Virtual Fifteenth Annual International Pharmaceutical and Medical Device Ethics and Compliance Congress

Virtual Online Video Live and Archived

www.internationalpharmacongress.com

May 16 – 20, 2022

All Times are CET

AGENDA

PRECON: MONDAY, MAY 16, 2022

CHIEF COMPLIANCE OFFICER ROUNDTABLE

Special complimentary, invitation-only, closed-door Chief Compliance Officer Roundtable hosted by ETHICS. Facilitated confidential peer-to-peer discussions. Hosted on live zoom meeting. Session not recorded.

2:00 pm Welcome, Introductions, Brief Presentation Facilitated Discussions of Key Ethics and Compliance Challenges

- EU Whistleblower
- Russian Sanctions
- Managing MEA Compliance Programs Remotely
- Environmental, Social, and Governance (ESG)

Roxana Family, Thèse de Doctorat Droit, Chair of Law and Business Ethics, CY Cergy Paris Université; Scientific Director, International Review of Compliance and Business Ethics, Cergy-Pontoise, France (Dialogue Facilitator)

4:00 pm ADJOURNMENT

DAY I: TUESDAY, MAY 17, 2022

MINI SUMMITS ROUND I 10:00 am – 11:00 am

MINI SUMMIT 1: Basic Training: Basic Elements of the Compliance Field and Profession

- Department of Justice Guidance on the importance and evaluation of compliance programs
- Elements of an Effective Ethics & Compliance Program
- Assessing the Program for internal and external purposes
- Careers in Compliance

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

Kathleen M. Boozang, JD, LLM, Dean and Professor of Law, Seton Hall University School of Law, Fellow, The Hastings Center, Newark, NJ, USA

Jacob T. Elberg, JD, Associate Professor of Law, 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, US Department of Justice, Newark, NJ, USA

MINI SUMMIT 2: EU Whistleblowing Directive Update

- Scope of the EU-Whistleblowing Directive and current Status on the transposition
- Interpretation by EU Commission Discussion on group wide whistleblowing systems and how organizations are dealing with it
- Internal handling of reports or outsourcing
- Challenges around anti-retaliation

MINI SUMMIT 3: Ethics and Compliance Concerns in the Use of Social Media

Ethical and Compliance Concerns in the use of social media will be addressed, including:

- the analysis of the current status in the use of social media within our industry.
- people’s appetite to use social media and the variety of requests coming our way.
- spotlighting common and also hidden risks
- how companies approach and guardrail the use of social media
- recommendations for changes to facilitate industries adoption of social media.

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

Michelle Cockayne, Director of Risk Management Policy & Training and DPO International, Amicus Therapeutics; Former Governance and Compliance Lead for Global Procurement, AstraZeneca, Marlow, England, UK

Rosa Magistri, Compliance Lead for Global Procurement, Roche, Council Member, IPCAA, Basel, Switzerland

Stephanie Wingrove, MSc, Director, Ipsen; Former Associate Investigator, Parliamentary and Health Service Ombudsman, NHS; Former Detective Constable, London Metropolitan Police, Slough, UK

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

Désirée Maier, Partner, Compliance and Investigations, Hogan Lovells; Lecturer, University of Augsburg, Munich, Germany (Co-discussion Coordinator)

Antje Meyer, LLM, Senior Manager, Forensic & Integrity Services, EY, Düsseldorf, Germany (Co-discussion Coordinator)

MINI SUMMIT 4: Educational Conferences: From Presentational to Virtual: Challenges and Opportunities

- What is the short- and long-term impact of the pandemic on the medical congress and conference model?
- How are companies, medical societies, healthcare professionals, and conference organisers adjusting to new formats, such as virtual, or so-called ‘hybrid’ conferences combining in-person and virtual audiences?
- What new compliance (and economic) challenges does this new paradigm raise?
- What evolutions can be expected in the coming years?
- Are these changes temporary, or are they here to stay?

Session continued next page
MINI SUMMIT 5: Global Updates: Annual Central and Eastern Europe (CEE) Compliance Best Practices Update
- Maintaining an effective compliance function in the COVID era
  - Impact upon investigations
  - Impact upon training
  - Impact upon delivery of the corporate compliance message
  - Readiness for post COVID times
- Recent geo-political events – further challenges for the compliance function
- Legislative developments in the region

MINI SUMMIT 6: Basic Training: Beyond Compliance Programs, Empowering Ourselves as Thinkers: A Run through Ethics Theory as Applied to Healthcare Compliance
In this basic training session, Piergiorgio will answer the question, “How can we empower ourselves as thinkers beyond the technical aspects of our compliance programs?” Classical ethics theory will be discussed as a means to help one understand and face difficult dilemmas resulting from increasingly complex business models and transactions, the impact of the pandemic in creating unprecedented scenarios, and the growing role of artificial intelligence in healthcare.

