

The Thirteenth International Pharmaceutical and Medical Device Compliance Congress

GRAND HYATT ATHENS • ATHENS, GREECE

APRIL 8 – 10, 2019

For Early Bird
Registration Discount
Register by Friday,
February 15, 2019.



www.InternationalPharmaCongress.com



CO CHAIRS:

Dante Beccaria, Senior VP, Global Compliance Officer, Head of Ethics & Business Integrity Department, Sanofi



Stephen Nguyen Duc, Global Head, Ethics & Compliance, Medday Pharmaceuticals, Board, ETHICS



Suzanne Durdevic, LLM, Former Senior Director & GC Europe, Boston Scientific International; Strategic Committee, ETHICS



Dominique Laymand, Esq., Executive VP, Chief Ethics & Compliance Officer and CSR, Ipsen; Honorary President, ETHICS



Roeland Van Aelst, Regional VP, HCCO MD & EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson; Chair, ETHICS

SPONSOR:



CONTINUING EDUCATION CREDITS:

Accounting Professionals: Approved for up to 18.5 NASBA CPE credits.

Attorneys: Approved for up to 14.00 Pennsylvania CLE Credits.

Compliance Professionals: This education activity has been submitted to the Compliance Certification Board (CCB)[®] and is currently pending their review for approval of CCB CEUs.



KEYNOTE SPEAKERS:

Julie Bonhomme, Legal and Compliance Director, EFPIA



Rachel Cooper, LLB, MSc, Director, Pharmaceuticals & Healthcare Programme, Transparency International



Holger Diener, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA); Vice Chair, Code Committee, EFPIA



Robert I. Dodge, JD, Assistant Director, FCPA Unit, US SEC



Abhiroop Gandhi, MS, MBA, Trust and Compliance Officer, Verily Life Sciences



José F. Zamarriego Izquierdo, MBA, PhD, Director, Code of Practice Surveillance Unit, Farmindustria; Chair, EFPIA Code Committee; Chair, IFPMA's Code Complaint Procedure Appeal Group



Sofie Melis, Head of Ethics and Compliance, IFPMA



Guido Palazzo, PhD, Professor of Business Ethics, University of Lausanne



Piergiorgio Pepe, MA EU Law, President, Quantum Ethics; Ethics & Compliance Lecturer, SciencesPo



Rami A. Rajab, Chairman, Mecomed Medical Technology, Association Middle East and Africa (MECOMED)



Harout Semerjian, MBA, Executive Vice-President & Chief Commercial Officer, Ipsen



Heather Simmonds, Director, Prescription Medicines Code of Practice Authority



Christopher L. White, JD, COO & General Counsel, AdvaMed

MEDIA PARTNERS:



POLICY & MEDICINE
COMPLIANCE UPDATE



DIAMOND GRANTOR:



SILVER GRANTORS:



BRONZE GRANTORS:



SPECIAL RATES
AVAILABLE FOR:



The First International Pharmaceutical Compliance Congress and Best Practices Forum was held in June 2007 to bring together company compliance professionals, regulators, lawyers, and consultants working in this interesting and expanding field. The purpose was to hold a truly global conference addressing the key issues impacting our industries. The first international conference agenda was developed with inputs from company compliance professionals on topics they wanted to know more about, which continues to be one of the greatest strengths of these conferences.

The 2019 Co-Chairs led the design of the Congress around relevant global pharma and medical device compliance codes updates, current compliance issues, and emerging trends pertaining to:

- Anticorruption and Anti-bribery Policy
- Relationships with Patient Support Programs
- Compliance Issues Raised by Pharma & Device New Business Models
- Third-Party Risk Management, Due Diligence, and Compliance Monitoring
- EU General Data Protection Regulation (GDPR)
- Update on the new French Sapin II Law
- Compliance Issues in Market access and Outcomes-Based Value-Added Services
- Annual Central and Eastern Europe (CEE) Compliance Update
- Annual Middle East Africa (MEA) Compliance Update
- Transforming Compliance into a Profession
- The next Generation of Ethics and Compliance Programs.

This year the Congress features keynote speakers from important organizations and industry associations including Transparency International (TI), the International Society of Healthcare Ethics and Compliance Professionals (ETHICS), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the UK Prescription Medicines Code of Practice Authority, the Code of Practice Surveillance Unit, Farmaindustria (Spain), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), MedTech Europe, the Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA) and the US Securities & Exchange Commission (SEC).

Listen to and engage in dialogue with our keynote speakers, industry experts working within pharmaceutical and medical devices companies, as well as, legal counsel and industry partners as we navigate the current landscape, share best practices, and discuss practical guidance for the future of our profession.

Over the years, the International Congresses have been held in Berlin (2010), Brussels (2007, 2015), Budapest (2012), Dubai (2014), Istanbul (2011), Madrid (2013), Paris (2008), Rome (2009), Warsaw (2016), Lisbon (2017) and Vienna (2018). In 2019, we are pleased to hold the Thirteenth International Pharmaceutical Compliance Congress and Best Practices Forum in Athens, Greece.

