Virtual Fourteenth International Pharmaceutical and Medical Device Ethics and Compliance Congress

GHC LIFE SCIENCES
Global Health Care, LLC

Virtual Online Video Live and Archived
www.internationalpharmacongress.com

June 14 – 17, 2021
All Times are CET

DAY I: MONDAY, JUNE 14, 2021

OPENING PLENARY SESSION

10:30 am **Co-chair Welcome and International Pharmaceutical and Medical Device Ethics & Compliance Congress Vision and Overview**

10:45 am **Keynote Address**

Hani Abouhalka, MBA, *Company Group Chairman, Medical Devices EMEA, Johnson & Johnson, New Brunswick, NJ, USA*

11:15 am **ETHICS Keynote Roundtable on Ethics and Compliance Lessons Learned from COVID-19**

Anne-Sophie Bricca, *Deputy General Counsel & Senior Director Legal Affairs & Compliance, Terumo BCT Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Chair, Ethics and Compliance Group MedTech Europe, Brussels, Belgium*

Stephen Nguyen Duc, *Vice-President, Global Head of Human Resources and Ethics & Compliance, Medday Pharmaceuticals; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Dominique Laymand, Esq., *Executive Vice President, Chief Ethics and Social Responsibility Officer, Ipsen; Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Roeland Van Aelst, *EMEA Lead, Third Party Intermediary, Ethics & Compliance, Johnson & Johnson; President, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Europe Code Committee, Brussels, Belgium*

N. Craig Smith, *Chaired Professor of Ethics and Social Responsibility, Academic Director of ESRI (the INSEAD Ethics and Social Responsibility Initiative), and Programme Director for the Healthcare Compliance Implementation Leadership Programme, INSEAD Fontainebleau, France (Discussion Coordinator)*

12:30 pm **Luncheon Break/Visit Exhibit Hall**

1:00 pm **Senior Ethics & Compliance Professionals Roundtable**

Adam Dubow, JD, *Senior Vice President, Chief Compliance and Ethics Officer, Bristol-Myers Squibb, Princeton, NJ, USA*

Mwana Lugogo, JD, MPP, *Chief Ethics and Compliance Officer, Takeda Pharmaceuticals International GmBh, Zurich, Switzerland*

Pascale Schmidt, *Chief Compliance Officer and Chair, Corporate Sustainability Committee, F. Hoffmann-La Roche Ltd, Basel, Switzerland*

Trudy Tan, *Global Head Ethics, Risk & Compliance, Pharma, Novartis; Former Vice President Compliance, International, AstraZeneca, Basel, Switzerland*

Mariusz Witalis, *Partner, Forensic & Integrity Services, EY, Warsaw, Poland (Discussion Coordinator)*

2:15 pm **Day I Plenary Session Adjournment/ Transition Break**

AFTERNOON MINI SUMMITS:
MINI SUMMITS ROUND I **2:30 pm – 3:30 pm**

MINI SUMMIT 1: Ethics and Compliance Considerations for Small to Mid-sized Organizations

Join industry leaders as they share insights and actions to help navigate the unique ethics and compliance-related challenges and opportunities that come with working at small to mid-sized life sciences organizations.

- Required modifications to ensure continuity of the ethics and compliance program in a quickly changing environment presented by the pandemic.
- Discuss challenging aspects of building ethics and compliance programs while building a growing company and how those challenges evolved during the pandemic.
- Identify practical tools to rely on when building programs under resource constraints, such as data analytics.
- Guidance on how to keep teams motivated during the pandemic.
- Insight on how to ensure that ethics and compliance has a seat at the table in rapidly evolving businesses and changing risk profiles.
- Modifications to ethics and compliance programs to adapt to the rapid shift towards virtual engagement.
- Best practices on how to adapt ethics and compliance programs to address risks arising from social media activities or interactions with patient influencers.
- Discuss priorities as organizations enter a "new normal" business environment.

2:30 pm **Introductions, Panel Discussion and Q&A**

Kalwant Dhindsa, CIPP/E, CCEP, *Compliance Director, Convatec; Former Senior Corporate Compliance Counsel, Bayer, Reading, UK*

Rosa Magistri, CIPP/E, *Head of Legal and Compliance Europe, SeaGen International GmbH; Former Regional Director Office of Ethics and Compliance, Western Europe & Canada, Region South & Israel, AbbVie; Former Associate Compliance Director, Shire, Zug, Switzerland*

Chrisoula Nikidis, LL.L., *Head of Ethics and Compliance, Takeda Canada; Former Vice President, Ethics, Integrity, & Governance, Innovative Medicines Canada, Toronto, Canada*

Madina Torchinova, JD, *Vice President, Head Global Compliance, MorphoSys; Former Regional Head of Compliance, Central & Eastern Europe, Middle East & Africa, and Global OTC, Sandoz, Munich, Germany*

Mario Prohasky, *Principal, EMEA Compliance Consulting Lead, IQVIA, London, UK (Discussion Coordinator)*

All Times are CET

MINI SUMMIT 2: Annual Medical Device Compliance Roundtable

From a medtech industry perspective, the pandemic raised many new questions on how to deal with virtual aspects (e.g., audits/controls) that could not be addressed by existing rules and codes. Ethics and compliance professionals from pharma and medical device industries and trade associations share challenges & opportunities that resulted, including:

- Changes between industries and health care professionals resulting from virtual interactions.
- Revisions to Advamed and MedTech Europe codes focusing on the impact of the Special Fraud Alert and scrutiny of in-person events, the resulting impact internationally, and differences between pharma and medtech industries (i.e., product & procedure trainings).
- Expected changes in the upcoming MedTech Europe code revision.
- Ethics and compliance by third-party intermediaries (i.e., distributors).
- New ways of approaching interactions with distributors (e.g., toolkit, hybrid training)
- The merge between EFPIA's e4ethics platform and MedTech Europe's Conference Vetting System (CVS) followed by a discussion on the practical impact on companies and lessons learned from which pharma companies can glean best practices.

2:30 pm **Introductions, Panel Discussion and Q&A**

Aline Lautenberg, LLM, *General Counsel, Director Legal & Compliance, MedTech Europe, Brussels, Belgium*

Laetitia Thevenon, *Compliance and External Collaboration Manager EMEA, ResMed; Former Chair, Compliance Committee, SNITEM, Lyon, France*

Nancy S. Travis, MS, *Vice President, Global Compliance and Governance, Advanced Medical Technology Association (ADvaMed), Washington, DC, USA*

Roeland Van Aelst, *EMEA Lead, Third Party Intermediary, Ethics & Compliance, Johnson & Johnson; President, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Europe Code Committee, Brussels, Belgium*

Fabien Roy, *Partner, Hogan Lovells, Brussels, Belgium (Discussion Coordinator)*

MINI SUMMIT 3: Best Practices for Ethics and Compliance Training

Rob Stephenson, Director, PwC, and industry ethics and compliance professionals share their thoughts and experiences on current and future trends in ethics and compliance training. Often times, compliance training in any organisation is considered a mandatory tick the box exercise. But compliance training and more recently ethics and compliance training is such a core component of any compliance program and is key in promoting not just compliant practices, but ethical behaviours and decision making across an organisation. The panel will address best practices in ethics and compliance training, key considerations, and how to engage the business in this crucial training with something that resonates and is memorable.