MINI SUMMIT 7: EU’s Artificial Intelligence Act and the EU’s Planned Regulation of AI-systems
The session provides an introduction to European Commission’s proposal on an Artificial Intelligence Act, the first ever legal framework on AI. With its proposal the European Commission aims for setting a standard for the regulation of AI systems and provide a globally recognized blueprint for AI legislation and provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. The session will also provide an introduction into the related proposals for a Data Governance Act, a Data Act and an European Health Data Act, which were published recently.

MINI SUMMIT 8: Global Update on HCP Transparency Reporting/Aggregate Spend
Global Updates on HCP transparency including:
- Newly added covered recipients
- Open payments changes for reporting entities
- Recent enforcement actions

MINI SUMMIT 9: Compliance Considerations in Developing a Global HCP Hub
- Objectives of a Global HCP Hub
- Operational considerations for setting up a Global HCP Hub
- Navigating global Compliance standards on HCP Interactions
- Practical consideration to align objectives, operational considerations, and compliance standards
- Key considerations to support implementation success

MINI SUMMIT 10: Competition Law Compliance Update
The Life Sciences and pharmaceutical sector continue to be focused on competition law enforcement, especially in Europe, and recently had very high profile investigations into high prices of pharmaceutical products that have led to significant fines in different countries in the European Union, as well as in the UK. The increasing cost of providing health care has become an issue worldwide and particularly with the COVID crisis. It’s become a central point of focus for governments, including competition authorities, as a number of issues make pricing of pharmaceuticals particularly controversial. Ingrid will discuss how to assess whether a price is excessive and the risk of pharmaceutical exposure, competitor collaborations, and distribution and supply agreements.

Session continued next page
1:00 pm  Co-chair Welcome and Introductions

Anne-Sophie Bricca, Deputy General Counsel & Senior Director, Legal Affairs & Compliance, Terumo BCT, Chair, Ethics and Compliance Group and Member, Code Committee, MedTech Europe, Brussels, Belgium

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 Integrity, AEME Region, Sanofi; Former Head of Compliance Middle East, Laura Nassar, PharmD, Global Head of Ethics & Compliance and Executive Counsel, GE Healthcare Pharmaceutical Diagnostics, Board Member, Strategic Committee, ETHICS, Paris, France

Roeland Van Aelst, EMEA Lead, Third Party Intermediary, Ethics & Compliance, Johnson & Johnson, President, ETHICS, Chairman, MedTech Europe Code Committee, Brussels, Belgium

1:30 pm  Keynote Address

Antoinette Gawin, MSC, President & Chief Executive Officer, Terumo BCT, Chair, AdvaMed Board Ethics & Healthcare Compliance Committee, Denver, CO, USA

Interviewed by:
Anne-Sophie Bricca, Deputy General Counsel & Senior Director, Legal Affairs & Compliance, Terumo BCT, Chair, AdvaMed Board Ethics & Healthcare Compliance Committee, Denver, CO, USA

MINI SUMMIT 11: Global Updates: Annual Middle East Africa (MEA) Compliance Update

- Africa compliance update: will cover Egypt, North Africa, South Africa and selected sub-Saharan countries mainly on their code development, enforcement, and Trade Association. Will also cover legal and regulatory environment updates
- MEA compliance update: Trade Association and MEA code, in addition to legal updates mainly Gulf countries
- New go-to-market strategy: Omnichannel ecosystem in MEA and will cover reasons, consequences, compliance and laws Gulf countries
- New emerging business model in MEA: Outsourcing and will cover reasons, third party risks, case study of existing model on how to establish assurances, trust and sustainability for global pharma

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

Els Janssens, LLM, Counsel, Baker & McKenzie, Brussels, Belgium

Minal Patel, MS, Health Care Compliance Officer, Pharma and Consumer, Johnson & Johnson; Innovative Pharmaceutical Association South Africa Representative, Code Technical Advisory Committee, Johannesburg, South Africa

Hady Zohdy, Head of Ethics & Business Integrity, Sanofi Egypt, Sudan & Ethiopia; Chair, ESFRO Compliance Committee, Cairo, Egypt

Joe Henein, President and Chief Executive Officer, NewBridge Pharma; Former Regional Managing Director, Middle East & North Africa, Wyeth 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)

12:15 am  Luncheon Break and Visit Exhibit Hall

2:00 pm  AI, Data, Online Platforms: Risks and Regulations

Technology, particularly the internet and today's AI, create new opportunities but also new risks. Misinformation and echo chambers online, AI medical devices that may bias decisions or lead to outright unsafe outcomes, data privacy and new cyber-threats linked to data and AI, or AI embedded devices that evolve in unpredictable ways are just some of the new risks businesses need to understand and manage. Regulators are now preparing a series of new regulations that will impact anyone developing or using these technologies. Meanwhile, business stakeholders including the customers increasingly demand the safe and beneficial use of tech enabled products and services.