WHO SHOULD ATTEND:

- Pharmaceutical Manufacturers
- Medical Device Manufacturers
- Generic Pharmaceutical Manufacturers
- Site Management Organizations
- Clinical Research Organizations
- Management Companies
- Wholesale, Retail, Mail Order and Internet Pharmacies
- Health Care Regulators and Policy Makers
- Pharmaceutical and Health Care Executives and Board Members
- Regulatory and Compliance Professionals
- Medical Directors
- Physicians and Other Health Care Professionals
- Pharmacists
- Food and Drug Law Attorneys
- Health Care Attorneys and In-house Counsel
- Compliance Officers
- Privacy Officers
- Ethics Officers and Corporate Social Responsibility Personnel
- Pharmaceutical Consultants
- Investment Bankers
- Venture Capitalists
- Health Services Researchers and Academics
- Auditors
- Promotion Signatories/Approvers
- Risk Management Personnel
- Governmental Policy Makers and Regulators

SPONSOR:



INTERNATIONAL SOCIETY OF HEALTHCARE ETHICS AND COMPLIANCE PROFESSIONALS (ETHICS) was incorporated as an Association governed by French law in January 2012, currently comprised of around 50 members all active in major pharma and medical device companies. ETHICS aims to be recognised as an independent international association of

professionals, which sets standards of Ethics and Compliance and shapes and influences strategies in the changing Healthcare environment for the ultimate benefit of Patients and Society at large.

EXHIBIT AND SPONSORSHIP OPPORTUNITIES

Take advantage of this unique opportunity to expand your reach! The Congress is attended by highly influential and experienced professionals. Sponsorship offers you strategic positioning as an industry leader. For more information call **206-673-4815** or email exhibits@hcconferences.com.

AGENDA AT A GLANCE

MONDAY, APRIL 8

9:00 am **PRECONFERENCE SYMPOSIA**

PRECONFERENCE I: A WORKSHOP ON PRACTICAL CASE STUDIES AND EXERCISES IN ETHICS AND COMPLIANCE

PRECONFERENCE II: ADVANCED INVESTIGATIONS

Noon **Adjournment and Lunch on Your Own**

DAY I: OPENING PLENARY SESSION 1:00 pm – 5:30 pm

1:00 pm **International Pharma Congress Vision and Overview**

1:15 pm **Keynote Address: Pharma Executive**

1:45 pm **Compliance and Ethics Issues Raised by Pharma and Device New Business Models: Product vs. Value and Outcome Based Approaches, and the Emergence of Analytics, Big Data and AI**

2:45 pm **BREAK**

3:15 pm **Global Compliance Codes Update with Special Focus on the New IFPMA Code**

4:15 pm **Chief Compliance Officer Roundtable**

5:30 pm **ADJOURNMENT AND NETWORKING RECEPTION**

TUESDAY, APRIL 9

DAY II: MORNING PLENARY SESSION 8:30 am – 10:15 am

8:30 am **Co-chair Welcome and Overview**

8:45 am **Transparency International Annual Keynote Address**

9:15 am **Annual Anticorruption Roundtable**

10:15 am **BREAK**

10:45 am **MINI SUMMITS ROUND I 10:45 am – 11:45 am** *Choose one:*

I: Annual Medical Device Ethics and Compliance Best Practices Roundtable

II: Compliance in the Light of Digitalization

III: Data Privacy, Consent Management and GDPR Update

IV: Ethics and Compliance Issues in Patient Relationships, Including Patient Access and Support Programs

V: Annual Middle East Africa (MEA) Compliance Update

11:45 am **NETWORKING LUNCHEON**

12:45 pm **MINI SUMMITS ROUND II 12:45 pm – 1:45 pm** *Choose one:*

VI: Whistleblower Updates: New EU-wide Standards to Protect Whistleblowers & US Qui Tam Actions against Foreign Pharma and Device Companies doing Business in the US

VII: The Evolution of Risk Assessment and Using Risk Assessment to Design Compliance Programs

VIII: Analytics with Reference to Transparency and/or Monitoring

IX: The Next Chapter — Improving the Future of Compliant HCP Engagements

X: Annual Central and Eastern Europe (CEE) Compliance Best Practices Update

1:45 pm **TRANSITION BREAK**

2:00 pm **MINI SUMMITS ROUND III 2:00 pm – 3:00 pm** *Choose one:*

XI: Reducing FCPA Exposure through Better Use of Data

XII: Compliance Issues Raised by Patient and Foundation Petitions for Government Coverage of Certain Drugs

XIII: Behavioral Science to Enhance Effectiveness of Compliance Programs

XIV: Third Party Due Diligence and Management

XV: Structuring an Efficient Digital Compliance Framework: Overcome Cross-jurisdictional Boundaries, Process Complexity and Dispersed Resources

AFTERNOON PLENARY SESSION 3:30 pm – 5:30 pm

3:30 pm **Update on the New French Sapin II Law: Responding to the French Anticorruption Questionnaire, Inspections and Prosecutions**

