will leave with practical strategies for connecting training outcomes to behavioral indicators, right-sizing learning investments by risk level, and producing the audit-ready documentation that holds up under DOJ and OIG scrutiny.

11:10 am **Introductions, Discussions and Q&A**

Adriana Davies, JSM, *Vice President Compliance and Privacy US and China, Smith+Nephew; Former Senior Program Director. Compliance Officer Surgical Innovations, Renal Care Solutions and Robotics, Medtronic; Former Regional Director Americas Ethics and Compliance & Group Corporate Programs, Terex Corporation; Jacksonville, FL*

A.D. Detrick, CPTM, *Measurement & Analytics Consultant, Tier1 Performance; Covington, KY*

Jaya Saigal, *Senior Director, Compliance Training, Revolution Medicines; Former Senior Director, C&E Policy, Education, Communications, Culture of Integrity and Ombuds, Bristol Myers Squibb; Redwood City, CA*

Lily Zimmerman, *Learning Solution Architect, Tier1 Performance; Covington, KY (Moderator)*

Mini Summit 46: AI in Clinical Practice: Compliance, Governance & FDA Oversight — INTERNATIONAL EAST

Regulation of AI in Clinical Practice, Including Clinical Decision Support Tools, Documentation, FDA Clearance Requirements, and Provider Credentialing Considerations

11:10 am **Introductions, Discussions and Q&A**

Jim Foote, MBA, CISSP, *Chief Executive Officer, First Ascent Biomedical; Board Member, Sepire; Board Member, NETRAVINE; Principal Security Advisor, The CSO Advisors; Beaverton, OR*

Julie K. Taitsman, MD, JD, *Managing Director, BDO, US; Former Chief Medical Officer, Office of Inspector General (OIG), US Department of Health & Human Services; Former Special Counsel for Health & Science, United States Senate Committee on Finance; Washington, DC*

Georgia Ravitz, JD, *Partner, FDA & Healthcare Regulatory, Orrick, Herrington & Sutcliffe; Washington, DC; (Moderator)*

12:00 pm **Networking Luncheon**

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12:00 pm **Networking Luncheon with Dessert and Coffee in the Exhibit Hall** — JEFFERSON-LINCOLN

LUNCHEON MINI SUMMITS GROUP 9 (12:10 pm – 1:00 pm)

Pickup your box lunch in the Exhibit Hall and take it to the Luncheon Mini Summit room of your choice.

Mini Summit 47: Direct-to-Consumer (DTC) Models in the Pharmaceutical Space — GEORGETOWN WEST

- Discuss different DTC program models
- Provide an overview of recent OIG guidance and key laws and regulations impacting DTC programs
- Discuss compliance risk considerations related to execution of DTC programs with pharmacies, telehealth providers and other partners

12:10 pm **Introductions, Discussions and Q&A**

Kala Shankle, JD, *Vice President, Regulatory Affairs, Healthcare Distribution Alliance; President Elect, American Society for Pharmacy Law; Washington, DC*

Alison J. Fethke, JD, *Member of the Firm, Epstein Becker Green; Former Division Counsel, Legal Regulatory & Compliance, AbbVie; Chicago, IL (Moderator)*

Mini Summit 48: ROI of AI: Separating Value from Hype — CABINET

AI has rapidly become a strategic priority across organizations, but the path from adoption to measurable value remains uneven. Many teams are piloting tools, investing in platforms, and exploring use cases, yet fewer can clearly articulate where AI is delivering sustained ROI.

This discussion will focus on separating high-value AI applications from hype-driven initiatives. Participants will share how their organizations are measuring success, what metrics they are using, which use cases are producing tangible impact, and where AI has fallen short of expectations.

- Difference definitions of ROI for AI
- Measuring Value in quantitative and qualitative terms
- Creating value while avoiding AI overload and fatigue
- Continued success with and without AI

12:10 pm **Introductions, Discussions and Q&A**

Michelle Dineen Jerrett, JD, *Regional Head of Investigations & Monitoring, North America, Sanofi; Former Legal Director, Endoscopy, Boston Scientific; Former Assistant United States Attorney, US Attorney's Office, District of Massachusetts; Cambridge, MA*

Stephanie Macholtz, JD, MBA, *Adjunct Faculty, Suffolk University Law School; Former Vice President, Healthcare Compliance, Organogenesis; Former Senior Director Global Compliance and Deputy General Counsel, Clinical Affairs, Apellis Pharmaceuticals; Cambridge, MA*