- What exactly are these new risks and how can we manage them?
- What do these new risks and regulations mean for businesses and compliance?
- What organisational and governance changes will be needed to ensure a safe and compliant development and use of digital technologies?
- What makes AI different from the point of view of risk management and compliance?

Theodoros Evgeniou, MEng, PhD, Professor, INSEAD, Academic Partner, Artificial Intelligence, World Economic Forum, Fontainebleau, France

2:30 pm  The Implications of Russian Sanctions on Pharmaceutical and Medical Device Company Operations

Sven De Knop, LLM, Partner, Sidley Austin, Brussels, Belgium

Justine Fassion, Senior Managing Associate, Sidley Austin; Former Attorney, French Permanent Mission, World Trade Organization, Brussels, Belgium

3:00 pm  Annual Senior Ethics and Compliance Professionals Best Practices Roundtable

Dirk Brinckman, LLM, Chief Compliance Officer, Johnson & Johnson, New Brunswick, NJ USA

Kirsten Bröckers, MBLT, Vice President, Head Legal Affairs, EMEA, Novartis Gene Therapies; Former Head Legal & Compliance EMEA, Novartis Gene Therapies (formerly AveXis); Former Head of Legal and Compliance, Vifor Fresenius Medical Care Renal Pharma, Basel, Switzerland

Betania Glorio, Global HC Chief Compliance Officer, EMD Serono, Inc.; Former Global Head of Compliance, Healthcare, Merck KGaA, Boston, MA

Bella Hovhannisyan, Chief Ethics & Compliance Officer, CSL Behring AG, Member, ETHICS; Former Compliance & Ethics Lead, Spain & Portugal, Bristol Myers Squibb, Berne, Switzerland

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

4:15 pm  DAY I ADJOURNMENT
MINI SUMMIT 12: Recent Trends & Developments Driving Multijurisdictional Enforcement in the Life Sciences Industry

The session will look at global regulatory and law enforcement trends that may impact, directly or indirectly, law enforcement in life science. The session will cover the following regulatory developments and/or case law in the following areas:

- Anti-bribery and corruption
- ESG
- Sanctions
- Whistleblowing
- Business and human rights

MINI SUMMIT 13: Enabling Compliance Transformation through Technology

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 everyone’s expectation that Compliance will prevent risks without inhibiting the customer experience. The pace of change continues and 2022 looks like being no exception.

- For most organizations, throwing in more people at the compliance challenges is not really an option. Compliance functions are under pressure to do more work and provide greater results with fewer and fewer resources
- In today’s panel we will focus on the technology aspect. We would like to discuss some perspectives on how compliance functions can cope with the increasing digitization across the value chain and how data and technology can enable the compliance function and can drive effectiveness as well as efficiency of global compliance programs?

MINI SUMMIT 14: EU Clinical Trial Risks and Fraud in the Conduct of Clinical Trials

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 these 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.

MINI SUMMIT 15: Compliance Officer Role: Increasing your Impact: Four Key Strategies for Life Sciences Compliance Officers

- How to prioritize not by risk, but by risk impact
- How to leverage stakeholders to free up bandwidth
- How to increase Compliance’s relevance by factoring in human decision-making
- How to make Compliance’s value-add more appreciated


Justin will lead the discussion on the evolution of compliance and operations and the strategic overlap between companies compliance and operational teams, including HCP interactions as a key multifunction operational activity. Over the last two years, as a result of the pandemic, compliance gained a seat at the table to help organizations achieve business objectives efficiently. Join the panel as they discuss how to leverage these learnings, think less tactically, and better understand the business strategy and business objectives to evolve the profession.

MINI SUMMIT 17: Basic Training: Necessary Skill Sets for Ethics and Compliance Professionals

The panelists share:

- How they each got into this profession;
- What was their initial motivation and what keeps them going;
- Some of the main skills needed to be successful in this profession;
- The growing expectations of all stakeholders;
- Tools and techniques to help in personal development.
MINI SUMMIT 18: Compliance Considerations in Response to In Vitro Diagnostic Regulation (IVDR)
- Determination of appropriate classification of an IVD following entry into application of the Regulation.
- Will classification under the IVDR result in up-classification of an IVD already available on the EU market? Will these IVDs benefit from a transitional period as provided in the EU?
- What is the content of the new Technical Documentation and how can manufacturers leverage existing Technical Files to prepare this Documentation?
- Is there a future for Home Brews?
- Importance of training on the new obligations imposed by the IVDR, including identification and appointment of a Person Responsible for Regulatory Compliance?
- Experience of IVDR to date?

