

The Eleventh International Pharmaceutical and Medical Device Compliance Congress

LISBON MARRIOTT HOTEL, LISBON, PORTUGAL

MAY 15 – 17, 2017



www.InternationalPharmaCongress.com

CONFIRMED KEYNOTE SPEAKERS:



Nicola Bonucci, DEA, DESS, LLM, Director, Directorate for Legal Affairs, OECD, Paris, France



Tarek Helou, Esq., Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, Washington, DC, USA



Sophie Peresson, LLM, MSc, Global Health Policy Director, Pharmaceuticals & Healthcare Programme, Transparency International UK; Former Regional Director, International Diabetes Federation European Region; Former Communications and Advocacy Manager, European Council on Refugees and Exiles, London, UK



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



Neill Stansbury, Esq., Co-founder and Director, Global Infrastructure Anti-Corruption Centre; Chair, International Organization for Standardization Anti-Bribery Project Committee; Vice Chair, Anti-corruption Standing Committee, World Federation of Engineering Organization, Buckinghamshire, UK



Thomas Cueni, Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Geneva, Switzerland



George "Ren" McEachern, CFE, CAMS, Supervisory Special Agent, International Corruption Squad, US Federal Bureau of Investigation, Washington, DC, USA



Aleksandar Rusanov, Esq., Legal Advisor, Legal Department, European Medicines Agency (EMA), London, UK

ALSO FEATURING CHIEF COMPLIANCE OFFICERS:



Sujata Dayal, JD, Vice President, Health Care Compliance and Privacy, Global Chief Compliance Officer, Pharmaceuticals, Johnson and Johnson; Former Chief Compliance Officer and Corporate Vice President, Biomet, Inc.; Former Ethics and Compliance Officer, Abbott Laboratories, Titusville, NJ, USA



Lori V. Queisser, CPA, Senior Vice President and Global Compliance Officer, Teva Pharmaceuticals, Philadelphia, PA, USA



Uffe Kåre Rasmussen, M.Sc., Senior Director and Chief Compliance Officer, H. Lundbeck A/S; Former Principal Scientist, Novo Nordisk A/S, Copenhagen, Denmark

CONTINUING EDUCATION CREDITS:

Accounting Professionals: Approved for up to 17.0 NASBA CPE credits.

Attorneys: Pending approval for PA MCLE credits.

Compliance Professionals: Pending approval for Compliance Certification Board CCB credits.

CONGRESS CO-CHAIRS:



Dante Beccaria, Senior Vice President, Global Head of Ethics and Business Integrity, Sanofi, Paris, France



Stephen Nguyen Duc, Office of Ethics & Compliance Area Director, International Operations, Western Europe & Canada, AbbVie; Board Member, Strategic Committee International Society of Healthcare, Ethics, and Compliance Professionals (ETHICS), Rungis, France



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



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

OFFERED IN SEQUENCE WITH AN EFPIA STAKEHOLDER WORKSHOP:

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent EFPIA STAKEHOLDER WORKSHOP on Monday, May 15, 2017.



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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 of the day. The first international conference agenda was developed with inputs from company compliance professionals around the topics they wanted to know more about, which continues to be one of the great strengths of these conferences. The 2017 Co-Chairs and Planning Committee have designed the Congress around the themes of anti-corruption/anti-bribery compliance programs, data privacy, new marketplace, transparency, and the next generation of ethics and compliance programs.

The Congress this year features Keynote Plenary Session speakers from important organizations including the European Medicines Agency (EMA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the International Organization for Standardization Anti-Bribery Project Committee (ISO 37001), the Organisation for Economic Co-operation and Development (OECD), Transparency International, the United States Department of Justice FCPA Unit and the United States Federal Bureau of Investigations International Corruption Squad. The Mini Summit panels include experts working within the pharmaceutical and medical device companies as well as legal counsel and consultants who will discuss the practical implementation of compliance control measures.

