

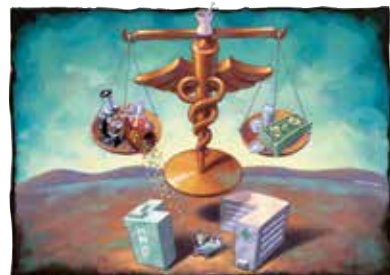
THE TENTH INTERNATIONAL

# Pharmaceutical Compliance Congress and Best Practices Forum

**GHC** LIFE SCIENCES  
Global Health Care, LLC

May 10 – 12, 2016

Hilton Warsaw Hotel and Convention Centre  
Warsaw, Poland



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## OFFERED IN SEQUENCE WITH AN EFPIA CODES TRAINING WORKSHOP

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent EFPIA CODES TRAINING WORKSHOP on Tuesday, May 10, 2016.

## FEATURING CHIEF COMPLIANCE OFFICERS:



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



**Ann Beasley**, Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA



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



**Eric Cornut, LLM, PhD**, Chief Ethics, Compliance and Policy Officer, Novartis; Former Chief Commercial Officer, Novartis, Basel, Switzerland



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



**Marc-Olivier Lamaro**, Chief Compliance Officer, Sanofi Pasteur MSD; Former Director, Compliance Officer, Johnson & Johnson, Lyon, 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



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



**Ashley Watson, Esq.**, Senior Vice President, Chief Ethics and Compliance Officer, Merck Sharp Dohme (MSD); Former Counsel, Chief Ethics and Compliance Officer, Hewlett-Packard, Philadelphia, PA, USA

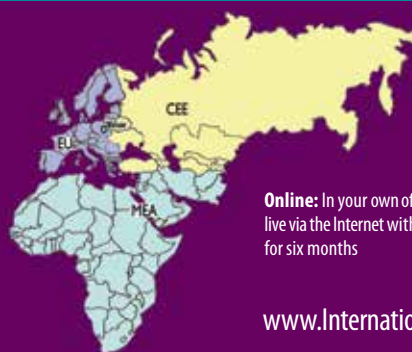
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See page 2

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## KEYNOTE SPEAKERS:



**Marc Bartel, LLM, MBA**, Managing Partner France, Partner, Legal and Board Practices, Heidrick & Struggles, Paris, France



**Sadek Beloucif, MD**, Professor, Department of Anesthesiology and Critical Care Medicine, Avicenne University Hospital; Chairman, Ethics Committee of the Biomedicine Agency, Paris, France



**Hui Chen, Esq.**, Compliance Counsel Expert, US Department of Justice; Former Global Head, Anti-Bribery and Corruption, Standard Chartered Bank; Former Assistant General Counsel, Pfizer, Washington, DC, USA



**Peter Dieners, Esq.**, Partner and Head, Global Healthcare and Life Sciences Group, Clifford Chance; Co-chair, Legal Affairs Focus Group and Co-chair, Compliance Network, EUROMED, Düsseldorf, Germany



**Gejaa Gobena, Esq.**, Chief, Health Care Fraud Unit, US Department of Justice, Washington, DC, USA



**Dr. Krzysztof Łanda**, Vice Minister of Health in Charge of Drug Policy, Polish Ministry of Health; Founder, Watch Health Care Foundation; Former President, Central & Eastern European Society of Technology Assessment in Health Care, Warsaw, Poland



**Sophie Peresson, LLM**, Director, Pharmaceuticals and Healthcare Programme, Transparency International UK, London, UK



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



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



**Paweł Sztwiertnia**, Chief Executive Officer, Employers' Union of Innovative Pharmaceutical Companies (INFARMA); Former Undersecretary of State, Polish Ministry of Health, Warsaw, Poland