Omar S. Richardson, MBA, *Executive Director, Compliance, Shionogi; Former Compliance Officer, Grünenthal Group; New York, NY*

Katie Jacyna, *Chief Product Officer, HELIO; Denver, CO (Moderator)*

Mini Summit 49: Lean, Credible, Defensible: Compliance Programs That Work Without Big Budgets — INTERNATIONAL EAST

Building an effective compliance program does not always require a large team or budget. This session will explore practical, low-cost strategies for creating a risk-based compliance program that is credible, sustainable, and responsive to regulatory expectations. Panelists will discuss how organizations can prioritize limited resources, focus on high-impact activities, and demonstrate that their compliance programs are working effectively.

12:10 pm **Introductions, Discussions and Q&A**

Loren Becher, MPH, *Executive Director, Ethics & Compliance, Knoa Pharma; Former Senior Director, Quality, Ethics, Compliance & Risk Enterprise Programs, Emergent BioSolutions; Former Director, Compliance Operations & Planning, AstraZeneca; Rye Brook, NY*

Julian Gabbard, JD, *Associate General Counsel, Meso Scale Diagnostics; Former Head of Legal and Compliance, Corporate Counsel, Kolon TissueGene; Former Senior Director, Arcellx; Washington, DC*

Elizabeth R. Weiss, JD, *Vice President, Chief Compliance & Privacy Officer, Invivyd; Former Head of Compliance for Americas & EMEA, Lupin; Former Senior Director, US Risk and Compliance, LEO Pharma; Former Assistant General Counsel, Compliance Lead, Global Health & Patient Access, Pfizer; Livingston, NJ*

Robert A. Wells, JD, *Health Care Regulatory Shareholder, Chair, Health Law and Government Solutions, Baker, Donelson, Bearman, Caldwell & Berkowitz; Baltimore, MD (Moderator)*

Mini Summit 50: A Look Under the Hood: Exploring PBM and Payer Arrangement Risks and Emerging Reporting Requirements — MONROE

PBM and payer arrangements face increasing scrutiny as federal and state authorities focus on drug pricing, rebates, and transparency. This session will examine:

- Federal and state scrutiny of PBMs and their financial relationships with manufacturers
- Manufacturer, PBM, and prescription drug plan arrangements and the flow of funds
- Auditing and monitoring strategies for channel partner arrangements
- The intersection of these arrangements with drug pricing reforms
- Emerging PBM reporting requirements involving formularies, pricing, and manufacturer arrangements
- Implications for Market Access interactions and formulary negotiations

Panelists will share practical considerations for evaluating these complex arrangements as part of a broader compliance risk-management strategy.

12:10 pm **Introductions, Discussions and Q&A**

Daryl Berke, JD, *Assistant General Counsel, Specialty US Market Access Lead, Sanofi; Washington DC*

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*

Andrew Bonasera, MS, CFE, *Senior Managing Director, FTI Consulting; Washington, DC*

Katherine C. Norris, MPA, *Senior Managing Director, Healthcare Risk Management & Advisory, FTI Consulting, Washington, DC (Moderator)*

Mini Summit 51: Collaborating to Create Lasting Solutions During and After Monitoring or Investigations — GEORGETOWN EAST

When monitoring or investigatory teams come back with findings, frequently there is a wish to manage the response narrowly rather than taking the more challenging step of identifying and addressing the root cause. The presentation will discuss strategies and practicalities of collaborating across compliance and business teams during and after monitoring and investigations. The presentation will cover collaboration within compliance, collaboration with the business, and managing both mundane and higher risk findings—all with the goal of creating lasting results. It will include audience interaction. Presenters have served in both business partnering and monitoring/ investigatory roles and have managed internal and external investigations.

12:10 pm **Introductions, Discussions and Q&A**

Katherine "Kate" Dyson, JD, *Head of US Compliance, Alexion Pharmaceuticals; Former Head of Assurance, Alexion, AstraZeneca RDU; Former Senior Director, Neurology Compliance Business Partner; Alexion Pharmaceuticals; Boston, MA*

Naveen Ganesh, MA, JD, *Vice President, Global Head of Investigations, Ethics & Compliance, Takeda; Former Head of Investigations & Monitoring, North America & Global Specialty Care, Sanofi; Former Compliance Assurance & Investigations (Lead), Verily;; Boston, MA*