11:15 am | Introductions, Panel Discussion and Q&A
Jenny Pu, CPA, CFE, Associate Director, Guidehouse Europe, Member, ETHICS, London, UK
Tamara Tubin, Director, Ethics & Healthcare Compliance, Corporate, Johnson & Johnson, Board & Strategic Committee Member, ETHICS; Former Intl. Compliance Director, Corporate, Wright Medical Group N.V., Zurich, Switzerland
Sue Egan, MBA, Director, Sue Egan Associates, Board and Co-chair, Strategic Committee, ETHICS, Great Missenden, UK (Discussion Coordinator)

MINI SUMMIT 19: People, Not Just Policies: The Role of Human-Centered Ethics and Compliance
Compliance is often viewed as a rote corporate exercise, yet can be as interesting and vibrant as the companies building the programs. How do we do that? In this panel, we will be discussing how putting people at the center of our approach to compliance, as well as acknowledging the role of culture in shaping thoughts, actions, and behavior, can improve effectiveness and increase engagement. Our conversation will cover topics such as the importance of measurement, the role of the behavioral sciences in improving programming and implementation, and concrete examples of how to take a human-centered approach.

11:15 am | Introductions, Panel Discussion and Q&A
Hui Chen, JD, Ethics & Compliance Expert, Former Compliance Counsel Expert (Consultant), US Department of Justice; Former Assistant General Counsel, Pfizer, Honolulu, Hawaii, USA
Irina Dragulev, LLB, LLM, Vice President, Compliance Training and Communication and Global Vaccines Compliance Counsel, Pfizer, New York, NY, USA
Caitlin Handron, PhD, Senior Lab Consultant and Behavioral Scientist, R&G Insights Lab, Ropes & Gray LLP; Former Research Scientist, Stanford University, Stanford, CA, USA
Zachary N. Coseglia, JD, Managing Principal, Head of Innovation and Co-Lead, R&G Insights Lab, Ropes & Gray LLP; Former Assistant General Counsel, Head of Global Compliance Monitoring, Analytics and Digital, Pfizer, Boston, MA, USA (Discussion Coordinator)

MINI SUMMIT 20: Fair Market Value Considerations for HCPs and non-HCPs
In this summit, we’ll talk about how companies approach fair market value, including FMV for non-HCPs, especially patients:
- Critical components of a defensible FMV methodology
- Setting and disseminating rates — in both centralized and decentralized corporate cultures
- Engaging in dialogue with affiliates to manage local regulations and requests for rate reviews
- Adjusting FMV systems for non-physicians
- Tiering and remunerating patient experts based on experience and service provided
- Working with patient organization representatives across different markets
No two FMV systems are the same, and the panel will address the pros, cons, and unsolved challenges of different approaches.

11:15 am | Introductions, Panel Discussion and Q&A
Michael Bartke, PhD, Strategic Committee, ETHICS; Former Director Ethics & Compliance, Alexion; Former Director Compliance Management, Daiichi, Sankyo, Europe, Munich, Germany
Andreas Gascard, Senior Director Compliance & Technology Integration, HCC Global Operations, Johnson & Johnson, Baseline, Germany
Jan Hinnerks, Head Compliance Solutions, F. Hoffmann-La Roche AG, Basel, Switzerland
Nicole Wicki, MS, Program Manager, The Synergist.org; Former Patient Advocacy Programme Manager, Myeloma Patients Europe, Brussels, Belgium
Eric Bolesh, Chief Operating Officer, Cutting Edge Information, Raleigh-Durham, NC, USA (Discussion Coordinator)

MINI SUMMIT 21: Global Updates: Annual Asia Pac (except China) Compliance Updates
The APAC session is a approximately a 55 minute evolving conversation delving into 3 key areas. The conversation will cover diverse perspectives from life science logistics/distributors, industry consultants and inhouse lawyers discussing implications to compliance and legal professionals in the APAC region.
- The first conversation hones in on the Asia Pacific recent Trends, developments and perspectives on the implications to compliance and legal professionals in the APAC of environment, social responsibility, and governance.
- The second conversation will look at the rise & fall & resurrection of overseas conferences/sales face to face events and revisiting marketing risks. The session will also focus on increasing risks regarding off label use. During the conversation, the discussions will cover the ongoing scepticism of regulators after 2 years of zero overseas conferences.
- The third conversation will look into APAC e commerce and B2B for Rx/Cx and Vx products including the notable issues and rising trends from e commerce for medicinal products, vaccines and devices particularly in South East Asia and the rest of the APAC region. The conversation will hone in on the types of data, doctors and patients, principals and particularly the management of data requests and issues arising therefrom. Views will be share about the meteoric rise of data privacy officers in the region in the last few years and the emergence of the role of integrity officers transitioning from compliance officers.