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) and Warsaw (2016). In 2017, we are pleased to hold the Eleventh International Pharmaceutical Compliance Congress and Best Practices Forum in Lisbon, Portugal with the local partnership of APIFARMA, Portuguese Association of the Pharmaceutical Industry, and regional partnership of EFPIA (The European Federation of Pharmaceutical Industries and Associations). The Congress sponsor remains The International Society of Healthcare Ethics and Compliance Professionals (ETHICS) with the Pharmaceutical Compliance Forum (PCF) as a co-sponsor.



WHO SHOULD ATTEND:

- Pharmaceutical Manufacturers
- Generic Pharmaceutical Manufacturers
- Medical Device 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) is a new professional Society established in 2012 currently comprised of around 50 members, all active in major pharma and medical device companies. ETHICS intends to become the reference professional society for ethics and compliance practitioners in the healthcare sector with the ultimate goal to contributing to the professional development of individuals and the success of ethics and compliance organizations..

CO-SPONSOR:



THE PHARMACEUTICAL COMPLIANCE FORUM (PCF) is a coalition of senior compliance professionals and legal counsel from more than 60 of the largest research-based pharmaceutical manufacturers. The PCF was

founded in early-1999 by compliance professionals from the pharmaceutical industry to promote effective corporate compliance programs. The members meet twice a year, for two days, focusing on open and informal sharing of compliance information, best practices, and current developments in the field, and sponsors a three-day compliance congress each Fall.

MONDAY, MAY 15, 2017

8:00 am Registration Opens

PRECONFERENCE

9:00 am Welcome and Introductions

EFPIA PRECONFERENCE SESSION:

The Privilege of Self-Regulation

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent session on Monday, May 15, 2017 from 9:00 am to 12:00 pm.

The session will address the role of self-regulation against the background of applicable laws and regulations, and how global ethical principles translate into the variety of local standards, rules, and procedures in Europe. The session also will discuss the evolution of norms, often following practice, and self-regulation anticipating evolution of new approaches and practices.

12:00 pm Adjournment

MONDAY, MAY 15, 2017

INTERNATIONAL PHARMA CONGRESS DAY I: OPENING PLENARY SESSION

1:00 pm Welcome to Lisbon from APIFARMA



Heitor Costa, Executive Director, Portuguese Association of the Pharmaceutical Industry (APIFARMA), Lisbon, Portugal

1:10 pm CONGRESS CO-CHAIR WELCOME AND OVERVIEW



Dante Beccaria, Senior Vice President, Global Head of Ethics and Business Integrity, Sanofi, Paris, France (Co-chair)



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



Stephen Nguyen-Duc, Area Director Ethics & Compliance Western, Europe-Israel and Canada, AbbVie; Former Director, Ethics & Compliance Officer, Eli Lilly and Company, Paris, France (Co-chair)



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

1:30 pm Chief Compliance Officer Roundtable:
Key Risks for the Industry and the Future of
Ethics and Compliance Programs



Dante Beccaria, Senior Vice President, Global Head of Ethics and Business Integrity, Sanofi, Paris, France



Sujata Dayal, JD, Vice President, Health Care Compliance and Privacy, Global Chief Compliance Officer, Pharmaceuticals, Johnson and Johnson; Former Chief Compliance Officer and Corporate Vice President, Biomet, Inc.; Former Ethics and Compliance Officer, Abbott Laboratories, Titusville, NJ, USA



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



Lori V. Queisser, CPA, Senior Vice President and Global Compliance Officer, Teva Pharmaceuticals, Philadelphia, PA, USA



Uffe Kåre Rasmussen, M.Sc., Senior Director and Chief Compliance Officer, H. Lundbeck A/S; Former Principal Scientist, Novo Nordisk A/S, Copenhagen, Denmark



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

2:30 pm

Safeguarding Against Bribery and Corruption: Outreach from the Investigating Agencies



George "Ren" McEachern, CFE, CAMS, Supervisory Special Agent, International Corruption Squad, US Federal Bureau of Investigation, Washington, DC, USA

3:00 pm

US Department of Justice and US Securities and Exchange Commission Update on FCPA Enforcement



Tarek Helou, Esq., Assistant Chief, FCPA Unit, Fraud Section, Criminal Division, US Department of Justice, Washington, DC, USA



Charles Cain, Esq. (Invited), Deputy Chief, FCPA Unit, US Securities and Exchange Commission, 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)

3:45 pm

Networking Break

MINI SUMMITS ROUND I 4:15 pm – 5:30 pm

MS 1: Transparency: Now that We Have the Data, How Can We Leverage It to Improve Compliance?