Kathryn Harris, JD, *Head of US Compliance, Galderma; Former Senior Director, Global Compliance, Emergent BioSolutions; Former Compliance Business Partner (Market Access, Patient Services, and Strategic Accounts); Alexion Pharmaceuticals; Boston, MA*

Audrey DeGuarde, MSJ, *Vice President, General Manager, Commercial Compliance Solutions, Medispend; Morristown, NJ (Moderator)*

Mini Summit 52: Annual FDA Office of Prescription Drug Promotion Update — INTERNATIONAL CENTER

This session will explore the evolving compliance landscape for drug advertising and promotion from the perspective of Twyla Mosey, the Director of the Office of Prescription Drug Promotion ("OPDP"), US Food and Drug Administration. The discussion will examine enforcement trends, including the surge in warning and untitled letters since the administration's "crackdown" on deceptive drug advertising announced in September 2025, as well as OPDP's current priorities and areas of focus. The discussion will provide practical guidance for companies on responding to OPDP enforcement letters, engaging constructively with OPDP, and strengthening compliance processes to mitigate advertising and promotion risk.

12:10 pm **Introductions, Discussions and Q&A**

Twyla Mosey, PharmD, RPh, *Director, Office of Prescription Drug Promotion, US Food and Drug Administration, Washington, DC*

Joshua (Josh) Oyster, JD, *Partner, Life Sciences Regulatory & Compliance Practice, Ropes & Gray; Former Counsel, Humana; Silver Spring, MD (Moderator)*

1:00 pm **Transition Break**

CLOSING PLENARY SESSION

INTERNATIONAL CENTER

1:10 pm **Welcome and Introduction**



Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

1:15 pm **Keynote Annual DOJ Civil Division Update Fireside Chat**



Brenna Jenny, JD, MPH, *Deputy Assistant Attorney General, Commercial Litigation Branch, Civil Division, US Department of Justice; Former Principal Deputy General Counsel & Chief Legal Officer, Centers for Medicare & Medicaid Services, US Department of Health and Human Services; Washington, DC*



Interviewed by:
Scott A. Memmott, JD, *Partner, Morgan, Lewis & Bockius LLP; Former Special Assistant US Attorney, Criminal Division, US Attorney's Office, Eastern District of Virginia and Former Trial Attorney, US Department of Justice, Civil Division, US Department of Justice; Washington, DC*

1:45 pm **Investigations, Enforcement and Prosecutions Roundtable**



Jennifer L. Bragg, JD, *Partner, Latham & 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*



Preeya Noronha Pinto, JD, *Partner, DLA Piper; Former Acting General Counsel, US Department of Health and Human Services; Washington, DC*



Kip F. Ebel, MBA, *Principal, Forensic & Integrity Services, EY; New York, NY (Moderator)*

2:15 pm **Updates from AdvaMed, BIO and PhRMA**



John Delacourt, JD, *Deputy General Counsel, Biotechnology Innovation Organization; Former Chief Antitrust Counsel, Office of Policy Planning, US Federal Trade Commission; Washington, DC*



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



Julie Ritchie Wagner, JD, *Assistant General Counsel, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US Department of Health and Human Services; Washington, DC*



Mark C. Scallon, MHA, *Principal, Risk Advisory, Life Sciences Consulting, Compliance and Ethics Market Leader, Baker Tilly; Richmond, VA (Moderator)*

2:45 pm **Market Access in 2026 and Beyond: A Shifting Compliance Landscape**







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

Christian Scognamillo, JD, *Associate General Counsel, US Market Access & Pricing, Abbvie; Former Senior Corporate Counsel, Market Access & Commercial Transactions, Exelixis; Former Senior Director, Legal, Access & Transactions, Alnylam, San Francisco, CA*

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

3:15 pm **Networking Break in the Exhibit Hall** JEFFERSON-LINCOLN



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3:45 pm **Burgeoning Compliance Risks**



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



Jennifer Dubas, JD, *Chief Ethics and Compliance Officer, Jazz Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Cencora; Former Senior Vice President, Chief Compliance Officer, AmerisourceBergen; Ambler, PA*



Shannon Kelley, JD, *Executive Vice President, Chief Legal Officer, Madrigal; Former Vice President, Head of Compliance; North America and Global Specialty Care GBU, Sanofi; Former Assistant US Attorney & Deputy Chief of Litigation, US Attorney's Office District of Massachusetts; Boston, MA*



John S. Rah, JD, *Counsel and Head, Life Sciences Compliance Practice, Potter & Murdock; Potomac, MD*