11:15 am | Introductions, Panel Discussion and Q&A
Maija Burtmanis, LLB, LLM, General Counsel & Chief Compliance Officer, ZueLLi; Former Compliance Director, Japan/Asia Pacific, Shire; Former Healthcare CO, Asia Pacific Medical Sciences, Johnson & Johnson, Former Associate GC, Alcon Russia, Singapore
Campbell Clark, LLB, MJ, Vice President, Legal & Compliance, APAC, Medtronic, Covalin Private Limited, Chair, Legal, Ethics and Compliance Committee, Asia Pacific Medical Technology Association (APACMed), Singapore
Gareth Lee, LLB, Chief Compliance Officer & Asia Pacific General Counsel, Cordis; Former VP, Legal & Compliance, Asia Pacific, Cardinal Health; Former General Counsel & Head of Compliance, Asia Pacific, Allergan, Singapore
Maria Eugenia (Maru) Quindimil, MBA, CEO and Founder, Socrates Compliance Consulting; Former Executive Director JAPAC, Amgen; Former APAC Ethics and Compliance Head, UCB, Waisanae, HI, USA
Geeta Thakerar, JD, Founder, Geeta Thakerar Consultancy Services; Former Chief Legal Counsel, Asia Pacific, Kimberly Clark; Former VP and Associate General Counsel, Asia Pacific/Japan, GlaxoSmithKline plc, Singapore (Discussion Coordinator)

12:15 pm | Luncheon Break/Visit Exhibit Hall
DAY II PLENARY SESSION

1:00 pm  Co-chair Welcome and Introductions

1:15 pm  Introduction to Environmental, Social, and Governance (ESG) Plenary Session

Dominique Laymand, Of Counsel, Clifford Chance; Former Executive Vice President, Ethics & Social Responsibility Officer, Ipsen; Honorary President, ETHICS, Paris, France (ESG Chair)

1:20 pm  ESG Strategies for Creating a Sustainable Corporate Future

Colin Coulson-Thomas, PhD, President, Institute of Management Services, Chancellor and Professonal Fellow, School for the Creative Arts (Ghana); Director-General, UK and Europe, Institute of Directors (India), Peterborough, UK

1:40 pm  World Economic Forum ESG Keynote Address

Emily Bayley, MBA, Head of ESG, Private Sector, World Economic Forum, Geneva, Switzerland

2:00 pm  ESG Legal Issues and Avoidance Strategies

Peter Dieners, 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

2:15 pm  ESG Roundtable

Dominique Laymand, Of Counsel, Clifford Chance; Former Executive Vice President, Ethics & Social Responsibility Officer, Ipsen; Honorary President, ETHICS, Paris, France

Jim Massey, MS, Chief Sustainability Officer, Zai Lab; Former VP ESG Sustainability, Ethics, Compliance, AstraZeneca, Washington, DC

Maximilien Roche, MBA, JD, Compliance and Risk Officer, World Economic Forum, Geneva, Switzerland

Thomas Voland, LLM, Partner and Member, Global ESG Board, Clifford Chance; University Lecturer, Leupiz University, Düsseldorf, Germany

Peter Dieners, 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)

3:45 pm  DAY II ADJOURNMENT

DAY III: THURSDAY, MAY 19, 2022

MINI SUMMITS ROUND V 10:00 am – 11:00 am

MINI SUMMIT 22: Basic Training: Understanding our Duties and Our Rights under Codes of Conduct for Ethics and Compliance Professionals

• ETHICS Code of Professional Conduct for Healthcare Ethics and Compliance Professionals
• Health Care Compliance Association Code of Ethics for Health Care Compliance Professionals

10:00 am  Discussion and Q&A

Piergiorgio Pepe, MA, EU Law, Chief Executive Officer, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo, Board Member ETHICS; Former Compliance Director, Western Europe & Canada, AbbVie; Former Director, Compliance & Ethics MEA, Bristol-Myers Squibb, Paris, France

MINI SUMMIT 23: The Blockchain Revolution & Digital Legal Compliance

How are we as legal and compliance leaders staying ahead of the game and equipping ourselves to be the blockchain digital leaders, advisors our businesses and the world needs? Digital is our present and future. Majority of pharmaceutical and medical device companies including Roche and many others are now starting to explore blockchain heavily. If one wants to be a progressive digital compliance leader then it’s crucial to have a solid foundation on which to advise and lead from in the sphere of blockchain.

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

Elvira Valverde Garcia, MA, LLM, Global Privacy Counsel, F. Hoffmann-La Roche Ltd; Former Corporate Counsel, Ethics & Compliance/Legal EMEA, Baxter International Inc., Zurich, Switzerland

Iñigo de la Maza Prieto, MSc, MBA, Data Scientist Solution Architect, F. Hoffmann-La Roche Ltd, Zurich, Switzerland

Nicole Peter, Global Compliance Leader, F. Hoffmann-La Roche Ltd, Zurich, Switzerland (Discussion Coordinator)

MINI SUMMIT 24: Pre and Post Ethics and Compliance Concerns in Mergers & Acquisitions

Following the disruption from the pandemic combined with a number of recent prosecutions, especially in the US, mergers and acquisitions are expected to increase. George will lead this esteemed panel on discussions pertaining to:

• Consideration of extra territorial laws and regulations (e.g., Sapin II, FCPA, UK Bribery Act, etc.) across multiple jurisdictions.
• Corporate criminal liability for past or ongoing corrupt practices of the acquired entity.
• An understanding of the values and ethical standards of the acquired entity to ensure future compliance.
• Changes and expectations of stakeholders including governments, regulators, investors and consumers coupled with growing demands for integrity, responsibility, accountability, and transparency.