4:15 pm **Annual FCPA Update Roundtable**

4:45 pm **Collaboration and Cooperation in Multi-jurisdictional Anticorruption Investigations and Prosecutions**

5:30 pm **ADJOURNMENT**

WEDNESDAY, APRIL 10

DAY III: MINI SUMMITS AND CLOSING PLENARY SESSION

8:30 am **MINI SUMMITS ROUND IV 8:30 am – 9:30 am** *Choose one:*

XVI: Auditing and Monitoring Workgroup

XVII: R&D and Clinical Trials Compliance Workgroup

XVIII: Communications and Collaboration with in-company Business Partners Workgroup

CLOSING PLENARY SESSION 9:45 am – 12:30 pm

9:45 am **Co-chair Welcome and Introductions**

10:00 am **The Panama Papers: Breaking the Story of How the Rich and Powerful Hide Their Money**

10:30 am **Ethics and Compliance Keynote Address**

11:00 am **The Emerging Role of Technology Companies in the Life Science Marketplace and the Ethical and Compliance Implications of this Development**

11:30 am **IFPMA Global Compliance Updates**

Noon **Transforming Compliance into a Profession**

12:30 pm **ADJOURNMENT**

MONDAY, APRIL 8, 2019

8:00 am Registration Opens

PRECONFERENCE SYMPOSIA

PRECONFERENCE I: A WORKSHOP ON PRACTICAL CASE STUDIES AND EXERCISES IN ETHICS AND COMPLIANCE

9:00 am Welcome and Introductions

Pablo Rojas Abad, LL.M., Manager, Legal and Compliance, MedTech Europe, Brussels, Belgium

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

Sue Egan, Director and Principal Consultant, Sue Egan Associates, Great Missenden, Buckinghamshire, UK

Karen Eryou, Head, Ethics & Compliance Programs, UCB Pharma; Former Co-chair, Asia Pacific Pharma Compliance Congress, Brussels, Belgium

Cecile Gousset, Head of Compliance Risk Assessment, Policies & Education, Global Ethics & Business Integrity, Sanofi, Paris, France

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

Roeland Van Aelst, Regional Vice President - HCCO MD & EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson; Chairman, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium

Noon Adjournment and Lunch on Your Own

PRECONFERENCE II: ADVANCED INVESTIGATIONS

9:00 am Welcome and Introductions

Ann Beasley, JD, Director, Navigant Consulting; Former Senior Vice President, Chief Compliance Officer, Biogen; Former Co-chair, International Pharmaceutical and Medical Device Compliance Congress, Boston, MA, USA

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

Betania Glorio, Global Compliance Officer Healthcare at Merck KGaA; Former Senior Director, Legal and Compliance EMEA, Horizon; Former Senior Counsel, Regional Compliance, Director, EUCAN, Pfizer, Darmstadt, Germany

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

Gary F. Giampetruzzi, Esq., Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Co-moderator)

Thomas K. Hauser, MA HSG, MSJ, Director, Life Sciences Governance, Risk Management, and Compliance Practice, Navigant; Former Global Chief Compliance Officer, Siemens Healthcare; Treasurer, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), London, UK (Co-moderator)

Noon Adjournment and Lunch on Your Own

MONDAY, APRIL 8, 2019

INTERNATIONAL PHARMA CONGRESS DAY I: OPENING PLENARY SESSION

1:00 pm



International Pharma Congress Vision and Overview

Dante Beccaria, Senior Vice President, Global Compliance Officer, Head of Ethics & Business Integrity Department; Former Vice President of Internal Audit, Sanofi, Paris, France (Co-chair)



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



Suzanne Durdevic, LL.M., Former Senior Director, General Counsel Europe, Boston Scientific International; Member, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Paris, France (Co-chair)



Dominique Laymand, Esq., Executive Vice President, Chief Ethics and Compliance Officer and CSR, Ipsen; President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Paris, France (Co-chair)



Roeland Van Aelst, Regional Vice President - HCCO MD & EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson; Chairman, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium (Co-chair)

1:15 pm



Keynote Address: Pharma Executive

Harout Semerjian, MBA, Executive Vice President and Chief Commercial Officer, Ipsen; Former Senior Vice President and Global Launch Lead, Ribociclib, Novartis Oncology, New York, NY, USA

1:45 pm



Compliance and Ethics Issues Raised by Pharma and Device New Business Models: Product vs. Value and Outcome Based Approaches, and the Emergence of Analytics, Big Data and AI

Julien Durand, MBA, PhD, Executive Director Compliance & Ethics, Amgen; Former Chief Privacy Officer and Global Technology Compliance Head, AstraZeneca, Zürich, Switzerland



Thomas K. Hauser, MA HSG, MSJ, Director, Life Sciences Governance, Risk Management, and Compliance Practice, Navigant; Former Global Chief Compliance Officer, Siemens Healthcare; Treasurer, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), London, UK and Berlin, Germany



Roeland Van Aelst, Regional Vice President - HCCO MD & EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson; Chairman, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium



Kathy Tench, MS, Director, Life Sciences Compliance, KPMG Switzerland; Former Senior Director of Compliance, Optimer Pharmaceuticals, Zürich, Switzerland (Moderator)

2:45 pm

Break

HOTEL INFORMATION/RESERVATIONS

The Thirteenth International Pharmaceutical and Medical Device Compliance Congress does not contract with any third party organization to make hotel reservations for attendees of the Summit. All attendees should make their hotel reservations directly with the hotel and not with a third party vendor.