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 **AI and the Evolving Compliance Function**



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



Jennifer Dubas, JD, *Chief Ethics and Compliance Officer, Jazz Pharmaceuticals; Former Senior Vice President, Chief Compliance Officer, Cencora; Former Senior Vice President, Chief Compliance Officer, AmerisourceBergen; Ambler, PA*



Rebekah Latchis, JD, *Vice President, Risk Intelligence & Investigations, Office of Privacy, Integrity & Compliance, Medtronic; Former Corporate Responsibility Director, Bon Secours; Washington, DC*



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

4:45 pm **Managing Risk in Unsettled Times**



Deborah A. Curtis, JD, *Partner & Co-Chair, White Collar Defense & Investigations Practice, Arnold & Porter; Former Deputy General Counsel, Central Intelligence Agency; Former Deputy Chief, Counterespionage Section, National Security Division, US Department of Justice; Former Deputy Chief, National Security Section, District of Columbia US Attorneys' Office; Washington, DC*



Ambassador Barbara A. Leaf, JD, *Senior International Policy Advisor, Arnold & Porter; Former Special Assistant to the President and Senior Director for the Middle East and North Africa; Former Assistant Secretary of State for Near Eastern Affairs, and Former US Ambassador to the United Arab Emirates, US State Department; Washington, DC*



Forrest Deegan, JD, *Principal Consultant, Spark Compliance Consulting, a Diligent brand; Co-Chair, Corporate Compliance & Ethics Subcommittee, Business Law Section, American Bar Association; Former Chief Ethics and Compliance Officer, Abercrombie & Fitch and Victoria's Secret; Columbus, OH (Moderator)*

5:15 pm **ADJOURNMENT**



Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*

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

PCF INDUSTRY-ONLY COMPLIANCE BEST PRACTICES THINK TANK

INTERNATIONAL CENTER

8:00 am **Welcome and Introductions**



Donna White, CCEP, *Vice President, Compliance Officer, Americas Region, Chiesi USA; Cary, NC (PCF Board Chair)*

Antitrust Admonition



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

8:10 am **Inside the New DOJ Initiative: The Rising Importance of Data Miners**

Data mining is becoming an increasingly important tool in healthcare enforcement, enabling the analysis of large public datasets to identify statistical anomalies, hidden patterns, and potential False Claims Act violations. This panel will examine how data-driven allegations may originate and evolve, what these developments mean for compliance teams, and practical steps organizations can take to strengthen monitoring, documentation, and response readiness. Panelists will offer perspectives from DOJ enforcement, economic and data analysis, pharmaceutical investigations, and FCA litigation.



Featuring:
Corey R. Amundson, JD, *Partner, Special Matters & Government Investigations Practice Group, King & Spalding; Former Head, Public Integrity Section, US Department of Justice; Former Acting US Attorney, Middle District of Louisiana; Washington, DC*



Andrée-Anne Fournier, MA, *Managing Principal, Analysis Group; Brookline, MA*



Mark A. Jensen, JD, *Co-Chair & Partner, Special Matters & Government Investigations, King & Spalding; Washington, DC*

8:45 am **Wins & Losses in the Early Days of AI – Audience Discussion Session**

AI has entered compliance workflows with remarkable speed—and with uneven results. Some teams are already seeing meaningful efficiency gains, while others are wrestling with adoption challenges, accuracy concerns, governance gaps, or cultural resistance.

We'll discuss early wins, early failures, and real-world lessons learned from attendees implementing AI in compliance programs. This is a candid, practical discussion about what's working, what isn't, and how organizations are navigating the realities of building AI-enabled compliance functions. Come prepared to share!



Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*



Donna White, CCEP, *Vice President, Compliance Officer, Americas Region, Chiesi USA; Cary, NC (PCF Board Chair)*



Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

9:15 am **Benchmarking and Q&A Forum**

Opportunity for polling, asking questions, and benchmarking against peers for valuable insights. Come prepared with questions!



Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*



Donna White, CCEP, *Vice President, Compliance Officer, Americas Region, Chiesi USA; Cary, NC (PCF Board Chair)*



Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

10:00 am **Networking Break**

10:20 am **Customer-Centric Complexity: Meeting Customer Needs While Balancing Field Pressures**

Customer expectations and field realities are shifting faster than traditional governance models can absorb. Field teams are navigating mounting office restrictions, expanding reimbursement responsibilities, role overlapping, emerging roles, and an escalating need for data, all within the constraints of firewalls and privacy requirements. Panelists will discuss how organizations can modernize governance to keep pace, enabling coordinated, compliant, and customer-centric engagement amid accelerating change. Drawing on diverse real-world experiences, panelists will share practical perspectives, including frontline field insights, on navigating these shifts and balancing customer needs with organizational realities.