**Jose F. Zamarriego Izquierdo, PhD**, Director Unidad de Supervisión Deontológica, FARMINDUSTRIA, Madrid, Spain

## FEATURING PLENARY SESSIONS:

- Transparency International Keynote
- Overview of the Anti-Corruption Landscape
- The National Anti-Corruption Strategy of Romania
- US Department of Justice Anti-Corruption Update
- Anti-Corruption Roundtable: Strategies to Foster Compliance
- Challenges in the New Marketplace 2.0
- Ethics and the Current Industry-Physician Relationship Model – Are They Compatible?
- EFPIA Keynote: Reflections on the Eve of Transparency
- Perspectives on Transparency from the Local Country Level: Voices From Poland
- Global Compliance Officer Roundtable: Key Risks for the Industry and the Future of Ethics and Compliance Programs
- Report from Compliance Survey Commissioned by ETHICS
- Updates on Global Codes

## AND MINI-SUMMITS:

- I: Anti-Corruption Case Study: Examining a Hypothetical Investigation from All Sides
- II: Annual CEE Compliance Update
- III: Ethics and Compliance Programs of the Future: New Strategies for Integrated Assessment and Management of Risks
- IV: Patient Programs — Managing the Various Risks of Getting Closer to the Patient
- V: Annual MEA Compliance Update
- VI: Anti-Corruption Case Study: Contracting with Third Parties and Optimizing the Relationship
- VII: New Marketplace Case Study: Ensuring a Compliant Product Launch
- VIII: Data Privacy Case Study: Evolving Requirements for Data Protection and Transfers
- IX: Implementation of Compliance Programs across Different Countries — Cultural Implications
- X: Using Predictive Analytics to Enhance Risk Management
- XI: Advanced Issues in Third Party Relationships: Cross-Border Engagements, Fair Market Value, Monitoring and Auditing of On-Going Relationships
- XII: New Ethics-Based Approaches to Policies and Training
- XIII: Medical Devices: The Changing Enforcement Landscape
- XIV: R&D Compliance — Case Study on Clinical Trial Data Disclosures
- XV: Advanced Issues In Applying Analytics — Using the Data to Provide Value and Partner with the Business

## CONTINUING EDUCATION CREDITS:

Approved for up to 19 NASBE CPE credits.  
Compliance Certification Board CCB credits.  
CA and PA MCLE credit pending approval.

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.

Since then, the International Compliance Congress has evolved to encompass global topics in the Plenary Sessions and more locally-focused issues in the Mini Summits as pertinent to the European Union (EU), Central and Eastern Europe (CEE), and the Middle East and Africa (MEA) regions. The 2016 conference continues this trend.

Over the past decade, the international conferences have been held in Brussels (2007, 2015), Paris (2008), Rome (2009), Berlin (2010), Istanbul (2011), Budapest (2012), Madrid (2013) and Dubai (2014). In 2016 we are pleased to hold The Tenth International Pharmaceutical Compliance Congress and Best Practices Forum in Warsaw, Poland with the local partnership of INFARMA, the Employers' Union of Innovative Pharmaceutical Companies. The Congress sponsor remains The International Society of Healthcare Ethics and Compliance Professionals (ETHICS) with the Pharmaceutical Compliance Forum (PCF) as a co-sponsor.

The Congress will feature the following plenary sessions and mini summits:

#### PLENARY SESSIONS:

- Transparency International Keynote
- Overview of the Anti-Corruption Landscape
- The National Anti-Corruption Strategy of Romania
- US Department of Justice Anti-Corruption Update
- Anti-Corruption Roundtable: Strategies to Foster Compliance
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- XV: Advanced Issues In Applying Analytics — Using the Data to Provide Value and Partner with the Business

## 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 of contributing to the professional development of individuals and the success of ethics and compliance organizations.

## CO-SPONSORS:



THE  
PHARMACEUTICAL  
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FORUM

THE PHARMACEUTICAL COMPLIANCE FORUM (PCF) is a coalition of senior compliance professionals and legal counsel from more than 50 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.



THE EMPLOYERS' ASSOCIATION OF INNOVATIVE PHARMACEUTICAL COMPANIES (INFARMA) represents 28 leading pharmaceutical companies engaged in research and development activities and the production of innovative medicines. INFARMA is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) - an international organization of the innovative pharmaceutical industry, the Employers of Poland (Pracodawcy RP) and the Polish Chamber of Commerce.