The Grand Hyatt Athens is the official hotel for The Thirteenth International Pharmaceutical and Medical Device Compliance Congress.

The Congress has negotiated a group rate for our attendees of €155.00 sgl/€175.00 dbl per night plus tax. The hotel will honor this rate until the block is filled.

To BOOK YOUR ROOM guest may call Hyatt Reservations on +30 24 402 1234 and mention The Thirteenth International Pharmaceutical and Medical Device Compliance Congress.

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3:15 pm



Global Compliance Codes Update with Special Focus on the New IFPMA Code

IFPMA Code

Holger Diener, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA); Member, Ethics and Compliance Committee and Vice Chair Code Committee, EFPIA; Member, IFPMA Code Compliance Network, Berlin, Germany



EFPIA Code

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



MedTech Europe Code

Serge Bernasconi, MA, MIM (Invited), Chief Executive Officer, MedTech Europe; Former Chief Executive Officer, Eucomed; Former Chief Executive Officer, European Diagnostic Manufacturers Association, Brussels, Belgium



MEA Code

Dream Samir (Invited), Consultant, AMICULUM-ME; Secretary General, Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG), Dubai, United Arab Emirates



MECOMED Code

Rami A. Rajab, Chairman, Mecomed Medical Technology, Association Middle East & Africa (MECOMED); Chairman, LIFE (LivaNova International Fellowship), International Corporate Social Responsibility; Former Vice President Market Access, Emerging Markets, LivaNova, Maidenhead, UK



AdvaMed Code

Christopher L. White, JD, Chief Operating Officer and General Counsel, Advanced Medical Technology Association (AdvaMed), Washington, DC, USA



Country Codes

Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, London, UK



José F. Zamarriego Izquierdo, MBA, PhD, Director, Code of Practice Surveillance Unit, Farmaindustria; Chair, EFPIA's Code Committee; Coordinator, EFPIA e4ethics Initiative; Chairman, IFPMA's Code Complaint Procedure Appeal Group, Madrid, Spain



David Andersen, Partner, Pharmaceuticals and Life Sciences, PwC, London, UK (Moderator)

4:15 pm



Chief Compliance Officer Roundtable

Dante Beccaria, Global Compliance Officer and Vice President, Sanofi; Former Vice President of Internal Audit, Sanofi, Paris, France



Suzanne Durdevic, LLM, Former Senior Director, General Counsel Europe, Boston Scientific International; Member, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Paris, France



Julie Kudyba, Head International Ethics & Compliance, Shire International GmbH; Former Global Head, Integrity & Compliance, Global Head Data Privacy, Alcon Laboratories Inc.; Former Global Privacy Officer, Novartis Pharma AG, Fort Worth, TX, USA



Leonardo Silva, LLM, Global Compliance Officer, Head of Global Compliance, Ferring International Center SA; Former Head of Compliance, Acino Group; Former Compliance Director, Emerging Markets, Takeda, St. Prex, Switzerland



Trudy Tan, Global Head Integrity & Compliance, Pharma, Novartis; Vice President, Compliance North America, AstraZeneca, Basel, Switzerland



Mariusz Witalis, Partner, Fraud Investigation & Dispute Services, EY, Warsaw, Poland (Moderator)

5:30 pm **Adjournment and Networking Reception**

TUESDAY, APRIL 9, 2019

7:30 am **Registration Commences**

DAY II: MORNING PLENARY SESSION

8:30 am **Co-chair Welcome and Overview**

8:45 am **TI Annual Keynote Address**



Rachel Cooper, LLB, MSc, Director, Pharmaceuticals & Healthcare Programme, Transparency International UK; Former Director, Global Health, Royal College of Obstetricians and Gynaecologists; Former Head, Government Relations, World Vision UK; Former Vice Consul, British Embassy, Copenhagen; Deputy Head of Mission, British Embassy, Bratislava, Deputy High Commissioner, Freetown, London, UK

9:15 am **Annual Anticorruption Roundtable**



Peter Dieners, Esq., Partner and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Co-chair, Legal Affairs Focus Group (LA FG), EUCOMED; Co-chair, Compliance Network (CN), EUCOMED, Düsseldorf, Germany



Michael K. Loucks, JD, Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, US Department of Justice, Washington, DC, USA



Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia



Satnam Tumani, LLB, Partner, Kirkland & Ellis International LLC; Former Head of Bribery & Corruption, Serious Fraud Office, London, UK