2:30 pm **Introductions, Panel Discussion and Q&A**

Signe Elbæk, JD, LLM, *Visitor Researcher, Faculty of Law, University of Copenhagen; Former Group Chief Compliance Officer, Coloplast; Former Vice Chair, Ethics and Compliance Committee and Member of the Code Committee, MedTech Europe; Former Compliance Manager, Attorney, Dako Denmark A/S; Copenhagen, Denmark*

Nicola Giovinazzi, EMBA, *Corporate Compliance Director, Menarini Group; Former Compliance and Ethics Lead Italy, Switzerland, and Austria, Bristol-Myers Squibb, Florence, Italy*

Bella Rafael Hovannisyan, *Chief Ethics & Compliance Officer, CSL Group; Former Compliance & Ethics Lead, Spain & Portugal, Russia & Turkey, Bristol-Myers Squibb; Berne, Switzerland*

Nadège Rochel, CCEP-I, *Global Compliance Manager, Hollister Incorporated, Milan, Italy*

Robert Stephenson, *Director, PwC UK, London, UK (Discussion Coordinator)*

MINI SUMMIT 4: Analytics and Behavioral Science in Successful Compliance Programs

Join us for a unique panel that will go beyond the laws, regulations and enforcement risks confronting the industry — by focusing, instead, on the human elements of compliance. The panelists (all of whom are practicing experts and thought leaders in compliance analytics and behavioral science) will start by defining key terms and "buzz words," and then transition into a discussion about the value proposition for a data-driven and human-centered approach to compliance and risk management. Finally, the panel will describe specific use cases from the pharmaceutical and medical device industry, offer their thoughts on how to overcome common challenges in this space, and provide predictions for how analytics and behavioral science will shape the future of compliance.

2:30 pm **Introductions, Panel Discussion and Q&A**

Amanda Bunten, DPsych, *Chartered Health Psychologist; Director of Behavioral Ethics, GlaxoSmithKline;Former Principal Behavioural Insights Advisor,Public Health England, London, UK*

Caitlin Handron, PhD, *Senior Lab Consultant and Behavioral Scientist, R&G Insights Lab, Ropes & Gray LLP, Silicon Valley, CA*

Tara Palesh, MS, *Senior Director, Compliance Analytics Lead, Pfizer, New York, NY, USA*

Sapan Singh, MBA, *Senior Director Compliance, Stryker Corporation, Mahwah, NJ, USA*

Zachary N. Coseglia, JD, *Managing Principal and Head of Innovation, R&G Insights Lab, Ropes & Gray, LLP, Boston, MA, USA (Discussion Coordinator)*

MINI SUMMIT 5: Annual Central and Eastern Europe (CEE) Compliance Best Practices Update

Join ethics and compliance professionals as they share their views on the most recent compliance developments in Central and Eastern Europe (CEE).

How the best manage this large and complex region? What are the business and compliance structures observed for companies operating in CEE? What was the impact of Covid-19 on compliance risks and culture in the region? What were the latest regulatory and enforcement activities in Russia and the CIS? What is the impact of the upcoming EU Whistleblower Directive on investigations in CEE? Does it change the long-standing perception on whistleblowers in the region? What are the expectations from compliance professionals in CEE for the next 6 to 12 months? What should they prioritize?

All of these and other questions will be addressed by the panel which would provide unique perspectives on CEE both from in-house ethics and compliance leaders responsible for global and EMEIA functions, deeply experienced in the region and local and regional industry experts specializing in advising life sciences companies operating in CEE.

2:30 pm **Introductions, Panel Discussion and Q&A**

Chelsea M. Keeton, JD, *Director and Senior Counsel, Global Compliance Investigations, Zimmer Biomet; Former Group Ethics & Compliance Counsel, VEON, Amsterdam, Netherlands*

Tomasz Kruk, LLM, MBA, *Head of Compliance, Vifor Pharma; Former Director International Compliance, Mallinckrodt; Former Director Global Ethics & Compliance, Actavis, Zürich, Switzerland*

Leonardo Silva, LLM, *Vice President, Global Chief Compliance & Privacy Officer, Ferring Pharmaceuticals; Former Head of Compliance, Acino Group, Acino International AG; Former Compliance Director, Emerging Markets, Takeda, Lausanne, Switzerland*

Paul J. Melling, JD, *Founding Partner, Baker & McKenzie, CIS, Limited, Moscow, Russia (Co-Discussion Coordinator)*

Mariusz Witalis, *Partner, Forensic & Integrity Services, EY, Warsaw, Poland (Co-Discussion Coordinator)*

All Times are CET

INTERACTIVE ZOOM VIDEO WORKGROUPS

3:30 pm – 4:30 pm

(Attendee may join any Discussion Session. The first 25 attendees will participate via video and audio. Attendees joining thereafter will participate in video/listen-only mode and engage via text chat and Q&A. Attendees may move among the various concurrent discussion sessions.)

Topic I: Practical Ways to Apply Behavioral Science to Foster Compliance Programs and Culture

Build practical understanding of cognitive biases to leverage or mitigate based on their potential to:

- Positively influence compliance in your organization
- Promote deliberate thinking when navigating gray areas and risks
- Identify behaviors that compliance professionals can consider tackling
- Interactive dialogue on well-known compliance failures that likely resulted from underestimating the power of cognitive biases
- Interactive dialogue on how you can start now to integrate understanding of behavioral science into best compliance practices

Eric J. Bottelier, *Director, Ethics, Risk & Compliance, US Oncology, Novartis Pharmaceuticals Corporation; Former NA Compliance & Business Ethics, Sanofi, Erwinna, Pennsylvania (Discussion Coordinator)*

Michael L. Shaw, JD, *Principal, Global Head of Risk & Compliance, ZS; Former Vice President & Compliance Officer - Global Therapy Areas & U.S. Pharma, GSK, Philadelphia, PA (Discussion Coordinator)*

Topic II: Compliance Risk Assessment Integrating Legal and Cultural Requirements

Dr. Peter Dieners, Clifford Chance, and James Dempsey, Principia, share their approach of an innovative holistic compliance risk assessment that will substantially contribute to an increased level of compliance. A compliance management system fully in line with all legal and organizational requirements is by itself no guarantee for a sufficient degree of compliant behavior. It is common ground that a sound culture is a decisive factor as well.

