The Thirteenth International Pharmaceutical and Medical Device Compliance Congress

GRAND HYATT ATHENS • ATHENS, GREECE

APRIL 8 – 10, 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

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, Farmaindustria; 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, SciencesPô
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

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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.


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
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, LLM, 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), 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

INTERNATIONAL PHARMA CONGRESS

DAY I: OPENING PLENARY SESSION

1:00 pm  International Pharma Congress Vision and Overview

Dante Becaria, 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, LLM, 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

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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TUESDAY, APRIL 9, 2019

DAY II: MORNING PLENARY SESSION

7:30 am  Registration Commences

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 Diener, Esq., Partner and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Co-chair, Legal Affairs Focus Group (LAFG), 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, DRESS, Coimtrin, 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)

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

Julie Lanzara, Director, Compliance, Ferring International Center SA; Former Head of Compliance, Acino Group; Former Compliance Director, Emerging Markets, Takeda, St. Prex, Switzerland

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)

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 (FSÄ), Member, Ethics and Compliance Committee and Vice Chair Code Committee, EFPMA, Member, IFPMA Code Compliance Network, Berlin, Germany

EFPMA Code

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

MECOMED 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

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, EFPMA’s Code Committee; Coordinator, EFPMA eEthics Initiative; Chairman, IFPMA’s Code Complaint Procedure Appeal Group, Madrid, Spain

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

5:30 pm  Adjournment and Networking Reception
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 Bionet, 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 Tilezinsky, MBA, PhD, Law and Compliance Lead for Central and Eastern Europe, Bristol-Myers Squibb, Uxbridge, Middlessex, UK

Niels Wohlwend, lic iur, MAES, Senior Director, Healthcare Compliance (HCC) Europe & Canada, Celgene; Member, WFPIA Ethics & Compliance Committee; Former Global Head of Compliance, ACNI; 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 Officer, Novartis International AG; Former Head of Legal and Compliance, Sandoz S.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 (PhRMA); Former Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon (Moderator)

11:45 am  
NETWORKING LUNCHEON

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

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

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

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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-Olaj 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 Tilezinsky, MBA, PhD, Law and Compliance Lead for Central and Eastern Europe, Bristol-Myers Squibb, United Kingdom, 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. Louches, 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, Persio 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, Sandzai, Basel, Switzerland
Antje Petersen Schmalnauer, Group General Counsel, Sanova Group; Former Interim Vice President Legal and General Counsel, Kautex Textron; Former Global Privacy and Data Protection Officer, Biomet, Cologne, Germany
Tjerk Schlufter, 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

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

MINI SUMMIT XVI: Ensuring Compliance in Central and Eastern Europe: Current Challenges and Best Practices
3:00 pm  Introductions, Panel Discussion and Q&A
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
Geoffrey Fife, Partner, Fraud Investigation & Dispute Services, EY; Former Executive Director, Compliance & Ethics, Bristol-Myers Squibb, Paris, France (Moderator)

MINI SUMMIT XVII: Managing Compliance Risks in a Global Environment
3:30 pm  Introductions, Panel Discussion and Q&A
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)
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

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MINI SUMMIT XVII: 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 América, Central America and Canada Regional Compliance Monitor, Novartis; Former Compliance Officer Brasil, Amgen; Former Compliance Officer Brasil, Sandor; 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 XVIII: Communications and Collaboration with in-company Business Partners Workgroup

8:30 am Introductions, Panel Discussion and Q&A
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 General Counsel, Head of Government Investigations, Pfizer Inc., New York, NY, USA (Co-moderator)

ADJOURNMENT
MEMBERSHIP APPLICATION FORM

Thank you for your interest in ETHICS. If you wish to join our society, please complete the form below and also email your CV to: bureau@ethicspros.com.

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.

You can also apply online at: www.ethicspros.com.

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Please specify the membership category you would like to apply for:  
- Contributing member: €1,500  
- Active Member: €250

Please briefly describe your experience in ethics and compliance roles, including function and reporting line, and your current role: *

What is your level of Seniority in your current position? *

How did you learn about our Association? *

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


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PRECONFERENCE (April 8 — Optional; Choose only one.):

☐ I: A WORKSHOP ON PRACTICAL CASE STUDIES AND EXERCISES IN ETHICS AND COMPLIANCE € 495

☐ II: ADVANCED INVESTIGATIONS € 495

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☐ Through Friday, February 15, 2019* €1,795

☐ Through Friday, March 15, 2019** €1,995

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

- 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
  - V: Annual Middle East Africa (MEA) Compliance Update

- ROUND II – 12:45 pm
  - 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 . . .

- ROUND IV – 8:30 am
  - XVI: Auditing and Monitoring Workgroup
  - XVII: R&D and Clinical Trials Compliance Workgroup
  - XVIII: Communications and Collaboration within company Business Partners Workgroup

- Wed., April 10

- ROUND IV – 3:30 am

- ROUND V – 5:00 am

- ROUND VI – 6:30 am

- ROUND VII – 7:45 am

- ROUND VIII – 9:00 am

- ROUND IX – 10:45 am

- ROUND X – 12:45 pm

- ROUND XI – 2:00 pm

- ROUND XII – 3:45 pm

- ROUND XIII – 5:30 pm

- ROUND XIV – 6:30 pm

- ROUND XV – 8:00 am

- ROUND XVI – 9:30 am

- ROUND XVII – 11:00 am

- ROUND XVIII – 12:30 pm

- ROUND XIX – 1:15 pm

- ROUND XX – 2:30 pm

- ROUND XXI – 3:45 pm

- ROUND XXII – 4:30 pm

- ROUND XXIII – 5:45 pm

- ROUND XXIV – 6:45 pm

- ROUND XXV – 7:45 pm

** This price reflects a discount for registration & payment received by February 15, 2019.

*** To qualify for the ETHICS/PCF/IPFMA/EFPIA/SFEE/Italian Network of Compliance Officers/MedTech Europe member rate an individual must be an individual member or an employee of a member company of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), Hellenic Association of Pharmaceutical Companies (SFEE), Italian Network of Compliance Officers or MedTech Europe.

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