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

10:15 am **Break**

MINI SUMMITS ROUND I 10:45 am – 11:45 am

MINI SUMMIT I: Annual Medical Device Ethics and Compliance Best Practices Roundtable

10:45 am **Introductions, Panel Discussion and Q&A**

Suzanne Durdevic, LLM, Former Senior Director, General Counsel, Europe, Boston Scientific International; Member, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Paris, France

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

Chrystel Lanxade, Regional Compliance Officer, Europe Middle East Africa, Alcon; Former Head of Legal & Compliance Alcon France, Legal & Compliance Head Novartis Consumer Health France, Legal Counsel, Leem; Lawyer at the Paris bar, DEA, DESS; Cointrin, Canton of Geneva, Switzerland

Roeland Van Aelst, Regional Vice President - HCCO MD & EMEA, Office Health Care Compliance and Privacy, Johnson & Johnson; Chairman, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS); Chairman, MedTech Compliance Network, Brussels, Belgium

Christopher L. White, JD, Chief Operating Officer and General Counsel, Advanced Medical Technology Association (AdvaMed), Washington, DC, USA

Ulf H. Grundmann, Partner, FDA and Life Sciences, King & Spalding LLP, Frankfurt am Main, Germany (Moderator)

MINI SUMMIT II: Compliance in the Light of Digitalization

10:45 am Introductions, Panel Discussion and Q&A

Gérald Hucky, Head Group Compliance, Sonova Group; Former Compliance Audit Manager, NameZimmer Biomet, Zürich, Switzerland

Marie-Claire Pickaert, Former Deputy Director General, Chief Financial Officer and Ambassador to the Medical Communities, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

Evgeny Tilezhinsky, MBA, PhD, Law and Compliance Lead for Central and Eastern Europe, Bristol-Myers Squibb, Uxbridge, Middlesex, UK

Niels Wohlwend, lic iur, MAES, Senior Director, Healthcare Compliance (HCC) Europe & Canada, Celgene; Member, WFPIA Ethics & Compliance Committee; Former Global Head of Compliance, ACINO; Former Head of Compliance APAC, LATAM and MEA, Mundipharma, Boudry, Canton of Neuchâtel, Switzerland

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

MINI SUMMIT III: Data Privacy, Consent Management and GDPR Update

10:45 am Introductions, Panel Discussion and Q&A

Riccardo Giannetti, Scheme Manager, Inveo, Roma, Italy

Nicola Orlandi, Head, Data Privacy Pharma, Global Privacy Office, Novartis International AG; Former Head of Legal and Compliance, Sandoz S.p.A., Basel, Switzerland

Eirini Tsotra, MS, CIPP/E, CIPM, CISA, Director, Privacy & Data Protection, Ferring International Centre SA, St-Prex, Switzerland

Giuseppe Saporito, LLM, Global Legal & Regulatory Expert, IQVIA, Milan, Italy (Moderator)

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

10:45 am Introductions, Panel Discussion and Q&A

Stephen Nguyen Duc, Global Head of Ethics & Compliance, Medday Pharmaceuticals; Board Member, Strategic Committee International Society of Healthcare, Ethics, and Compliance Professionals (ETHICS), Paris, France

Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA

Ariadna Quesada, MSJ, Law, Ethics and Compliance Officer, The Netherlands, AbbVie; Former Compliance Manager International, MicroPort Orthopedics Inc., Amsterdam, Netherlands

Ann Beasley, JD, Director, Navigant Consulting; Former Senior Vice President, Chief Compliance Officer, Biogen; Former Co-chair, International Pharmaceutical and Medical Device Compliance Congress, Boston, MA, USA (Moderator)

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

10:45 am Introductions, Panel Discussion and Q&A

Maria Khoury, MBA, PharmD, Compliance Officer Levant, Roche; Chair, Lebanese Group of International Pharmaceutical Companies and Iraq LAWG (Local Area Working Group), Beirut, Lebanon

Minal Patel, Health Care Compliance Officer, Pharma and Consumer, Johnson & Johnson, Johannesburg Area, South Africa

Rami A. Rajab, Chairman, Mecomed Medical Technology Association Middle East & Africa (MECOMED); Chairman, LIFE (LivaNova International Fellowship), International Corporate Social Responsibility; Former Vice President Market Access, Emerging Markets, LivaNova, Maidenhead, UK

Laura Nassar, PharmD, Head of Compliance Middle East, Roche Pharmaceuticals; Chair, Compliance Committee, Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG); Former Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon (Moderator)

11:45 am NETWORKING LUNCHEON

MINI SUMMITS ROUND II 12:45 pm – 1:45 pm

MINI SUMMIT VI: Whistleblower Updates: New EU-wide Standards to Protect Whistleblowers & US Qui Tam Actions against Foreign Pharma and Device Companies doing Business in the US

12:45 pm Introductions, Discussion and Q&A

Thomas W. Beimers, JD, Partner, Hogan Lovells; Former Senior Counsel for Administrative and Civil Remedies, Office of the Inspector General, Department of Health and Human Services, Minneapolis, MN, USA