Attorney Peter Dieners and Principia Advisor James Dempsey combine the legal perspective and the cultural aspects in a compliance risk assessment and introduce into an Integrated Organisational and Cultural Gap Analysis. They demonstrate the method how the legal and cultural efficacy of a compliance management system can be measured in a reliable and repeatable manner, what the results and recommendations look like and how an enterprise can benefit from such a holistic approach.

Peter Dieners, Esq., *Regional Managing Partner (Germany) and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Member, Legal Affairs Focus Group and Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany (Discussion Coordinator)*

David Rodin, PhD, *Founder and Chief Executive Officer, Principia Advisory, Former Co-Director, Institute for Ethics, Law, and Armed Conflict, Oxford University, Trélex, Vaud, Switzerland (Discussion Coordinator)*

Topic III: Why Friction between Compliance and the Business Is Good for Everyone

In this interactive Zoom Video Workshop, Michaela and Richard will invite perspectives on:

- How surfacing friction between compliance and business teams enables organizations to put compliance messages and initiatives into action.
- How bringing ethical dilemmas and struggles to the 'decision making table' allows both compliance and business teams to tackle them, together.
- How embracing E&C friction and tension among functions helps to bring values to life, through 'sparking' difficult yet productive discussions regarding ethical decision making.

Michaela Ahlberg, LLM, CCEP, CCEP-I, *Senior Advisor, Getinge; Ethics & Compliance and Anti Bribery Corruption Specialist, TheGreyZone, Göteborgsområdet, Sweden (Discussion Coordinator)*

Richard Bistrong, MA, *Chief Executive Officer, Front-Line Anti-Bribery, LLC; Contributing Editor, FCPA Blog; Former Confidential Human Source (CHS) and Cooperating Witness, FBI and US DOJ; Former Cooperating Witness, City of London Police, HMRC and CPS, UK New York, NY, USA (Discussion Coordinator)*

Topic IV: Best Practices Implementing Equity, Diversity & Inclusion into Ethics and Compliance Programs

Join industry Ethics & Compliance leaders as they share their insights and experiences on current and future trends in implementing equity, diversity and inclusion into ethics and compliance programs. The panel will address leading practices seen in equity, diversity & inclusion programs, key considerations, and how their organizations are approaching and making an impact in addressing this key topic. This will be an interactive panel discussion session with the audience.

Evelyne Lemaire, MA, *Vice President, Head of Ethics & Compliance Global Manufacturing & Supply and Global Quality, Takeda, Zurich, Switzerland (Discussion Coordinator)*

Michael R. Clarke, JD, CCEP, *Vice President, Global Chief Compliance Officer, ConvaTec; Former Vice President, Corporate Compliance, Indivior; Former Vice President, Ethics & Compliance, Americas, Actavis; Bridgewater, NJ, USA (Discussion Coordinator)*

Kishwar Chishty, ACA, *Partner Risk Advisory Life Sciences, Deloitte Switzerland, Basel, Switzerland (Discussion Coordinator)*

Trudy Tan, *Global Head Ethics, Risk & Compliance, Pharma, Novartis; Former Vice President Compliance, International, AstraZeneca, Basel, Switzerland (Discussion Coordinator)*

4:30 pm **Day I Adjournment**

All Times are CET

DAY II: TUESDAY, JUNE 15, 2021

MORNING MINI SUMMITS: MINI SUMMITS ROUND II **10:00 am – 11:00 am**

MINI SUMMIT 6: Best Practices in Virtual Investigations

With the unanticipated onset of COVID-19, internal investigations suddenly went from decades of predictable in-person processes to untested virtual ones, and companies and providers adapted, with new technical solutions flowing in. Is the end in sight? It looks that way for the pandemic, but virtual investigations seem here to stay. Here from industry leaders on:

- The challenges associated with virtual investigations
- Successful techniques to collect all forms of evidence virtually
- Virtual interviewing techniques, including privilege and safety issues
- Identify confidentiality and privacy challenges and associated solutions
- Differences with investigations across markets and company operations
- With the pandemic driver fading, what will the future be for the virtual review

10:00 am **Introductions, Panel Discussion and Q&A**

Keith Burn, *Global Investigations Director, Ipsen Former Associate Investigator, Parliamentary and Health Service Ombudsman, NHS; Former Detective Constable, London Metropolitan Police, Slough, UK*

Robert Ennis, JD, LLM, *Vice President and Lead Compliance Counsel, Pfizer New York, NY, USA*

Franziska Janorschke, *Global Head, Business Practices Office, Novartis International AG, Basel, Switzerland*

Anthony McQuillan, LLB, *Vice President Legal & Compliance EMEA, Medtronic International, London, UK*

Gary F. Giampetruzzi, JD, *Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Discussion Coordinator)*

MINI SUMMIT 7: How to Build and Manage Healthcare Compliance Risk Assessments

- What is a Healthcare compliance risk assessment (HCRA)?
- How have HCRAs changed over the years?
- How do HCRA risks fit into the company's overall risk management program?
- What is the best way to optimize use of analytics for HCRAs?
- How to prioritize risks and liabilities at stake

10:00 am **Introductions, Panel Discussion and Q&A**

Ann Beasley, JD, *Chief Compliance Officer, Zai Lab; Former Senior Vice President, Chief Compliance Officer, Biogen; Former Global Compliance Office, Novartis Pharma AG, Boston, MA, USA*

Anisa Dhalla, *Global Chief Compliance Officer, UCB, Inc., Atlanta, GA, USA*

Sue Egan, *Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK*

Lauri G. Opar, *Head, Enterprise Risk Management & Risk Analytics Global Ethics & Compliance, GlaxoSmithKline Brentford, Middlesex, UK*

Sylvie Gallage-Alwis, DEA, LLM, *Partner, Signature Litigation Avocat à la Cour Solicitor in England & Wales Committees Vice Chair, International Association of Defense Counsel, Paris, France (Discussion Coordinator)*

MINI SUMMIT 8: Ethics and Compliance Issues when Interacting with Third Parties

Join industry leaders as they share insights into the evolution of Third Party Due Diligence Programs and the challenges related to their effective implementation in the challenging business environment of today. More specifically, our discussion will cover:

- Challenges related to third party management and changes to processes as a result of COVID-19
- Shifting monitoring and auditing to remote methods without support of onsite teams
- Conducting proactive risk evaluation across all activities
- Resource identification and management

10:00 am **Introductions, Panel Discussion and Q&A**

Laetitia Ducroquet, *Vice President, Global Business Ethics, Ipsen, Boulogne-Billancourt, France*