Michelle Murphy, *Executive Director, Compliance, Regeneron; New York, NY*



Denis Jacob, *Ethics & Compliance Americas Regional Leader, Solventum; Former Ethics & Compliance Business Partner, Orthopedics, Henry Schein; Former Head of Compliance Audit and Investigations, GE; New York, NY*



George Kuri, *Former Area Business Leader, Novartis Oncology; Former District Sales Leader, Uro-Oncology/GI, Ferring Pharmaceuticals; Atlanta, GA*



Laura E. Heyduk, *Vice President, Head of Global Compliance, KalVista Pharmaceuticals; Former Head of US Compliance, Biogen; Former Compliance Director, Healthcare Compliance, Insulet Corporation; Cambridge, MA (Moderator)*

11:00 am **Breakout by Company Size: "Cross-Functional Account Planning & Guardrails"**

Participants will break into company-size peer groups to share experiences and discuss approaches to cross-functional account planning and collaboration. Discussions will focus on the roles and responsibilities of key stakeholders, the types of information that may be appropriately shared across functions, and the guardrails organizations employ to balance effective business collaboration with regulatory and compliance requirements. This session will provide an opportunity to benchmark practices, exchange lessons learned and discuss common challenges with peers from similar sized organizations.



Tara Shewchuk, JD, LLM, *Senior Vice President, Chief Privacy, Integrity & Compliance Officer, Medtronic; Minneapolis, MN (Pharma Congress Medical Device Executive Committee)*

11:30 am **Last Minute Questions and Benchmarking**



Anisa Dhalla, *Vice President, Chief Ethics and Compliance Officer; Global Head, Ethics and Compliance, UCB; Atlanta, GA (PCF Board Member)*

Noon **CONGRESS ADJOURNMENT**

PHARMA CONGRESS CONFERENCE APP INSTRUCTIONS

New features have been added to the Conference App for 2026. This instruction sheet is designed to help you navigate the app and its features.



HOME SCREEN

The first time you log onto the app be sure to click the check mark icon. This is where you can edit your privacy and settings.



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Your contact information is **NOT** visible to anyone until you accept a connection with them OR allow them to scan your QR code.

Your QR code can be scanned in 2 ways: from your badge (at close range) or if you show them your code from within your app.

The apps' privacy options default to allowing your connections to see all contact information provided when you registered. Edit fields you wish to be visible or opt out. **We recommend you review your options as soon as you download the conference app.**





EDIT PRIVACY SETTINGS

From here you can edit contact information shared with other attendees when you agree to a connection or permit your QR Code to be scanned. **We recommend you review your options as soon as you download the conference app.**

To prevent a field from being visible simply deselect it.

To opt out fully click on the second Virtual Name Badge option that shows your first name and last initial. Once this is selected your contact details are hidden. If you opt out, you will not be able to search for, chat/live chat, schedule meetings, or make connections through Meeting Hub or by scanning QR codes.

Scroll down below your contact information to add a short bio, switch to Do Not Disturb, or add social media accounts.

If you make changes to your Privacy & Settings page you must scroll to the bottom of the page and click UPDATE or your changes will not take effect.



Tap for your unique QR Code. **You must be in the app to scan QR Codes.** Your QR Code can also be found in Meeting Hub/Scan.

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To connect with an attendee through the app, tap the green circle to the right of their name. The app will send them a connection request. The circle will turn white with an x beside the user icon. When the attendee accepts the request, the x will change to a check mark.



Scan an attendee's QR Code

Click to scan another attendee's badge/QR Code.

To see their contact information tap Connections in Meeting Hub.

Click to have your QR Code scanned. Once your code is scanned the information checked in your Privacy & Settings page will be shared with them.



CHAT/LIVE CHAT/ MESSAGING

Chat is the app's text messaging between two **connected** attendees.