Ulf H. Grundmann, Partner, FDA and Life Sciences, King & Spalding LLP, Frankfurt am Main, Germany

MINI SUMMIT VII: The Evolution of Risk Assessment and Using Risk Assessment to Design Compliance Programs

12:45 pm Introductions, Discussion and Q&A

Karen Eryou, Head, Ethics & Compliance Programs, UCB Pharma; Former Co-chair, Asia Pacific Pharma Compliance Congress, Brussels, Belgium

Timur Khasanov-Batirov, LLM, Compliance Officer, Russia, CIS & Romania, Dr. Reddy's Laboratories; Author, Compliance Man of Integrity Corp. and Integrity Corp. 50 Tips for Your Compliance Program in the Post-Soviet States, Moscow, Russian Federation

Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA

Thomas K. Hauser, MA HSG, MSJ, Director, Life Sciences Governance, Risk Management, and Compliance Practice, Navigant; Former Global Chief Compliance Officer, Siemens Healthcare; Treasurer, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), London, UK (Moderator)

MINI SUMMIT VIII: Analytics with Reference to Transparency and/or Monitoring

12:45 pm Introductions, Discussion and Q&A

Ryan Burger, MS, Head, Global Assurance & Reporting Services, Astra Zeneca, New York, NY, USA

Arielle Hung, Compliance Counsel, Merck KGaA, Darmstadt, Germany

Laetitia Ducroquet Minel, Director, Ethics & Compliance, Ipsen, Boulogne-Billancourt, France

Monique Fonfara-Weinberg, Boehringer Ingelheim Corporate Center GmbH, Frankfurt Am Main, Germany

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

MINI SUMMIT IX: The Next Chapter — Improving the Future of Compliant HCP Engagements

12:45 pm Introductions, Discussion and Q&A

Michael Bartke, PhD, Director Ethics and Compliance, Alexion; Former Director, Compliance Management, Daiichi Sankyo Europe GmbH; Strategic Committee, ETHICS, Munich, Germany

Matt Coombs, Services Development Director, IQVIA; Former Strategic Business Director, Qforma, London, UK

Abdul Luheshi, MBA, Executive Director, Global Operations, Ethics & Compliance, Astellas Pharma EMEA; Former Vice President, Health Care Compliance, Johnson & Johnson, Chertsey, UK

Chris van Bronckhorst, Global Compliance Director, IQVIA, The Hague, Netherlands (Moderator)

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

12:45 pm Introductions, Discussion and Q&A

Martina Leposa, Healthcare Compliance Officer, Janssen-Cilag Ltd. (a Johnson & Johnson company); Chair, Compliance Committee, Association of Innovative Pharmaceutical Manufacturers, Budapest, Hungary

Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russian Federation

Madina Plieva, PhD, Legal and Compliance Head, Russia, Bristol-Myers Squibb; Legal Director, Association of International Pharmaceutical Manufacturers (AIPM); Former Head of Legal Department, Kutafin Moscow State Law Academy, Moscow, Russian Federation

Evgeny Tilezhinsky, MBA, PhD, Law and Compliance Lead for Central and Eastern Europe, Bristol-Myers Squibb, Uxbridge, Middlesex, UK

Mariusz Witalis, Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP, Warsaw, Poland (Moderator)

1:45 pm TRANSITION BREAK

MINI SUMMITS ROUND III 2:00 pm – 3:00 pm

MINI SUMMIT XI: Reducing FCPA Exposure through Better Use of Data

2:00 pm Introductions, Panel Discussion and Q&A

Michael K. Loucks, JD, Partner, Skadden Arps LLP; Former Acting United States Attorney, District of Massachusetts, US Department of Justice, Washington, DC, USA

Michael O'Connor, MS, Vice President of Compliance Technology, Porzio Life Sciences, LLC; Former Global Head Compliance and Ethics Operations, Alexion; Former Executive Director, Global Head, IS Business Consulting, Boehringer Ingelheim, New York, NY, USA (Moderator)

MINI SUMMIT XII: Compliance Issues Raised by Patient and Foundation Petitions for Government Coverage of Certain Drugs

2:00 pm Introductions, Panel Discussion and Q&A

Yogesh Bahl, CPA, MBA, Managing Director, Alix Partners, New York, NY, USA (Moderator)

MINI SUMMIT XIII: Behavioral Science to Enhance Effectiveness of Compliance Programs

2:00 pm Introductions, Panel Discussion and Q&A

Sue Egan, Director and Principal Consultant, Sue Egan Associates, Great Missenden, Buckinghamshire, UK

Brett Hudson, MBIM, Head, Group Integrity & Compliance, Novartis; Former Global Program Director - Integrity & Compliance, Sandoz, Basel, Switzerland

Antje Petersen Schmalnauer, Group General Counsel, Sonova Group; Former Interim Vice President Legal and General Counsel, Kautex Textron; Former Global Privacy and Data Protection Officer, Biomet, Cologne, Germany