Alex Fell, *Head Ethics, Compliance and DPO International, Amicus Therapeutics; Former Vice President, Global Ethics and Compliance, Head of Strategy, Planning and Operations, GlaxoSmithKline, London, UK*

Keith Korenchuk, MPH, JD, *Vice President and Chief Compliance Officer, DH Diagnostics, a Danaher Company, Chevy Chase, MD, USA*

Gina Nese, JD, *Vice President Global Compliance and Ethics Officer, Align Technology; Former Chief Compliance Officer, Advanced Sterilization Products Bellevue, WA, USA*

Mario Prohasky, *Principal, EMEA Compliance Consulting Lead, IQVIA, London, UK (Discussion Coordinator)*

MINI SUMMIT 9: Tech Enablement of Your Global Compliance Program

Ethics and compliance teams face challenging times ahead with continuously increasing regulation, the new normal, digital transformation of the core value chain, and at the same time managing everyone's expectation that Compliance will prevent risks without inhibiting the customer experience. The pace of change continues and 2021 looks like it is no exception. For most organizations, adding additional human resources to address these compliance challenges is not a viable option. Compliance functions are under pressure to do more work and provide greater results with fewer and fewer resources. Steffen Esche, Director, Consulting, Risk & Regulatory, PwC, and a panel of industry experts will focus on the technology aspect to provide their perspectives on how data and technology can enable the compliance function and drive effectiveness, as well as efficiency of global compliance programs.

10:00 am **Introductions, Panel Discussion and Q&A**

Matt Abrahamson, MBA, *Senior Compliance Analyst, DH Diagnostics LLC, a Danaher company, Buffalo Grove, IL, USA*

Ethan Gumpert, *Global Ethics, Compliance & Governance, Advanced Medical Technology Association (AdvaMed), Washington, DC, USA*

Vahan Minassian, JD ,*Digital Compliance Counsel, Compliance Division, Global Programs, Pfizer, Philadelphia, PA, USA*

Sharon Muscato, *Director, Compliance Operations, Moderna; Former Director, Transparency & Compliance Operations, Alexion Pharmaceuticals, Inc.; Cambridge, MA*

Vanessa Westphal, JD, MS, *Head of Compliance Center of Excellence, Merck KGaA, Darmstadt, Frankfurt Am Main Area, Germany*

Steffen Esche, *Director, Consulting, Risk & Regulatory, PwC, Frankfurt, Germany (Discussion Coordinator)*

11:00 am **Transition Break**

All Times are CET

MINI SUMMITS ROUND III **11:15 am – 12:15 pm**

MINI SUMMIT 10: Challenges and/or Considerations in Maintaining a Methodology in a Fair Market Value (FMV) Analysis

Join a panel of industry veterans and Eric Bolesh of Cutting Edge Information for an engaging discussion on the challenges of establishing and maintaining a bulletproof FMV system for HCP compensation. Listen as the panelists discuss key risk areas, picking an FMV methodology, implementing rates around the globe — then dive into nuanced trouble spots like tiering, FMV for patients and other non-HCPs, prep time, travel considerations, and more.

11:15 am **Introductions, Panel Discussion and Q&A**

Peter Dieners, Esq., *Regional Managing Partner (Germany) and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Member, Legal Affairs Focus Group and Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany*

Pascale Schmidt, *Chief Compliance Officer and Chair, Corporate Sustainability Committee, F. Hoffmann-La Roche Ltd, Basel, Switzerland*

Heidi Teresi, *Director, US Ethics & Compliance, Bausch Health; Former Lead, Education and Communication, US Compliance and Ethics, Bristol-Myers Squibb, Princeton, NJ*

Eric Bolesh, *Chief Operating Officer, Cutting Edge Information, Raleigh-Durham, NC, USA (Discussion Coordinator)*

MINI SUMMIT 11: Ethics and Compliance Considerations for Gene Therapy and Ultra Rare Disease Products

Join industry leaders as they share insights and actions to help navigate the unique ethics and compliance-related challenges and considerations that come with working in the area of rare diseases.

- Provide an overview of rare diseases including what are rare diseases and how they differ from ultra rare diseases, how does the patient journey differ from other types of diseases, what is the role of the pharmaceutical industry and what challenges does the industry face when working in rare diseases, what are some recent regulatory and enforcement actions that are relevant to rare diseases
- Discuss the types of stakeholders involved in rare diseases and the challenges the pharmaceutical industry faces when managing interactions with these stakeholders
- Review the pricing and reimbursement model for rare diseases and the impact it has on patients, caregivers and the pharmaceutical industry
- Consider the impact activities related to rare diseases may have on ethics and compliance programs and whether any programmatic elements should be modified to adapt to these activities

11:15 am **Introductions, Panel Discussion and Q&A**

Sandra González, JD, *Senior Associate, Life Sciences and Healthcare Practice Group, Paul Hastings, New York, NY, USA*

Dominique Laymand, Esq., *Executive Vice President, Chief Ethics and Social Responsibility Officer, Ipsen Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Piergiorgio Pepe, MA, *EU Law, President, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo Board Member, Strategic Committee International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Compliance Director Western Europe & Canada, AbbVie, Former Director, Compliance & Ethics EMEA, Bristol-Myers Squibb, Paris, France*

Steve Vincze, JD, LLM, MBA, *President and Chief Executive Officer, TRESTLE Compliance, LLC; Former Senior Vice President and US Chief Compliance Officer, Privacy Officer and Senior Legal Counsel; Former Vice President, Ethics & Compliance Officer, TAP Pharmaceuticals, Boston, MA, USA*

Oscar Perdomo, *Director, Pharmaceutical & Life Sciences, Advisory Services, PwC Switzerland, Zurich, Switzerland (Discussion Coordinator)*

MINI SUMMIT 12: GDPR and the Tumultuous World of Data Privacy

- What are some of the trends that you see with regards to transparency disclosure?
- How do data protection concerns/regulations continue to impact the overall HCP disclosure process?
- How do we effectively use transparency data analytics to drive better compliance decisions while ensuring compliance with data protection requirements?