<http://www.infarma.pl/>

## PARTICIPATION OPTIONS TRADITIONAL ONSITE ATTENDANCE

Simply register, travel to the conference city and attend in person.

PROS:  
subject matter immersion;  
professional networking  
opportunities; faculty interaction.



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## LIVE AND ARCHIVED INTERNET ATTENDANCE

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PROS:  
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TUESDAY, MAY 10, 2016

## EFPIA CODES TRAINING WORKSHOP



The European Federation of Pharmaceutical Industries and Associations (EFPIA) is offering an independent EFPIA CODES TRAINING WORKSHOP on Tuesday, May 10, 2016 from 10:00 am to 12:45 pm, including a luncheon.

### Faculty:

**Richard Bergström**, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

**Julie Bonhomme, Esq.**, Legal Affairs and Compliance Deputy Director, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

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

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

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

### What can we learn from each other?

- Come and work through practical cases to help improve your understanding of the Codes and global requirements as well as their implementation by national associations.
- Each section will include presentation of a realistic case scenario with a description of the relevant requirements from the national, EFPIA, and/or IFPMA codes.

1:00 pm



### TRANSPARENCY INTERNATIONAL KEYNOTE

**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



**Introduction by Ann Beasley**, Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA (Co-chair)

1:30 pm



### OVERVIEW OF THE ANTI-CORRUPTION LANDSCAPE

**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

2:00 pm



### THE NATIONAL ANTI-CORRUPTION STRATEGY OF ROMANIA

**Corneliu Virgiliu Calinescu** (Invited), Head of National Office for Crime Prevention and Cooperation with Assets Recovery Offices, Ministry of Justice, Romania; Head, Romania's National Delegation, Group of States against Corruption (GRECO); Member, International Academic Advisory Board, International Anticorruption Academy (IACA), Bucharest, Romania



**Introduction by Mariusz Witalis**, Partner, Fraud Investigation and Dispute Services, EY, Warsaw, Poland

2:30 pm



### US DEPARTMENT OF JUSTICE ANTI-CORRUPTION UPDATE

**Hui Chen, Esq.**, Compliance Counsel Expert, US Department of Justice; Former Global Head, Anti-Bribery and Corruption, Standard Chartered Bank; Former Assistant General Counsel, Pfizer; Former Assistant US Attorney, US Attorney's Office, Eastern District of New York, Washington, DC, USA



**Gejaa Gobena, Esq.**, Chief, Health Care Fraud Unit, US Department of Justice, Washington, DC, USA



**Gary Giampetruzzi, Esq.**, Partner, Paul Hastings; Former Vice President and Assistant General Counsel, and Head, Government Investigations, Pfizer Inc., Washington, DC, USA (Moderator)

3:15 pm



### ANTI-CORRUPTION ROUNDTABLE: STRATEGIES TO FOSTER COMPLIANCE

**Peter Dieners, 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



**Cristian Ducu, PhD**, Founder and General Manager, Centre for Advanced Research in Management and Applied Ethics; Member, National Bioethics Commission of the National Commission of Romania for UNESCO; Founding Member, Research Centre in Applied Ethics, Faculty of Philosophy, University of Bucharest, Bucharest, Romania



**Michael K. Loucks, Esq.**, Partner, Skadden Arps LLP; Former Acting United States Attorney, US Attorney's Office for the District of Massachusetts, 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



**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)

4:15 pm

Break

TUESDAY, MAY 10, 2016

## INTERNATIONAL PHARMA CONGRESS DAY I: OPENING PLENARY SESSION

12:45 pm

### WELCOME FROM INFARMA



**Pawel Sztwierz**, Chief Executive Officer, Employers' Union of Innovative Pharmaceutical Companies (INFARMA); Former Undersecretary of State, Polish Ministry of Health, Warsaw, Poland

12:50 pm

### THE GABOR DANIELFY MEMORIAL KEYNOTE OVERVIEW AND INTERNATIONAL PHARMA CONGRESS WELCOME



**Ann Beasley**, Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA (Co-chair)



**Michael Bartke, PhD**, Director, Compliance Management, DAIICHI SANKYO EUROPE GmbH, Munich, Germany (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 and Compliance Western Europe-Israel and Canada, AbbVie; Former Director, Ethics and Compliance Officer, Eli Lilly and Company, Paris, France (Co-chair)