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

Anne-Sophie Bricca, Deputy General Counsel & Senior Director, Legal Affairs & Compliance, Terumo BCT; Chair, Ethics and Compliance Group and Member, Code Committee, MedTech Europe, Brussels, Belgium

Nicola Giovagnetti, MBA, Head of Global Compliance, MENARINI Group, Rome, Italy

Laetitia Ducroquet Minel, Vice President, Global Business, Ipsen, Paris, France

George Fife, Partner, Forensic & Integrity Services, EY; Former Executive Director, Compliance & Ethics, Bristol-Myers Squibb, Paris, France (Discussion Coordinator)
MINI SUMMIT 25: Digital Responsibility and Digital Ethics: Making the Difference

Oscar Perdono, Director Pharmaceutical & Life Sciences, Advisory Services, PwC, will lead a team of industry experts on digital responsibility and digital ethics, including:

- An overview on the meaning of digital tools and digital technology and current use in the industry.
- Challenges and opportunities in the use of those that form of technology.
- The definition of digital ethics and digital responsibility, how companies are incorporating both into their daily business and culture, and the challenges related to that transition.
- Panelists recommendations, best practices, and learnings from the industry.

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

Angela Belloumini, JD, Senior Healthcare Compliance Leader, Genentech, San Francisco, CA, USA

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

Sharmeen Ali Khan, LLM, Executive Director Compliance, Europe Latin America Middle East Africa & Canada, Amgen; Former Regional Compliance Director-Africa, Middle East, Pfizer, Zug, Switzerland

Oscar Perdono, Director, Pharmaceutical & Life Sciences, Advisory Services, PwC Switzerland, Zurich, Switzerland

MINI SUMMIT 26: Global Updates: Annual China Compliance Update

The anti-corruption compliance environment in China for multinational pharmaceutical and medical device companies is changing rapidly. On one side, the Chinese government has been increasing its scrutiny of corruption schemes and practices in these industries, and also heightening its enforcement. On the other side, companies are coming up with new business models and initiatives, which have brought about new challenges to anti-corruption compliance. Particularly noteworthy is the rising tide of digitalization, i.e., using digital platforms to carry out physician and patient training events. Also, companies are striving to use digital tools and data analytics to maximize their efficiency of compliance monitoring. In this mini summit, we will discuss these changes, and the challenges and opportunities given rise to.

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

Vivian Chen, LLB, MBA, BiMBA, Compliance Director for Greater China, Medtronic; Former Head of Compliance China, Alcon; Former Head of Ethics and Compliance, Greater China, Baxter, Beijing, China

Vanessa Han, Head of Compliance for Region China, Novo Nordisk, Shanghai, China

Mohit Grover, Partner, Deloitte; Former Regional CIO, Astra Zeneca Asia Pacific, Hong Kong (Co-discussion Coordinator)

Lei Li, LLM, Partner, Sidney Austin; Former Third Secretary, Ministry of Commerce, People’s Republic of China, Beijing, China, (Co-discussion Coordinator)

11:00 am  Transition Break

MINI SUMMIT 27: Basic Training: Being Ethical Is Harder Than You Think: An Interactive Workshop Which Tests your Presumption about Ethics and Ethical Decision Making

Being Ethical is Harder Than You Think! — In this completely interactive exercise, participants will learn how their mind will alter and transform facts and situations in order to achieve personal desires over organizational goals. These transformations occur automatically in the subconscious mind and without establishing proactive methods to mitigate these processes, organizations may inadvertently be promoting unethical behaviors by their leaders and employees.

Learning Objectives: After this block of instruction, the participants will be able to:

- Describe the effects of bounded ethicality.
- Assess how perspective, life experiences and culture can change ethical perceptions.
- Discuss the psychological need to look at our actions favorably.
- Compare/Contrast the effects of power and mindset.
- Create mental triggers to improve ethical outcomes.

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

Michael “Bret” Hood, MBA, CEO, 21st Century Learning & Consulting LLC; Former FBI Special Agent; Former Leadership Instructor, FBI’s National Academy; Winner, US Attorney’s Office Special Agent of the Year, Economic Crimes Agent of the Year and Forfeiture Agent of the Year, Hillsborough, NC, USA

MINI SUMMIT 28: The Role of Data Analytics in Ethics and Compliance

- How data analytics is deployed in Ethics and Compliance programmes.
- What are the benefits of having data analytics within the programme?
- What are some of the common challenges that have to be overcome to achieve success?
- The journey continues — what lies ahead?