11:15 am **Introductions, Panel Discussion and Q&A**

Stefano Biondi, LLB, PhD, *Compliance Manager and Group Data Protection Officer, Menarini Group, Florence, Italy*

Rika De Ville, *Vice President Global Compliance, Privacy & Data Protection Officer, Perrigo Company plc, Nazareth, Belgium*

Ariadna Quesada, MSJ, *Compliance Director Europe and MEATI, Hillrom; Former Law, Ethics and Compliance Officer, The Netherlands, AbbVie; Former Compliance Manager International, MicroPort Orthopedics, Amsterdam, Netherlands*

Giuseppe Saporito, LLM, *Global Legal & Regulatory Expert, IQVIA, Milan, Italy*

Elisabeth Kohoutek, *Senior Associate, FDA and Life Sciences, King & Spalding LLP, Frankfurt am Main, Germany (Discussion Coordinator)*

MINI SUMMIT 13: Ethics and Compliance Issues in Patient Relationships, Including Patient Access and Support

Join us for a roundtable of industry professionals as they discuss compliance issues surrounding the diverse patient interactions with life sciences companies:

- Impact of the pandemic in providing broader patient support and treatment
- Challenges and insights around patient advocates and influencers
- Personal perspectives from key global compliance leaders

11:15 am **Introductions, Panel Discussion and Q&A**

Duygu Beyazo, LLB, *Senior Associate, NSN Law Firm Former Compliance Manager (Secondment), Business Conduct, Gilead Sciences, Istanbul, Turkey*

Martin Eschbach, JD, *Head Ethics, Risk and Compliance and Legal Patient Engagement, Novartis International AG, Baden-Württemberg, Germany*

Larisa K. Jasnic, LLB, LLM, *Head of Ethics & Compliance, International, Alnylam Pharmaceuticals; Former Regional Compliance Officer, Region Europe, Novartis, Zug, Switzerland*

Piergiorgio Pepe, MA, *EU Law, President, Quantum Ethics; Ethics and Compliance Lecturer, SciencesPo; Board Member, Strategic Committee International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Compliance Director Western Europe & Canada, AbbVie; Former Director, Compliance & Ethics EMEA, Bristol-Myers Squibb, Paris, France*

Paul Silver, *Principal, Regulatory & Compliance Life Sciences Leader, Deloitte Advisory, Atlanta, GA, USA (Discussion Coordinator)*

12:15 pm **Luncheon Break/Visit Exhibit Hall**

All Times are CET

DAY II PLENARY SESSION

1:00 pm **Introduction to Global Anticorruption Landscape: Government Enforcement**

Tom Gregory, MBA, *Partner, Forensic & Integrity Services, EY, Atlanta, GA, USA (Session Moderator)*

1:05 pm **EU Public Prosecutor's Office (EPPO) Update**

Anna-Elisabeth Krause-Ablass, JD, *European Delegated Prosecutor, European Public Prosecutor's Office; Former Specialized Public Prosecutor for White Collar Crime Frankfurt, Frankfurt, Germany*

Peter Dieners, Esq., *Regional Managing Partner (Germany) and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Member, Legal Affairs Focus Group and Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany (Discussion Coordinator)*

1:25 pm **Agence Française Anti-corruption (AFA) Update**

Clément Grospiron, *Mission Head to the Chief Supervision Directorate, Agence Française Anti-corruption (AFA), Paris, France*

George Fife, *Partner, Forensic & Integrity Services, EY, Paris, France (Discussion Coordinator)*

1:45 pm **UK Serious Fraud Office Update**

Judy Krieg, JD, *Head of Fraud, Bribery and Corruption, Division B, UK Serious Fraud Office; Former Chief Compliance Officer, Rolls-Royce plc, London, UK*

2:05 pm **OECD Anti-bribery Update**

Gemma Aiolfi, *Head of Compliance, Corporate Governance and Collective Action, Basel, Switzerland*

2:35 pm **US FCPA and European Enforcement Update**

Nicola Bonucci, MA, DEA, DESS, *Partner, Global Trade and Investigations & White Collar Defense, Paul, Hastings; Former Director of Legal Affairs, Organisation for Economic Cooperation and Development's (OECD), Paris, France*

David Fuhr, JD, *Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC, USA*

Eugenio Fusco, *Deputy Attorney at the Court, Public Prosecutor at the Court of Milan, Milan, Italy*

Gary F. Giampetruzzi, JD, *Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Discussion Coordinator)*

3:15 pm **Transition Break**

3:30 pm **China Update**

Lei Li, LLM, *Managing Partner, Beijing and Shanghai Offices, Sidley Austin Former Third Secretary, Ministry of Commerce, People's Republic of China, Beijing, China*

3:45 pm **LATAM Update**

Imelda Álvarez, LLB, MBA, *Chief Executive Officer, Comply Latam, SC; Former Regional Integrity & Compliance Head Latin America and Canada, Novartis, Mexico City, Mexico*

4:00 pm **Global Anticorruption Roundtable**

Imelda Álvarez, LLB, MBA, *Chief Executive Officer, Comply Latam, SC; Former Regional Integrity & Compliance Head Latin America and Canada, Novartis, Mexico City, Mexico*

Peter Dieners, Esq., *Regional Managing Partner (Germany) and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Member, Legal Affairs Focus Group and Compliance Network, MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany*

George Fife, *Partner, Forensic & Integrity Services, EY, Paris, France*

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

Lei Li, LLM, *Managing Partner, Beijing and Shanghai Offices, Sidley Austin Former Third Secretary, Ministry of Commerce, People's Republic of China, Beijing, China*

Tom Gregory, MBA, *Partner, Forensic & Integrity Services, EY, Atlanta, GA, USA (Session Moderator)*

5:00 pm **Day II Adjournment**

All Times are CET

DAY III: WEDNESDAY, JUNE 16, 2021

DAY III PLENARY SESSION

10:00 am **Ethical Interactions between the Health Care Sector and Other Stakeholders**

Pedro Carrascal, MBA, *President, European Multiple Sclerosis Platform (EMSP); Chief Executive Officer, EME (Multiple Sclerosis Spain), Biscay MS Society and MS Basque Foundation Board, Multiple Sclerosis International Federation (MSIF), Bilbao, Spain*

Christian-Claus Roth, *Global Head Scientific Engagement Governance, Novartis; Co-president, International Pharmaceutical Congress Advisory Association (IPCAA); Member, Ethics and Business Integrity Committee, IFPMA, Basel, Switzerland*

Sarah Wheeler, MA, *Director of Global Industry Engagement, International Association for the Study of Pain, Washington, DC*

Anne-Sophie Bricca, MA, DEA International Law, DES European Law, *Deputy General Counsel & Senior Director Legal Affairs & Compliance, Terumo BCT, Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Chair, Ethics and Compliance Group MedTech Europe, Brussels, Belgium (Moderator)*

10:45 am **Artificial Intelligence and Digital Health**

Abhiroop Gandhi, *Trust and Compliance Officer, Verily Life Sciences (an Alphabet company); Former Vice President, Corporate Compliance, Mallinckrodt San Francisco, CA, USA*

Iordanis Kerenidis, PhD, *Director, Paris Centre for Quantum Computing (PCQC), CNRS Senior Researcher (DR2), Algorithms and Complexity Group IRIF, University Paris Diderot, Paris, France*

Mirgen Jaku, MA, *Ethicon EMEA PMO & Digital Surgery Leader, Johnson & Johnson, Hamburg, Germany*