**Roeland Van Aelst**, Regional Vice President, HCCO MD&D EMEA and Canada, Office of 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 (Co-chair)

## MINI SUMMITS ROUND I

### MINI SUMMIT I: ANTI-CORRUPTION CASE STUDY: EXAMINING A HYPOTHETICAL INVESTIGATION FROM ALL SIDES

**4:45 pm** Introductions, Discussion and Q&A

**Pierre E. Dupourque, Esq.**, Assistant General Counsel, Regional Compliance Lead EMEA, Canada, Pakistan, India, Pfizer, Mannheim, Germany

**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

**Daniel Schafaghi**, Corporate Ethics and Compliance, Boehringer Ingelheim GmbH, Ingelheim, Germany

**Ashley Watson, Esq.**, Senior Vice President, Chief Ethics and Compliance Officer, Merck Sharp Dohme (MSD); Former Counsel, Chief Ethics and Compliance Officer, Hewlett-Packard, Philadelphia, PA, USA

**Gary Giampetruzzi, Esq.**, Partner, Paul Hastings; Former Vice President and Assistant General Counsel, and Head, Government Investigations, Pfizer Inc., Washington, DC, USA (Moderator)

**6:00 pm** Adjournment and Networking Reception

### MINI SUMMIT II: ANNUAL CEE COMPLIANCE UPDATE

**4:45 pm** Introductions, Discussion and Q&A

**Cristian Ducu, PhD**, Founder and General Manager, Centre for Advanced Research in Management and Applied Ethics; Member, National Bioethics Commission of the National Commission of Romania for UNESCO; Founding Member, Research Centre in Applied Ethics, Faculty of Philosophy, University of Bucharest, Bucharest, Romania

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

**Katalin Pungor, MD, PhD, MBA**, Director, Healthcare Compliance, Emerging Markets and CEE, Johnson & Johnson, Budapest, Hungary

**Milena Yakimova, LLM**, Director, Ethics and Compliance, Central and South East Europe, Allergan, Sofia, Bulgaria

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

**6:00 pm** Adjournment and Networking Reception

### MINI SUMMIT III: ETHICS AND COMPLIANCE PROGRAMS OF THE FUTURE: NEW STRATEGIES FOR INTEGRATED ASSESSMENT AND MANAGEMENT OF RISKS

**4:45 pm** Introductions, Discussion and Q&A

**Ann Beasley**, Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA (Co-chair)

**Isaure Kergall-Gayet**, Compliance and Business Integrity Director France, Sanofi, Paris, 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 (Co-chair)

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

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

**6:00 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](mailto:exhibits@hcconferences.com).

## HOTEL INFORMATION/ RESERVATIONS



**The International Pharma 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.**

The Hilton Warsaw Hotel and Convention Centre is the official hotel for the Tenth International Pharma Compliance Congress. A special group rate of PLN 540.00 per night (plus tax) has been arranged for Congress Attendees.

For your convenience, we are pleased to provide you with a dedicated website so you are able to book your hotel reservations online. To make your online reservation at the special group rate, please go to [www.internationalpharmacongress.com/travel.html](http://www.internationalpharmacongress.com/travel.html).

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### MINI SUMMIT IV: PATIENT PROGRAMS — MANAGING THE VARIOUS RISKS OF GETTING CLOSER TO THE PATIENT

**4:45 pm** Introductions, Discussion and Q&A

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

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

**Oscar Perdomo**, Director, Pharmaceuticals and Life Sciences, PwC, Switzerland

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

**6:00 pm** Adjournment and Networking Reception

### MINI SUMMIT V: ANNUAL MEA COMPLIANCE UPDATE

**4:45 pm** Introductions, Discussion and Q&A

**Flavia Bolliger** (Invited), Head, Compliance & Integrity, MENA, Novartis Pharma Services AG, Dubai, United Arab Emirates