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

Ash Aggarwal, MBA, Senior Director, Compliance Excellence & Transformation, Astellas Europe; Former Audit Director and Analytics Lead, AstraZeneca, London, UK

Philip Morris, Senior Compliance Director, Audit, Analytics & Monitoring, Smith & Nephew, Pembroke Dock, UK

Sarah Venable, JD, MS, Director of Data Science and Risk Analytics, Global Legal and Compliance, GSK, Raleigh, NC, USA

Carl Judge, Partner, Forensic & Integrity Services, EY, London, UK (Discussion Coordinator)

MINI SUMMIT 29: Annual Medical Device Compliance Update

Join Veronique and this prestigious panel as they provide Medical Devices Updates, including:

- Code revision: Why?
- Third Party Due Diligence and Business conduct
- EU Directive on Corporate Sustainability Due Diligence: work in progress where does that stand?
- Donation: code and practical exceptions on specific circumstances
- Ethics principals and Artificial intelligence: What’s coming up?

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

Anne-Sophie Briaca, Deputy General Counsel & Senior Director Legal Affairs & Compliance, Terumo BCT; Chair, Ethics and Compliance Group and Member, Code Committee, MedTech Europe, Brussels, Belgium

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

Philippa Montogomerie, LLB, Vice President, Legal & Compliance, Medtronic, Edinburgh, Scotland, UK

Roeland Van Aelst, EMEA Lead, Third Party Intermediary, Ethics & Compliance, Johnson & Johnson, President, ETHICS, Chairman, MedTech Europe Code Committee, Brussels, Belgium

Veronique Monjardet, PhD, Compliance Director, SME and Communication, Life Sciences, IQVIA, Paris, France (Discussion Coordinator)
MINI SUMMIT 30: Global Updates: Annual Latin America Compliance Update
To discuss key trends impacting the healthcare industry in Latin America, the key topics seen on the agenda of the compliance teams, the emerging risks and to exchange some ideas to address them.

11:15 am Introductions, Panel Discussion and Q&A
- **Gildas Durand**, Partner/Principal, Forensic & Integrity Services, EY, Miami, FL, USA
- **Juan Luis Fuentes**, Ethics, Risk & Compliance, Head Latin America & Canada, Oncology, Novartis, Former Head of Legal and Compliance, Sanzoo, East Hanover, NJ, USA
- **Sergio Pinto**, MBA, Sr. Director Compliance, Third Party Ethics & Compliance, Americas, Johnson & Johnson, Committee Member, Compliance Council Brasil, São Paulo, Brazil
- **Maria Teresa Cantú Reus**, Legal Advisor and Compliance Officer, Latin American Federation of the Pharmaceutical Industry (FIFARMA), External Compliance Officer, Mexican Association of Pharmaceutical Research Industries (AMIPIC), Mexico City, Mexico
- **Imelda Álvarez**, MBA, Chief Executive Officer & Founder, Comply Latam, SC, Former Regional Integrity & Compliance Head, Latin America and Canada, Novartis, Mexico City, Mexico (Discussion Coordinator)

12:15 pm Luncheon Break/Visit Exhibit Hall

DAY III PLENARY SESSION

1:00 pm Co-chairs Welcome and Introductions

1:15 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**, 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)

1:45 pm Agence Française Anti-corruption (AFA) Update
- **Benjamin Clady, MSc**, Chargé de Secteur, Département de l’Appui aux Acteurs Economiques, Agence Française Anticorruption, Paris, France
- **George Fife**, Partner, Forensic & Integrity Services, EY, Paris, France (Discussion Coordinator)

2:15 pm FCPA Enforcement Update
- **Robert I. Dodge, JD**, Assistant Director, FCPA Unit, US Securities & Exchange Commission; Former Assistant Section, Environmental Defense Section, US Department of Justice, Washington, DC
- **Derek J. Ettinger, JD**, PhD, Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC, USA
- **Gary F. Giampetruzzi, JD**, Partner, Litigation Department; Global Chair Life Sciences Department; and Vice-Chair Investigations and White-Collar Practices, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Discussion Coordinator)

3:00 pm Annual Global Anti-corruption Roundtable
- **Imelda Álvarez, LLB, MBA**, Chief Executive Officer & Founder, Comply Latam, SC, Former Regional Integrity & Compliance Head, Latin America and Canada, Novartis, Mexico City, Mexico
- **Campbell Clark, LLB, MJ**, Vice President, Legal & Compliance, APAC, Medtronic, Covidien Private Limited, Chair, Legal, Ethics and Compliance Committee, Asia Pacific Medical Technology Association (APACMed), Singapore
- **Peter Dieners, JD**, Regional Managing Partner (Germany) and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Member, Legal Affairs Focus Group and Compliance and MedTech Europe; Member, Legal Affairs Committee and Healthcare Compliance Committee, BVMed, Düsseldorf, Germany
- **George Fife**, Partner, Forensic & Integrity Services, EY, Paris, France
- **Lei Li, LLM**, Managing Partner, Beijing and Shanghai Offices, Sidley Austin; Former Third Secretary, Ministry of Commerce, People’s Republic of China, Beijing, China
- **Michael K. Loucks, JD**, Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, US Department of Justice, Washington, DC, USA