4:15 pm Introductions, Discussion and Q&A

Anna Byrom, LLM, Associate Director, Compliance EUCA, Intercept Pharmaceuticals; Former Associate Director, Astellas Pharma Europe, London, UK

Filipa Godinho, Business Consultant, Global Transparency, Eli Lilly and Company, Lisbon, Portugal

Fabien Roy, DESS, Senior Associate, Hogan Lovells; Member, EFGCP-MedTech Europe Working Party, Brussels, Belgium

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

MS 2: Annual MEA Compliance Roundtable

4:15 pm Introductions, Discussion and Q&A

Mostafa Abdelrahman, Ethics and Compliance Director, Eli Lilly and Company, Riyadh, Kingdom of Saudi Arabia

Rifat Bozacioglu, Area Compliance Director, Middle East, GlaxoSmithKline plc, Istanbul, Turkey

Laura Nassar, Head of Compliance, Middle East, Roche Pharmaceuticals, Dubai, United Arab Emirates

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

Maged Zaki, MD (Invited), Health Care Business Integrity Officer, Pharma GCC Cluster, Middle East, West Asia and Africa, Johnson and Johnson, Dubai, United Arab Emirates

Joe Henein, Pharm.D., President and Chief Executive Officer, NewBridge Pharmaceuticals FZ LLC, Dubai, United Arab Emirates (Moderator)

**MS 3: Health Economics and Outcomes Research (HEOR)—
Emerging Risks of Data Collection, Use, and Secondary Use**
4:15 pm Introductions, Discussion and Q&A

Peter W.L. Bogaert, MA, LJ, Partner, Covington & Burling LLP, Brussels, Belgium

Bella Rafael Hovhannisyan, Compliance and Ethics Lead, Spain, Portugal, and Nordic Region, Bristol-Myers Squibb, Madrid, Spain

Pascale Paimbault (Invited), Executive Director, EMEA Ethics and Compliance, ABAC, Astellas Pharma Europe; Former Compliance Officer, France -Benelux, Biogen, Treasurer and Strategic Committee Member, ETHICS; Former Chief Compliance Officer EMEA, Wright Medical Inc.; Former Senior Director, Compliance and Ethics, Business Program, EMEA, Bristol-Myers Squibb, Paris, France

Ken Walsh, MA, MSc, Director, Life Sciences Consulting, Navigant, London, UK

Ann Beasley, JD, Director, Healthcare and Life Sciences Disputes, Compliance and Investigations, Navigant Consulting; Former Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis, Boston, MA, USA (Moderator)

**MS 4: Evolving Privacy Requirements: Preparing for the
General Data Protection Regulation**

4:15 pm Introductions, Discussion and Q&A

Martin Fuerle, MBA, General Counsel and Chief Compliance Officer, Vice President Risk & Compliance, Daiichi Sankyo Europe GmbH, Munich, Germany

William Long, LLB, Partner, Sidley Austin LLP, London, UK

Audrey Mills, JD, Sr. Director Ethics and Compliance and Chief Privacy Officer, Eli Lilly and Company, Indianapolis, IN, USA (Moderator)

MS 5: Managing Medical Device Anti-Corruption Risks

4:15 pm Introductions, Discussion and Q&A

Anne-Sophie Bricca, Deputy General Counsel, Senior Director Law and Compliance, EMEA, Terumo BCT, Brussels, Belgium

Ariadna Quesada, MPP, Compliance Manager Europe, Middle-East and Africa, MicroPort Orthopedics Inc., Amsterdam, Netherlands

Michele Tagliaferri, Esq., Partner, Sidley Austin LLP, Brussels, Belgium

Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY, USA (Moderator)

5:30 pm Adjournment and Networking Reception

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.