Anne-Sophie Bricca, *Deputy General Counsel & Senior Director, Legal Affairs & Compliance, Terumo BCT; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Chair, Ethics and Compliance Group MedTech Europe, Brussels, Belgium (Discussion Coordinator)*

11:30 am **Industry Codes Co-creation Approach**

IFPMA

Sofie Melis, *Director HR and Ethics & Compliance, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Geneva, Switzerland*

EFPIA

Julie Bonhomme, *Legal & Compliance Director, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium*

MedTech Europe

Aline Lautenberg, *General Counsel and Director, Legal & Compliance, MedTech Europe, Brussels, Belgium*

Asia Pac Update

Lei Li, LLM, *Managing Partner, Beijing and Shanghai Offices, Sidley Austin Former Third Secretary, Ministry of Commerce, People's Republic of China, Beijing, China*

LATAM Update

Imelda Álvarez, LLB, MBA, *Chief Executive Officer, Comply Latam, SC; Former Regional Integrity & Compliance Head Latin America and Canada, Novartis, Mexico City, Mexico*

Discussion Coordinator

Arthur Muratyan, Esq., *Secretary General, International Society of HealthCare Ethics and Compliance Professionals (ETHICS), Chair, MedTech Compliance Panel; Former VP-Head of Legal Corporate and Global Compliance Officer, Sanofi, Paris, France (Discussion Coordinator)*

12:30 pm **Plenary Session Adjournment/ Luncheon Break/ Visit Exhibit Hall**

AFTERNOON MINI SUMMITS:
MINI SUMMITS ROUND IV **1:15 pm – 2:15 pm**

MINI SUMMIT 14: Best Practices in Virtual Monitoring

Join Healthcare-industry leaders sharing insights on their journey to digitalize their compliance monitoring approach.

- Learn about the challenges in an organization to digitalize compliance monitoring
- Insights on how to cope with challenges of digitalization
- Use of dashboards, data analytics including outlook on AI, machine learning and predictive analytics
- How Covid impacted the way of conducting compliance monitoring — challenges of virtual monitoring
- Impact on Talent aspects: How the team capabilities shifted
- Best practices on how to fund such an program

1:15 pm **Introductions, Panel Discussion and Q&A**

Giota Papamarkou, *Vice-President, Business Ethics Global, France, Ipsen Former EMEA Compliance and Ethics Manager, Bristol-Myers Squibb, Paris, France*

Carrie (Ashcom) Pennington, MBA, PhD, *Vice President, Global Compliance Monitoring & Internal Controls, Zimmer Biomet; Former Global Compliance Manager, Books & Records, GE Healthcare, Warsaw, IN, USA*

Vanessa Westphal, JD, MS, *Head of Compliance Center of Excellence, Merck KGaA, Darmstadt, Frankfurt Am Main Area, Germany*

Anita Kyung-Hee Kim-Reinartz, *Partner, Forensic & Integrity Services, EY Düsseldorf, Germany (Discussion Coordinator)*

All Times are CET

MINI SUMMIT 15: US DOJ's Evaluation of Corporate Compliance

Join experts from the legal and life sciences industries in a lively and practical discussion about the Department of Justice's Effective Corporate Compliance Program Guidance. We'll be joined by DOJ Fraud Section's Sally Molloy to hear firsthand her perspective on why the guidance was drafted, how it is used by prosecutors, and to demystify the corporate resolution process. The panel will also explore individual elements of the guidance and how in-house panelists have used the guidance.

1:15 pm **Introductions, Panel Discussion and Q&A**

Abdul Luheshi, MBA, *Independent Consultant, Ethics and Compliance; Former Compliance Officer, International Markets, Myriad Genetics; Former Executive Director, Global Operations, Ethics & Compliance, EMEA, Astellas; London, UK*

Sally Molloy, JD, *Chief, Strategy, Policy and Training Unit, Fraud Section, US Department of Justice, Washington, DC, USA*

Caroline H. West, JD, *Former Global Chief Compliance Officer, Olympus Corporation; Former Senior Vice President, Chief Compliance and Risk Officer, Shire, Philadelphia, PA, USA*

Amanda N. Raad, JD, *Partner and Co-Chair of Global Anti-Corruption and International Risk Practice and R&G Insights Lab, Ropes & Gray, LLP, London, UK (Discussion Coordinator)*

MINI SUMMIT 16: Company Principle-based Professional Codes (Not Industry Codes)

Join industry leaders from Big pharma and mid-Size Pharma Industry as they share in an interactive session, insights and experiences on Company Principle Based Professional codes:

- Recognizing that such codes are key nowadays to foster an ethical and compliant culture, and how the Company Culture is influencing in return the codes content
- Understanding how such codes can be evolving from Policies/ rules based to Principle based tools
- Identifying what works best/ what doesn't when creating such Codes in Organizations
- Listening to key leaders' experiences and cultural/ regional differences that may surface when implementing these codes
- Overseeing future trends and how the Pandemic may have reinforced the need for sensible Codes to address key stakeholders needs.

1:15 pm **Introductions, Panel Discussion and Q&A**

Brett Hudson, MBIM, *Global Head Ethics, Risk & Compliance Strategy, Innovation, & Corporate Functions, Novartis; Former Global Program Director Integrity & Compliance, Sandoz, Zurich, Switzerland*

Sobia Akram, MSC, *Corporate Vice President, Global Business Ethics Compliance Office & Programme, Novo Nordisk A/S, Copenhagen, Capital Region, Denmark*

Giota Papamarkou, *Vice-President, Business Ethics Global, France North America & Global Monitoring, Ipsen; Former EMEA Compliance and Ethics Manager, Bristol-Myers Squibb, Paris, France*

Pascale Paimbault, *President, CEO and Founder, Consulting Alley; Strategic Committee, Strategic Committee International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Executive Director, EMEA Ethics and Compliance, ABAC, Astellas Pharma Europe, Paris, France (Moderator)*

MINI SUMMIT 17: Compliance in Clinical Trials and Investigations

Clinical studies raise numerous compliance issues, some of which relate to good clinical practice and may jeopardize the use of clinical data for regulatory purposes. The panelists will discuss several of those issues, providing the audience with not only a worldwide perspective but also a twofold, i.e., big pharma and small biotech, perspective. Some issues chosen by the Panel are in the news like the COVID pandemic, the publication of clinical study results, or the interactions between sponsors and patients. Other issues are long-standing but nevertheless crucial issues such as payments, data privacy, or compassionate use after clinical study. Clinical studies raise various compliance issues. Join the panel for their discussion on payments, COVID, publication of clinical study results, data privacy, and compassionate use after clinical study.