Tjerk Schluffer, Senior Vice President Compliance, Fresenius SE; Former General Counsel, Imaging & Therapy Systems, Siemens AG, Frankfurt Am Main, Germany

Katharina Wegmann, Associate Partner, Forensic & Integrity Services, EY, Düsseldorf, Germany (Moderator)

MINI SUMMIT XIV: Third Party Due Diligence and Management

2:00 pm Introductions, Panel Discussion and Q&A

Betania Glorio, Global Compliance Officer Healthcare, Merck KGaA; Former Senior Director, Legal and Compliance EMEA, Horizon; Former Senior Counsel, Regional Compliance Director, EUCAN, Pfizer, Darmstadt, Germany

Edoardo Lazzarini, PhD, Healthcare Compliance Consultant; Former EuCan Ethics & Compliance Initiatives Director, Takeda Pharmaceuticals; Former Compliance Officer EMEA (Europe, Middle East & Africa), Zimmer Biomet, Milan, Italy

Tamara Tubin, International Compliance Director, Corporate Compliance, Wright Medical Group N.V.; Vice Chair, Ethics & Compliance Committee, MedTech Europe, Member, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Zürich, Switzerland

Mario Prohasky, MBA, Principal, EMEA Compliance Consulting Practice Leader, IQVIA, London, UK (Moderator)

MINI SUMMIT XV: Structuring an Efficient Digital Compliance Framework: Overcome Cross-jurisdictional Boundaries, Process Complexity and Dispersed Resources

2:00 pm Introductions, Panel Discussion and Q&A

Carlo Geninazza, Senior Manager, CAWECO GmbH, Munich, Germany (Moderator)

3:00 pm TRANSITION BREAK

AFTERNOON PLENARY SESSION

3:30 pm Update on the New French Sapin II Law: Responding to the French Anticorruption Questionnaire, Inspections and Prosecutions



Gérald Begraner, Head of Department, Deputy Director, French Anti-Corruption Agency (APA), Paris, France



MINISTÈRE DE
LA JUSTICE

Eliane Houlette (Invited), Prosecutor, National Financial Prosecutor's Office (PNF), Paris, France



George Fife, Partner, Fraud Investigation & Dispute Services, EY; Former Executive Director, Compliance & Ethics, Bristol-Myers Squibb, Paris, France (Moderator)

4:15 pm Annual FCPA Update Roundtable



Robert I. Dodge, JD, Assistant Director, FCPA Unit, US Securities & Exchange Commission; Former Assistant U.S. Attorney, US Attorney's Office, Western District of Michigan; Former Assistant Section Chief, Environmental Defense Section, US Department of Justice, Washington DC



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

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POLICY & MEDICINE
COMPLIANCE UPDATE

4:45 pm

Collaboration and Cooperation in Multi-jurisdictional Anticorruption Investigations and Prosecutions



Gérald Begranger, Head of Department, Deputy Director, French Anti-Corruption Agency (APA), Paris, France



Robert I. Dodge, JD, Assistant Director, FCPA Unit, US Securities & Exchange Commission; Former Assistant U.S. Attorney, US Attorney's Office, Western District of Michigan; Former Assistant Section Chief, Environmental Defense Section, US Department of Justice, Washington, DC



MINISTÈRE DE LA JUSTICE

Eliane Houlette (Invited), Prosecutor, National Financial Prosecutor's Office (PNF), Paris, France



Satnam Tumani, LLB, Partner, Kirkland & Ellis International LLC; Former Head of Bribery & Corruption, Serious Fraud Office, London, UK



George Fife, Partner, Fraud Investigation & Dispute Services, EY; Former Executive Director, Compliance & Ethics, Bristol-Myers Squibb, Paris, France (Co-moderator)



Gary F. Giampetruzzi, Esq., Partner, Paul Hastings; Former Vice President and Assistant General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Co-moderator)

5:30 pm

ADJOURNMENT

WEDNESDAY, APRIL 10, 2019

7:30 am Registration Commences

DAY III: MINI SUMMITS AND CLOSING PLENARY SESSION

MINI SUMMITS ROUND IV 8:30 am – 9:30 am

MINI SUMMIT XVI: Auditing and Monitoring Workgroup

8:30 am Introductions, Panel Discussion and Q&A

Michael Bartke, PhD, Director Ethics and Compliance, Alexion; Former Director, Compliance Management, Daiichi Sankyo Europe GmbH; Strategic Committee, ETHICS, Munich, Germany

Antonio Cavallaro, Compliance Officer, Merck Serono Italy; Former Head of Compliance, Takeda Italy, Rome, Italy

Laura Nassar, PharmD, Head of Compliance Middle East, Roche Pharmaceuticals; Chair, Compliance Committee, Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG); Former Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon

Marcelo Nogueira, Latin America, Central America and Canada Regional Compliance Monitor, Novartis; Former Compliance Officer Brasil, Amgen; Former Compliance Officer Brasil, Sandoz; Former Legal Counsel and Compliance Officer, Gilead Sciences, Sao Paulo, Brazil

Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA (Moderator)