TUESDAY, MAY 16, 2017

DAY II: MORNING PLENARY SESSION

7:30 am



Registration Commences

8:00 am Welcome and Overview

Dante Beccaria, Senior Vice President, Global Head of Ethics and Business Integrity, Sanofi, Paris, France (Co-chair)



8:10 am OECD Update

Nicola Bonucci, DEA, DESS, LLM, Director, Directorate for Legal Affairs, Organisation for Economic Co-operation and Development, Paris, France



8:40 AM Transparency International Update

Sophie Peresson, MA, Global Health Policy Director, Pharmaceuticals and Healthcare, Transparency International; Former Regional Director; International Diabetes Federation, European Region; Former Senior Policy Advisor, Standing Committee of European Doctors, London, UK

**9:10 am The ISO Anti-Corruption Standard
(ISO 37001)**



Neill Stansbury, Esq., Co-founder and Director of the Global Infrastructure Anti-Corruption Centre; Chair, International Organization for Standardization Anti-Bribery Project Committee; Vice Chair, Anti-corruption Standing Committee, World Federation of Engineering Organization, Buckinghamshire, UK



9:40 am Anti-Corruption Enforcement Panel

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



Ulf H. Grundmann, Esq., Partner, Life Sciences Practice Group, King & Spalding LLP, Frankfurt am Main, Germany



Michael K. Loucks, Esq., 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



Vivian Robinson, Esq., Queen's Counsel, Partner, McGuire Woods; Former General Counsel of the UK Serious Fraud Office; Former Head, QEB Hollis Whiteman Chambers, Recorder of the Crown Court and Treasurer of Inner Temple, London, UK



Yuet Ming Tham, JD, Partner, Sidley Austin LLP; Former Asia Pacific Regional Compliance Director, Pfizer; Former Deputy Public Prosecutor Singapore, Hong Kong



Ted Acosta, Esq., Americas Vice Chair, Risk Management, EY; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY, USA and Paris, France (Moderator)

10:45 am Networking Break

MINI SUMMITS ROUND II 11:15 am – 12:30 pm

MS 6: Practical Implications of Brexit on Life Science Companies

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

Janet Kidd, Esq., Vice President, Legal EMEA, Aegerion Pharmaceuticals, Windsor, UK

Elisabethann Wright, Esq., Partner, Hogan Lovells International LLP, Brussels, Belgium (Moderator)

MS 7: The Interfaces Between the Roles of the Compliance and Quality Functions

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

David O'Shaughnessy, Vice President, Compliance, Emerging Markets, Quintiles; Board Member, ETHICS; Former Vice President Compliance, International Pharmaceuticals, GSK; Former Vice President, Global Compliance Strategy, AstraZeneca, Reading, UK

Fabien Roy, DESS, Senior Associate, Hogan Lovells; Member, EFGCP-MedTech Europe Working Party, Brussels, Belgium

Rajiv Joshi, ICAL, ISACA, CIA, CFE, Partner, Fraud Investigation & Dispute Services, EY, Mumbai, India (Moderator)

MS 8: Risk Assessments and Monitoring Plans, Part I

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

Jose Manuel Garcelan, Global Compliance Consultant, Chemo; Former Regional Compliance and Privacy Officer, Merck, Sharp, and Dohme, Madrid, Spain

Michael Alan Gleave, Compliance Officer, Corporate Compliance and CSR, H. Lundbeck A/S, Copenhagen, Denmark

Anita K. Kim-Reinartz, Partner, Fraud Investigation & Dispute Services, EY, Düsseldorf, Germany

Maria-Teresa Rico Pérez, MD, Europe and Canada Regional Compliance Officer, Biogen, Zug, Switzerland

Abdul Luheshi, MBA, Executive Director, Global Operations, Ethics & Compliance, Astellas Pharma EMEA; Former Vice President, Health Care Compliance, Johnson & Johnson; Former Co-chair, Asia Pacific Pharma Compliance Congress, Chertsey, UK (Moderator)

MS 9: Patient Programs and Interactions with Patient Organizations—Managing the Risks of Getting Closer to the Patient

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

Dominik Geller, Head Pharma Healthcare Compliance Office, Roche, Basel, Switzerland

Cécile Gousset, Associate Vice President, Compliance Risk Assessment, Education and Monitoring, Global Ethics & Business Integrity, Sanofi, Paris, France

Chris J. Holmes, Director, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant, London, UK