1:15 pm **Introductions, Panel Discussion and Q&A**

Masha Chestukhin, MSJ, *Associate Director, Compliance Officer R&D, IA, FMV, Sanofi Genzyme; Former Senior Manager NA Compliance, Sanofi; Jamaica Plain, MA, USA*

Ana Christian, JD, *Senior Director, Assistant General Counsel, Avanir Pharmaceuticals; Former Corporate Counsel, NantHealth, Los Angeles, CA, USA*

Stefanie Deronne, JD, *Legal Counsel, Argenx; Former Senior Corporate Legal Counsel R&D - DPO, Ablynx; Ghent, Belgium*

Genevieve Michaux, JD, *Partner, King & Spalding, Brussels, Belgium (Discussion Coordinator)*

MINI SUMMITS ROUND V **2:15 pm – 3:15 pm**

MINI SUMMIT 18: Annual Middle East Africa (MEA) Compliance Update

As 2020 marked a drastic change in the way we operate because of COVID 19 and its impact on humanity and business, how did this unfolding new environment impact Ethics and Business Integrity in MEA? A panel of industry Ethics and Compliance professionals share their thoughts and updates on emerging compliance risks, bringing different perspectives from pharma and medical devices companies, consulting firms, regulators and trade associations . The panelists look into the Future revealing new risk areas that require a continuous evolution of the compliance role as a competitive advantage to enable sustainable access of patients to innovation in MEA.

2:15 pm **Introductions, Panel Discussion and Q&A**

Ghadeer Al Yacoub, MSc, *Regional Head Healthcare Compliance Europe, Middle East and Africa Medical Devices, Johnson & Johnson, Dubai, UAE*

Els Janssens, LLM, *Counsel, Baker & McKenzie; Former Legal Adviser, European Medicines Agency; Former Senior Legal Counsel, Johnson & Johnson, Brussels, Belgium*

Samar Wakim, PharmD, *Ethics & Compliance Head MEA, Innovative Medicines, Novartis Pharma Services AG, Dubai, UAE*

Joseph W. Henein, PharmD, *President and Chief Executive Officer, NewBridge Pharmaceuticals, Dubai, UAE (Co-Discussion Coordinator)*

Laura Nassar, PharmD, *Vice President, Head of Ethics & Business Integrity, AEME Region, Sanofi; Former Head of Compliance Middle East, Roche Pharmaceuticals; Former Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon (Co-Discussion Coordinator)*

All Times are CET

MINI SUMMIT 19: Industry's Evolving Role in Medical Education

Industry plays an important role in Medical Education. However, there are some challenges for Compliance re the cooperation with Physicians Associations and Industry and in addition we have the pandemic situation. The panel will inform/ discuss the following topics:

- Pandemic situation — what has changed? digital formats — pitfalls and solutions
- Interaction between Industry and Physicians Associations — inform/discuss: what went well and conflict of interests
- What approaches to deliver neutral/unbiased information?
- Medical Education: how does it look like in 5 years? How to improve the coworking with HCPs/ HCOs/Physicians Associations and to implement a common (better) understanding of Medical Education

2:15 pm **Introductions, Panel Discussion and Q&A**

Holger Diener, *Healthcare Compliance Officer, Janssen-Cilag GmbH, Johnson & Johnson; Former Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("FSA"), Berlin, Germany*

Christian-Claus Roth, *Global Head Scientific Engagement Governance, Novartis; Co-president, International Pharmaceutical Congress Advisory Association (IPCAA);Member, Ethics and Business Integrity Committee, IFPMA, Basel, Switzerland*

Cerstin Steindorf, *Global Account Director Healthcare, MCI, Geneva, Switzerland*

Michael Bartke, PhD, *Strategic Committee, ETHICS; Former Director Ethics & Compliance, Alexion; Former Director Compliance Management, Daiichi, Sankyo, Europe Munich, Germany (Discussion Coordinator)*

MINI SUMMIT 20: EU Whistleblower Directive

In the EU in December 2021 the industry needs to be ready for meeting all requirements of the EU Whistleblower Directive. Join industry leaders with experience implementing whistleblower reporting channels. These questions will be discussed:

- How do compliance programs assess the impact of changes in existing whistleblower processes in light of the EU directive?
- What are areas of particular focus where existing programs needs to consider modifications in current approaches (i.e., retaliation provisions)?
- What are the risks for companies in case of noncompliance?
- Which sanctions may be imposed?
- Does the mindset of the whistleblower matters when reporting an issue, and do reports have to be made in good faith?
- What can companies do to adhere to the time requirements of the directive?
- Will reporting channels need to evolve as part of the new Directive?
- Does the EU Directive allow for anonymous reporting, and does it really matter?

2:15 pm **Introductions, Panel Discussion and Q&A**

Chelsea M. Keeton, JD, *Director and Senior Counsel, Global Compliance Investigations, Zimmer Biomet; Former Group Ethics & Compliance Counsel, VEON, Amsterdam, Netherlands*

Elisabeth Kohoutek, *Senior Associate, FDA and Life Sciences, King & Spalding LLP, Frankfurt am Main, Germany*

Keith Korenchuk, MPH, JD, *Vice President and Chief Compliance Officer, DH Diagnostics, a Danaher Company, Chevy Chase, MD, USA*

Sylvain Mansotte, *Co-Founder and Chief Executive Officer, Whispli, Sydney, New South Wales, Australia*

Ulf H. Grundmann, *Partner, FDA and Life Sciences, King & Spalding LLP, Lecturer, Frankfurt School of Finance and Management, Frankfurt am Main, Germany (Discussion Coordinator)*

MINI SUMMIT 21: Global Price Transparent Reporting Update

2:15 pm **Introductions, Panel Discussion and Q&A**

John Oroho, Executive VP & Chief Strategy Officer, Porzio Life Sciences leads the discussion on global price transparency. Most notable, price transparency is following the same trajectory that HCP spend transparency has followed over the last 10-15 years. While the new federal regulation in the US focuses on the methodology used to calculate price increases, in Europe price transparency is focused more around transparency into negotiated agreements between a country and a pharmaceutical company. Interest in pricing transparency followed the World Health Assembly Resolution adopted in May 2019, which was adopted by every member state except UK, Germany and Hungary. Thus, there seems to be a global trend towards price transparency and the panel will discuss the importance of compliance function working collaboratively with business partners to address challenges, identify best practices on how to operationalize compliance, and understand penalty provisions.

Brian P. Sharkey, *Director, US Commercial Compliance & Ethics, Teva Pharmaceuticals, Parsippany, New Jersey, USA*

Sara R. Simon, JD, *Associate, Porzio, Bromberg & Newman, PC, Morristown, NJ*

John Patrick Oroho, JD, *Executive VP & Chief Strategy Officer, Porzio Life Sciences, LLC; Principal, Porzio Bromberg & Newman, PC, Morristown, NJ, USA (Discussion Coordinator)*

3:25 pm **Closing Wrap-up**

INTERACTIVE ZOOM VIDEO WORKGROUPS

3:30 pm – 4:30 pm

(Attendee may join any Discussion Session. The first 25 attendees will participate via video and audio. Attendees joining thereafter will participate in video/listen-only mode and engage via text chat and Q&A. Attendees may move among the various concurrent discussion sessions.)