MINI SUMMIT XVII: R&D and Clinical Trials Compliance Workgroup

8:30 am Introductions, Panel Discussion and Q&A

Enno Behrendt, Compliance Officer, Siemens Healthcare GmbH; General Legal Counsel, evosoft GmbH, Erlangen, Germany

Glen Haith, JD, Global Head Integrity & Compliance Pharma Medical Affairs, Novartis Pharmaceuticals; Former Associate Vice President and Chief Compliance Officer, ImClone Systems, Bridgewater, NJ USA

Abdul Luheshi, MBA, Executive Director, Global Operations, Ethics & Compliance, Astellas Pharma EMEA; Former Vice President, Health Care Compliance, Johnson & Johnson, Chertsey, UK

Elisabethann Wright, LLB, Partner, Hogan Lovells; Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium (Moderator)

MINI SUMMIT XVIII: Communications and Collaboration with in-company Business Partners Workgroup

8:30 am Introductions, Panel Discussion and Q&A

Maïke Bermüller, Senior Legal Counsel and Global Healthcare Compliance Officer, Boehringer Ingelheim, Frankfurt Am Main, Germany

Stephen Nguyen Duc, Global Head of Ethics & Compliance, Medday Pharmaceuticals; Board Member, Strategic Committee International Society of Healthcare, Ethics, and Compliance Professionals (ETHICS), Paris, France

Sue Egan, Director and Principal Consultant, Sue Egan Associates, Great Missenden, Buckinghamshire, UK

Tomasz Kruk, LL.M, MBA, Head of Compliance, Vifor; Former Director International Compliance, Mallinckrodt; Former Director Global Ethics & Compliance, Actavis (now Allergan), Zurich, Switzerland

Ruth Sturm, Head of Compliance EMEA, Siemens Healthcare, Erlangen, Germany

Yogesh Bahl, CPA, MBA, Managing Director, Alix Partners, New York, NY, USA (Moderator)

9:30 am TRANSITION BREAK

CLOSING PLENARY SESSION

9:45 am Co-chair Welcome and Introductions

10:00 am Ethics and Compliance Keynote Address



Guido Palazzo, PhD, Professor of Business Ethics, Department of Strategy, Globalization and Society, University of Lausanne, Lausanne, Switzerland

10:30 am The Emerging Role of Technology Companies in the Life Science Marketplace and the Ethical and Compliance Implications of this Development



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

11:00 am IFPMA Global Compliance Updates



Sofie Melis, Head of Ethics and Compliance, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Geneva, Switzerland

11:30 am Transforming Compliance into a Profession



Piergiorgio Pepe, MA EU Law, President, Quantum Ethics, Ethics and Compliance Lecturer, SciencesPo; Former Compliance Director Western Europe & Canada, AbbVie; Former Director, Compliance & Ethics EMEA, Bristol-Myers Squibb, Paris, France

Noon

ADJOURNMENT



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The ETHICS Bureau meets regularly to consider membership applications and we normally aim to respond to prospective members within three weeks, although during holiday periods our response may take a little longer.

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<hr/>		
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What is your level of Seniority in your current position? *		
<hr/>		
How did you learn about our Association? *		
<hr/>		

SEE <http://www.ethicspros.com/how-to-join/membership-application/>.

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—Dominique Laymand, Honorary President, International Society of Healthcare Ethics and Compliance Professionals (ETHICS)

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SELECT YOUR MINI-SUMMITS (One from each group):

Tues., April 9

ROUND I – 10:45 am

- ☐ I: Annual Medical Device Ethics and Compliance Best Practices Roundtable
- ☐ II: Compliance in the Light of Digitalization
- ☐ III: Data Privacy, Consent Management and GDPR Update
- ☐ IV: Ethics and Compliance Issues in Patient Relationships, Including Patient Access and Support Programs
- ☐ V: Annual Middle East Africa (MEA) Compliance Update

ROUND II – 12:45 pm

- ☐ VI: Whistleblower Updates: New EU-wide Standards ... & US Qui Tam Actions ...
- ☐ VII: The Evolution of Risk Assessment ...
- ☐ VIII: Analytics with Reference to Transparency and/or Monitoring
- ☐ IX: The Next Chapter — Improving the Future of Compliant HCP Engagements
- ☐ X: Annual Central and Eastern Europe (CEE) Compliance Best Practices Update

ROUND III – 2:00 pm

- ☐ XI: Reducing FCPA Exposure ...
- ☐ XII: Compliance Issues Raised by Patient and Foundation Petitions ...
- ☐ XIII: Behavioral Science to Enhance Effectiveness of Compliance Programs
- ☐ XIV: Third Party Due Diligence ...
- ☐ XV: Structuring an Efficient Digital Compliance Framework ...

Wed., April 10

ROUND IV – 8:30 am

- ☐ XVI: Auditing and Monitoring Workgroup
- ☐ XVII: R&D and Clinical Trials Compliance Workgroup
- ☐ XVIII: Communications and Collaboration with in-company Business Partners Workgroup

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