Casey Horton, Director, Healthcare and Life Sciences Disputes, Regulatory Compliance and Investigations, Navigant, Chicago, IL, USA

Tamara Tubin, LLM, Compliance Director EUCAN, Takeda Pharmaceuticals International AG; Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Corporate Compliance Director, Biogen International; Former Ethics and Compliance Director International, Carefusion, Zurich, Switzerland (Moderator)

MS 10: Global Transparency Data Analytics: What They Mean for Your Company

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

Chrissy Bradshaw, JD, Vice President, Porzio Life Sciences, LLC, Morristown, NJ, USA

Kirtis Kraeuter, MGA, Head, Worldwide Compliance Committee and Monitoring Center of Expertise, Bristol-Myers Squibb, Princeton, NJ, USA

Marcel Maderitsch, LLM, Compliance Officer, Vifor Pharma, Zürich, Switzerland

Jeffrey Campbell, JD, President and Chief Executive Officer, Porzio Life Sciences, LLC, Morristown, NJ, USA (Moderator)

12:30 pm Networking Luncheon

DAY II: AFTERNOON PLENARY SESSION



1:40 pm Welcome and Overview

Stephen Nguyen-Duc, Area Director Ethics & Compliance Western, Europe-Israel and Canada, AbbVie; Former Director, Ethics & Compliance Officer, Eli Lilly and Company, Paris, France (Co-chair)



1:45 pm Overview of the New Marketplace in 2017 and Beyond

Frank Wartenberg, PhD, President, Central Europe, IMS Health, Frankfurt/Main, Germany

2:45 pm Panel Discussion of the Challenges of the New Marketplace

- Market Access
- Demonstrating the Value of Innovation and Value-Based Payment Structures
- The Future of Biosimilars
- Targeting Treatment with Companion Diagnostics
- Health Technology Assessments
- Role of the Compliance Function



Martin Fuerle, MBA, General Counsel and Chief Compliance Officer, Vice President Risk and Compliance, Daiichi Sankyo Europe GmbH, Munich, Germany



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



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



Frank Wartenberg, PhD, President, Central Europe, IMS Health, Frankfurt/Main, Germany



Michael Bartke, PhD, Former Director Compliance Management, DAIICHI SANKYO EUROPE GmbH, Munich, Germany (Moderator)

4:00 PM Networking Break

MINI SUMMITS ROUND III 4:30 pm – 5:30 pm

MS 11: Next Generation Compliance: Fostering Decision-Making in a Principle-Based Compliance Program

4:30 pm Introductions, Panel Discussion and Q&A

Timothy Ayers, JD, MPH, Vice President, Chief Compliance Officer, Horizon Pharma PLC; Former Vice President, Chief Compliance Officer, Dendreon; Former Associate General Counsel, Executive Director of Compliance, Seattle Genetics Chicago, IL, USA

Maureen McGirr, JD, Vice President, Office of Ethics, Global Compliance Organization, Merck, Sharp, and Dohme, Kenilworth, NJ, USA

Uffe Kåre Rasmussen, M.Sc., Senior Director and Chief Compliance Officer, H. Lundbeck A/S; Former Principal Scientist, Novo Nordisk A/S, Copenhagen, Denmark

Kirtis Kraeuter, MGA, Head, Worldwide Compliance Committee and Monitoring Center of Expertise, Bristol-Myers Squibb, Princeton, NJ, USA (Moderator)

MS 12: Risk Assessment and Monitoring Plans, Part II

4:30 pm Introductions, Panel Discussion and Q&A

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

Carl Judge, Partner, Fraud Investigation & Dispute Services, EY, London, UK

Gabriela Radu, Compliance Lead & Data Privacy Officer at Amgen Romania; Former Ethics and Compliance Associate, Eli Lilly and Company, Bucharest, Romania

Jolanta Wyszynska, Vice President, Compliance Europe, AstraZeneca, Warsaw, Poland

Abdul Luheshi, MBA, Executive Director, Global Operations, Ethics & Compliance, Astellas Pharma EMEA; Former Vice President, Health Care Compliance, Johnson & Johnson; Former Co-chair, Asia Pacific Pharma Compliance Congress, Chertsey, UK (Moderator)