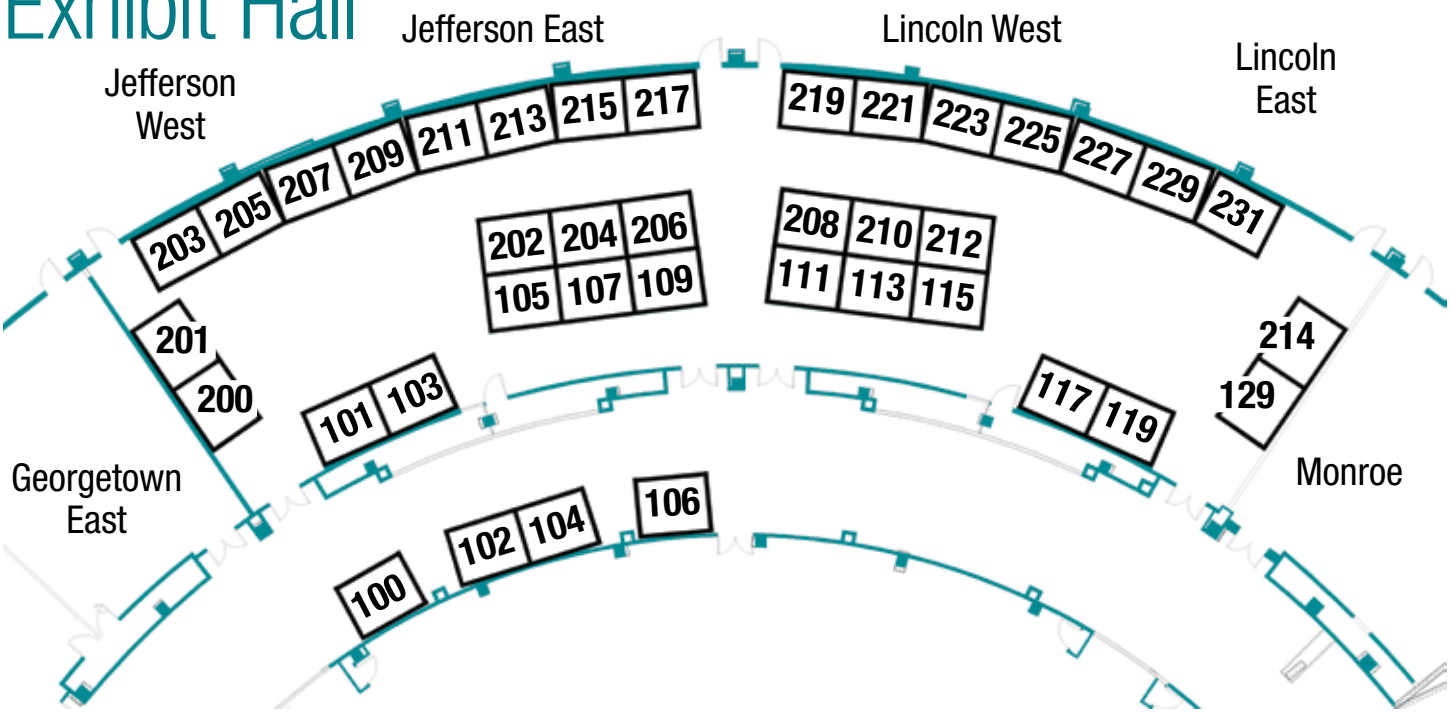
MESSAGING – text messaging between two unconnected attendees.

LIVE CHAT – Messaging between two connected attendees. The message will pop up on the attendee's screen. A timer will give you 10 seconds to respond. If no response is provided the timer stops.

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Exhibit Hall



Exhibitor	Booth
Ankura Consulting Group	107
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Baker Tilly	221
Barnes & Thornburg	106
BCG	129
CaseIQ	103
Cresen Solutions	211
Cutting Edge Information	115
Deloitte	109
Dovetail Consulting Group	209
Ethical Paths	214
FTI Consulting	210

Exhibitor	Booth
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HELIO	105
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Medispend	219
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Porzio Bromberg & Newman	204
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Wednesday, October 14

Exhibit Hall Opens/Networking Breakfast	**7:00 am – 8:00 am**
Networking Break	**9:50 am – 10:10 am**
Networking Luncheon	**12:00 pm – 1:15 pm**
Networking Break	**3:30 pm – 4:00 pm**
Networking Reception	**5:45 pm – 6:45 pm**

Thursday, October 15

Exhibit Hall Opens/Networking Breakfast	**7:00 am – 8:00 am**
Networking Break	**9:50 am – 10:10 am**
Networking Luncheon	**12:00 pm – 1:00 pm**
Networking Break	**3:15 pm – 3:45 pm**