4:15 pm

DAY III ADJOURNMENT
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<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker/Institution</th>
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<tbody>
<tr>
<td>10:00 am</td>
<td>Co-chair Welcome and Introductions</td>
<td>Christopher L. White, JD, General Counsel and Chief Policy Officer, AdvaMed, Washington, DC, USA</td>
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<tr>
<td>10:15 am</td>
<td>Industry Voluntary Compliance Codes Update</td>
<td>Christopher L. White, JD, General Counsel and Chief Policy Officer, AdvaMed, Washington, DC, USA</td>
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<td><strong>APACMed</strong></td>
<td>Campbell Clark, LLB, MJ, Vice President, Legal &amp; Compliance, APAC, Medtronic, Covidien Private Limited, Chair, Legal, Ethics and Compliance Committee, Asia Pacific Medical Technology Association (APACMed), Singapore</td>
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<td><strong>IFPMA</strong></td>
<td>Sofie Melis, MA, Director HR and Ethics &amp; Compliance, International Federation of Pharmaceutical, Manufacturers and Associations (IFPMA), Geneva, Switzerland</td>
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<td><strong>EFPIA</strong></td>
<td>Julie Bonhomme, Legal &amp; Compliance Director, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium</td>
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<td><strong>MEA LAWG</strong></td>
<td>Nisreen Sartawi, MBA, CPCC, ACC, Area Compliance Lead, Roche Middle East Advisory &amp; Coaching Chapter Co-Lead, Roche Health &amp; Compliance Office, Dubai, UAE</td>
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<td><strong>MECOMED</strong></td>
<td>Arwa Asiri, IMHL, Compliance Officer MEA Region, Medical Technology Association of Middle East &amp; Africa (Mecomed), Dubai, UAE</td>
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<td><strong>MedTech Europe</strong></td>
<td>Pablo Rojas Abad, LLM, Senior Legal Counsel and Senior Manager, Legal &amp; Compliance, MedTech Europe, Etterbeek, Belgium</td>
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<td><strong>PhRMA</strong></td>
<td>Julie Ritchie Wagner, JD, Senior Assistant General Counsel and Head of Global Ethics, Compliance &amp; Enforcement Legal Policy, PhRMA; Former Senior Counsel, Office of Counsel to the Inspector General, US Department of Health and Human Services, Washington, DC, USA</td>
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<td><strong>Kabeer Uddin</strong></td>
<td>Kabeer Uddin, Associate Principal Commercial Compliance, Consulting Life Sciences, IQVIA, London, UK (Discussion Coordinator)</td>
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<td>11:45 am</td>
<td>On the Eve of Retirement: Lessons Learned Representing Pharma and Device Companies for 30 Years in Moscow</td>
<td>Paul J. Melling, JD, Founding Partner, Baker &amp; McKenzie, CIS, Limited, Moscow, Russia</td>
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<td>12:15 pm</td>
<td>Luncheon Break and Visit Exhibit Hall</td>
<td>Klaus Moosmayer, PhD, Chief Ethics, Risk &amp; Compliance Officer and Member, Executive Committee, Novartis, Basel, Switzerland</td>
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<td>1:00 pm</td>
<td>Reimagining Ethics, Risk &amp; Compliance at Novartis</td>
<td>Klaus Moosmayer, PhD, Chief Ethics, Risk &amp; Compliance Officer and Member, Executive Committee, Novartis, Basel, Switzerland</td>
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<td>1:30 pm</td>
<td>Keynote Address: New Skills and Self-Care: Empowering Ethics and Compliance Professionals in the Face of New Challenges</td>
<td>Piergiorgio Pepe, MA, EU Law, Chief Executive Officer, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo, Board Member ETHICS; Former Compliance Director, Western Europe &amp; Canada, AbbVie; Former Director, Compliance &amp; Ethics EMEA, Bristol-Myers Squibb, Paris, France</td>
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<td>2:00 pm</td>
<td>How Great Enablers can Empower their Teams and Bring Both Greater Job Satisfaction and Efficiency</td>
<td>David Shore, Faculty, Harvard University, Faculty, The Governance Institute, Advisory Board, McKinsey &amp; Company; Distinguished Professor of Innovation and Change, Tianjin University (China) and University of Monterrey, Business School (Mexico), Cambridge, MA</td>
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<td>2:30 pm</td>
<td>Resilience</td>
<td>Oliver Medill, Managing Director, All About Impact; Author, The Impact Formula: Powerful Solutions for Turbo-charging your Influence, London, UK</td>
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<td>3:00 pm</td>
<td>Co-chair Closing Comments</td>
<td>Kabeer Uddin, Associate Principal Commercial Compliance, Consulting Life Sciences, IQVIA, London, UK (Discussion Coordinator)</td>
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