MS 13: The Challenges of New Channels: Digital Communications, Social Media, and Other New Technologies

4:30 pm Introductions, Panel Discussion and Q&A

Grant Castle, Esq., Partner, Covington & Burling LLP, London, UK

Giota Papamarkou, Global Ethics & Compliance Director, Ipsen; Former EMEA Compliance and Ethics Manager, Bristol-Myers Squibb, Paris, France

Melda Tanyeri, MS, MBA, Director, Fraud Investigation & Dispute Services, EY, London, UK (Moderator)

MS 14: Advanced Topics in Anti-Corruption Compliance Programs

4:30 pm Introductions, Panel Discussion and Q&A

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

Michael O'Connor, Senior Director, Global Head Ethics and Compliance Operations, Alexion Pharmaceuticals, Inc., Cheshire, CT, USA

Daniel Schafaghi, Global Compliance Operating Officer, Head of Compliance Emerging Markets, Boehringer Ingelheim GmbH, Ingelheim, Germany

Geert van Gansewinkel, Managing Partner, Europe and Asia Pacific, Polaris, Amsterdam, Netherlands (Moderator)

MS 15: Impact of Self-Regulation Schemes on Industry Relationships with HCPs, HCOs and Patient Organizations

4:30 pm Introductions, Panel Discussion and Q&A

Holger Diener, PhD, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry; Vice-Chair, Ethics and Business Integrity Committee (eBIC), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Berlin, Germany

Jose F. Zamariego Izquierdo, PhD, Director Unidad de Supervision Deontologica, Farmaindustria, Madrid, Spain

Jose Ramos, MBA, Compliance Officer for Italy, Portugal, and Spain, Biogen, Madrid, Spain

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

Brian Sharkey, JD, Vice President, Porzio Life Sciences, LLC, Morristown, NJ, USA (Moderator)

5:45 pm Adjournment

HOTEL INFORMATION/RESERVATIONS

The Marriott Lisbon is the official hotel for the International Pharmaceutical Compliance Congress. A special group rate of **€165.00 per night** including breakfast and wi-fi has been arranged. To make reservations online, please visit www.internationalpharmacongress.com and go to the **travel/hotel link**. Reservations at the group rate will be accepted until **April 21, 2017**. After this date, reservations will be accepted on a space-available basis at the prevailing rate.

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

Lisbon Marriott Hotel

Avenida dos Combatentes, 45, 1600-042 • Lisbon, Portugal
+351 21 723 5400



WEDNESDAY, MAY 17, 2017

7:30 am Registration Commences

DAY III: CLOSING PLENARY SESSION

8:30 am Welcome and Introduction



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

8:40 am IFPMA Keynote Speech



Thomas Cueni, Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Geneva, Switzerland

9:10 am Clinical Data Transparency: The EMA Experience



Aleksandar Rusanov, Esq., Legal Advisor, Legal Department, European Medicines Agency (EMA), London, UK

9:40 am Panel Discussion on Data Privacy



Aleksandar Rusanov, Esq., Legal Advisor, Legal Department, European Medicines Agency (EMA), London, UK



Elisabethann Wright, Esq., Partner, Hogan Lovells International LLP, Brussels, Belgium



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

10:45 am Networking Break

11:15 am



EFPIA Keynote Speech

Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

11:45 am



Current Initiatives of the Trade Associations

APIFARMA

Pedro Caridade de Freitas, LLM, PhD, Legal and Compliance Director, Portuguese Association of the Pharmaceutical Industry (APIFARMA), Lisbon, Portugal



EFPIA

Marie-Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations, (EFPIA), Brussels, Belgium



EUCOMED AND EMA CODE

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



IFPMA

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



MEA

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



Oscar Perdomo, Director, Pharmaceuticals and Life Sciences, PwC, Switzerland (Moderator)

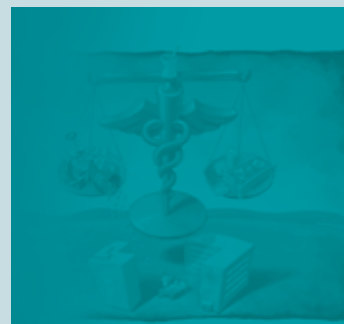
1:00 pm

Adjournment

The Eleventh International Pharmaceutical and Medical Device Compliance Congress

Watch Our Website for Information on the Conference App!