Topic V: Ethics & Compliance in a Third Party Management Beyond Due Diligence

Hear from subject matter experts that have built and operationalized third party due diligence programs that are right sized for the organization

- Where is your organization in its journey. . .one size does not fit all
- What are the inherit risks germane to your organization and how are you addressing them
- Gaining support through the business; making allies instead of internal enemies
- Risk vs. Reward: More than money and profits

J. Mark Farrar, MSJ, CPA, *Partner, Life Sciences Governance, Risk Management and Compliance, Guidehouse; Former Interim Chief Global Compliance Officer, Beckman Coulter, Atlanta, GA (Discussion Coordinator)*

Gina Nese, JD, *Vice President Global Compliance and Ethics Officer, Align Technology; Former Chief Compliance Officer, Advanced Sterilization Products; Bellevue, WA, USA (Discussion Coordinator)*

Topic VI: Ethics & Compliance Considerations for Small to Mid-sized Companies

Join industry leaders in this interactive discussion to share insights and actions to help navigate the unique compliance-related challenges and opportunities that come with working at small to mid-sized companies. Topics to be discussed include resourcing considerations (e.g., compliance department budgets, use of internal vs external resources), embedding compliance within the organization, and the importance of practical compliance advice.

Darren R. Jones, *Partner and Leader, Life Sciences Consulting Practice, Baker Tilly, New York, NY (Discussion Coordinator)*

Chrisoula Nikidis, LL.L., *Head of Ethics and Compliance, Takeda Canada; Former Vice President, Ethic (Discussion Coordinator)*

All Times are CET

Topic VII: Does the Corporation's Compliance Program Work in Practice

Effective ethics and compliance programs have never been more critical, yet there's no definitive way to determine if these programs are actually working. Join Prof. Jacob Elberg, Alex Fell and other ethics and compliance leaders for a thought provoking and lively debate on how do we really know if our compliance program is working? During this session we will:

- Hear practical insights on how enforcement agencies assess the effectiveness of a Corporation's Compliance program
- Compare and contrast the approach taken by enforcement agencies with those used by large and small Pharma companies
- Challenge how we know if our compliance program is being applied with the right intent, i.e. is it more than a paper program?
- Debate if and how ethical culture can be reliably measured.
- Consider how measures of success evolve over time as risk maturity increases and how we meet increasing stakeholder expectations

Jacob T. Elberg, JD, *Associate Professor, Seton Hall University School of Law; Former Chief, Health Care & Government Fraud Unit, and Assistant US Attorney, US Attorney's Office, District of New Jersey, Newark, NJ, USA (Discussion Coordinator)*

Alex Fell, *Head Ethics, Compliance and DPO International, Amicus Therapeutics; Former Vice President, Global Ethics and Compliance, Head of Strategy, Planning and Operations, GSK; London, UK (Discussion Coordinator)*

Topic VIII: Ethics and Compliance Lessons Learned from COVID

Brett and Ethan will lead this interactive workgroup to discuss lessons learned from the pandemic, strategies to move the company forward, and opportunities to work together as an industry. Covid provided an opportunity to show the value that Ethics & Compliance leaders can bring to the organization and how they could be part of the solution. As your organizations begin to navigate post-Covid, participants can discuss:

- What are your priorities and how has your role changed?
- How does compliance maintain the trust the industry established during Covid?
- What areas can be addressed collectively post Covid?
- How has your role changed due to ESG (Environment, Social, and Governance) and how do you build it into your organizational strategy?

Brett Hudson, MBIM, *Global Head Ethics, Risk & Compliance Strategy, Innovation, & Corporate Functions, Novartis; Former Global Program Director Integrity & Compliance, Sandoz, Zurich, Switzerland (Discussion Coordinator)*

Ethan Gumpert, *Global Ethics, Compliance & Governance, Advanced Medical Technology Association (AdvaMed), Washington, DC, USA (Discussion Coordinator)*

4:30 pm **Day III Adjournment**

DAY IV: THURSDAY, JUNE 17, 2021

CLOSING PLENARY SESSION

1:00 pm **Managing Ethics and Compliance in a Quickly Growing Enterprise**

Kirt Kraeuter, MGA, *Senior Director, Corporate Compliance, Moderna; Former European Compliance Director, Otsuka; Former, Executive Director, Worldwide Compliance Committee & Monitoring, Bristol-Myers Squibb, Yardley, PA, USA*

1:30 pm **Keynote Address: Integrating Ethics and Compliance During Challenging Times**

Piergiorgio Pepe, MA, *EU Law, President, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo, Board Member, Strategic Committee International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Compliance Director Western Europe & Canada, AbbVie, Former Director, Compliance & Ethics EMEA, Bristol-Myers Squibb, Paris, France*

2:15 pm **Drivers for a Sustainable Ethical Culture**

Roxana Family, Thèse de Doctorat Droit, *Vice-President, Chair in Law & Business Ethics and Program Director, Cergy Pontoise University, Cergy-Pontoise, France*

Sofie Melis, *Director HR and Ethics & Compliance, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Geneva, Switzerland*

Stephen Nguyen Duc, *Vice-President, Global Head of Human Resources and Ethics & Compliance, Medday Pharmaceuticals; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France*

Piergiorgio Pepe, MA, *EU Law, President, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo, Board Member, Strategic Committee International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Compliance Director Western Europe & Canada, AbbVie, Former Director, Compliance & Ethics EMEA, Bristol-Myers Squibb, Paris, France (Discussion Coordinator)*

3:00 pm **Value-Based Healthcare and Implications for Ethics and Compliance**

Bas Amesz, MSc, *Partner, Vintura, Baarn, Utrecht, Netherlands*

Anthony McQuillan, LLB, *Vice President Legal & Compliance EMEA, Medtronic International; Former Senior Attorney EMEA, Hewlett-Packard, London, UK*

Cláudia Vaz, *Head of Market Access and Health Policy, Roche Diagnostics International Ltd., Roche Diagnostics Solutions (RDS), Global Market Access & Public Policy Team (MAPP), Rotkreuz, Switzerland*

Adem Koyuncu, MD, PhD (Law), *Partner and Chair, Food, Drug & Device Practice Group, Covington Brussels, Belgium and Frankfurt, Germany (Discussion Coordinator)*

3:45 pm **Co-chair Closing Comments**

4:00 pm **Congress Adjournment**