www.InternationalPharmaCongress.com



2017 INTERNATIONAL PHARMA CONGRESS PLANNING COMMITTEE

CO-CHAIRS

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

Stephen Nguyen Duc, *Office of Ethics & Compliance Area Director, International Operations, Western Europe & Canada, AbbVie; Board Member, Strategic Committee International Society of Healthcare, Ethics, and Compliance Professionals (ETHICS), Rungis, France*

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

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

MEMBERS

Timothy Ayers, JD, MPH, *Vice President, Chief Compliance Officer, Horizon Pharma PLC; Former Vice President, Chief Compliance Officer, Dendreon; Former Associate General Counsel; Executive Director of Compliance, Seattle Genetics, Chicago, IL, USA*

Michael Bartke, PhD, *Former Director Compliance Management, DAIICHI SANKYO EUROPE GmbH, Munich, Germany*

Ann Beasley, JD, *Director, Healthcare and Life Sciences Disputes, Compliance & Investigations, Navigant Consulting; Former Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis, Boston, MA, USA*

Andy Bender, MS, MBA, *President and Founder, Polaris, New York, NY, USA*

Leonardo Cassara A. Silva, LLM, *Global Compliance Officer, Ferring International Center S.A.; Former Head of Compliance, Acino Pharma AG; Former Compliance Director, Emerging Markets, Takeda Pharmaceuticals, Saint-Prex, Switzerland*

Sujata Dayal, *Vice President, Health Care Compliance and Privacy, Global Chief Compliance Officer, Pharmaceuticals, Johnson & Johnson; Former Chief Compliance Officer and Corporate Vice President, Biomet, Inc.; Former Ethics and Compliance Officer, Abbott Laboratories, Titusville, NJ, USA*

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

Martin Fuerle, MBA, *General Counsel and Chief Compliance Officer, Vice President Risk & Compliance, Daiichi Sankyo Europe GmbH, Munich, Germany*

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

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Kirtis Kraeuter, MGA, *Head, Worldwide Compliance Committee and Monitoring Center of Expertise, Bristol-Myers Squibb, Princeton, NJ, USA*

Evelyne Lemaire, *Head of Compliance, Europe & Canada, Takeda Pharmaceuticals International GmbH; Former Director, Global Pharmaceutical and Life Sciences, PwC LLP, Zurich, Switzerland*

Maureen McGirr, JD, *Vice President, Office of Ethics, Global Compliance Organization, Merck, Sharp, and Dohme, Kenilworth, NJ, USA*

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David O'Shaughnessy, *Vice President, Compliance, Emerging Markets, Quintiles; Board Member, ETHICS; Former Vice President Compliance, International Pharmaceuticals, GSK; Former Vice President, Global Compliance Strategy, AstraZeneca, Reading, UK*

Maria-Teresa Rico Pérez, MD, *Europe and Canada Regional Compliance Officer, Biogen, Zug, Switzerland*

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

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Uffe Kåre Rasmussen, MSc, *Senior Director and Chief Compliance Officer, H. Lundbeck A/S; Former Principal Scientist, Novo Nordisk A/S, Copenhagen, Denmark*

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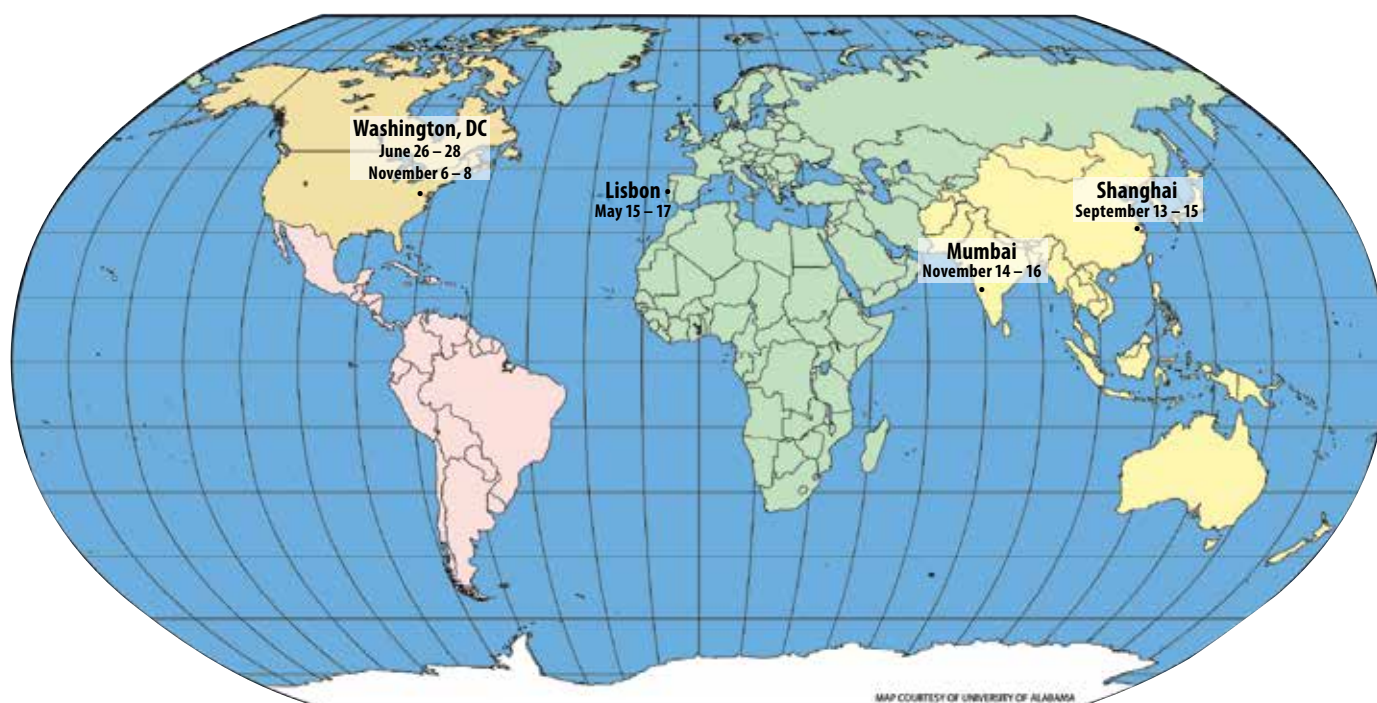
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SELECT YOUR MINI-SUMMITS (One from each group):

ROUND I – Monday, May 15, 4:15 pm

- ☐ 1: Transparency: Now that We Have the Data, How Can We Leverage It to Improve Compliance?
- ☐ 2: Annual MEA Compliance Roundtable
- ☐ 3: Health Economics and Outcomes Research (HEOR)— Emerging Risks of Data Collection, Use, and Secondary Use
- ☐ 4: Evolving Privacy Requirements: Preparing for the General Data Protection Regulation
- ☐ 5: Managing Medical Device Anti-Corruption Risks

ROUND II – Tuesday, May 16, 11:15 am

- ☐ 6: Practical Implications of Brexit on Life Science Companies
- ☐ 7: The Interfaces Between the Roles of the Compliance and Quality Functions
- ☐ 8: Risk Assessments and Monitoring Plans, Part I
- ☐ 9: Patient Programs and Interactions with Patient Organizations— Managing the Risks of Getting Closer to the Patient
- ☐ 10: Global Transparency Data Analytics: What They Mean for Your Company

ROUND III – Tuesday, May 16, 4:30 pm

- ☐ 11: Next Generation Compliance: Fostering Decision-Making in a Principle-Based Compliance Program
- ☐ 12: Risk Assessment and Monitoring Plans, Part II
- ☐ 13: The Challenges of New Channels: Digital Communications, Social Media, and Other New Technologies
- ☐ 14: Advanced Topics in Anti-Corruption Compliance Programs
- ☐ 15: Impact of Self-Regulation Schemes on Industry Relationships with HCPS, HCOS and Patient Organizations

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