**Rifat Bozacioglu, LPEC** (Invited), Area Compliance Director, GlaxoSmithKline, Istanbul, Turkey

**Abdallah El Saadi, CCP**, Regional Compliance Officer - Middle East, Turkey and Africa, Boehringer Ingelheim, Dubai, UAE

**Laura Nassar**, Head of Compliance, Middle East, Hoffmann-La Roche Ltd., Dubai, UAE

**Joe Henein**, President and Chief Executive Officer, NewBridge Pharmaceuticals; Former Regional Managing Director, Middle East, and North Africa, Wyeth Pharmaceuticals, Dubai, United Arab Emirates (Moderator)

**6:00 pm** Adjournment and Networking Reception

WEDNESDAY, MAY 11, 2016

## DAY II: MORNING PLENARY SESSION

7:30 am Registration Commences

8:30 am Welcome and Overview



**Michael Bartke, PhD**, Director, Compliance Management, DAIICHI SANKYO EUROPE GmbH, Munich, Germany (Co chair)

### CHALLENGES IN THE NEW MARKETPLACE 2.0

8:35 am The New Marketplace Overview: A 2016 Update



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

9:10 am Roundtable Discussion

- Market Access
- Value-added Services
- Tendering, Pricing, and Innovative Contracting Strategies
- Comparative Effectiveness Research



**Lee Betteridge**, Director, Pharmaceuticals and Life Sciences, PwC, London, UK



**Patrick Delavault, MD**, Senior Vice President, Chief Medical Officer, Global Medical and Regulatory Sciences, Ipsen, Paris, France



**Maarten Meulenbelt, Esq.**, Partner, Food, Drug, and Medical Device Regulatory Group, Sidley Austin LLP, Brussels, Belgium



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



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



**Andrew White**, Head of Medicine Management - NHS, Greater Manchester Commissioning Support Unit, Manchester, UK



**Olivier Wong, MD**, Specialist in Family Medicine; Former Voting Member, French Transparency Committee, Paris, France



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

10:15 am Networking Break

## MINI SUMMITS ROUND II

### MINI SUMMIT VI: ANTI-CORRUPTION CASE STUDY: CONTRACTING WITH THIRD PARTIES AND OPTIMIZING THE RELATIONSHIP

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

**Anthony Alvizu, CPA, EnCE, CFE**, Senior Director, Global Risk & Investigations Practice, FTI Consulting, Chicago, IL, USA

**Maureen McGirr, Esq.**, Vice President, Office of Ethics, Global Compliance Organization, Merck Sharp Dohme (MSD), Philadelphia, PA, USA

**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

**Nathalie Raynaud**, Corporate Compliance Officer, Ethics and Business Integrity Department, Sanofi, Paris, France

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

12:00 pm Networking Luncheon

### MINI SUMMIT VII: NEW MARKETPLACE CASE STUDY: ENSURING A COMPLIANT PRODUCT LAUNCH

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

**Patrick Delavault, MD**, Senior Vice President, Chief Medical Officer, Global Medical and Regulatory Sciences, Ipsen, Paris, France

**Zeynep Didem Degirmencioğlu, LLM**, Regional Head of Group Compliance, Intercontinental Region, Merck Serono, Istanbul, Turkey

**George Fife**, Executive Director, Fraud Investigation and Dispute Services, EY; Former Executive Director, Compliance and Ethics, Bristol-Myers Squibb, Paris, France

**Hubertus Stockmann, MBA**, Divisional Compliance Officer, Merck KgaA, Frankfurt, Germany

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

12:00 pm Networking Luncheon

### MINI SUMMIT VIII: DATA PRIVACY CASE STUDY: EVOLVING REQUIREMENTS FOR DATA PROTECTION AND TRANSFERS

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

**Caroline Cavaillier, Esq.** (Invited), Senior Corporate Counsel, Global Data Privacy Officer, Bristol Myers-Squibb, Need location

**Tanya Daniels, Esq.**, Senior Legal Director, EU Head of Data Protection, Deputy Global Chief Privacy Officer, Quintiles, Reading, UK

**Madina Plieva** (Invited), Legal Counsel, Russia, Bristol Myers-Squibb; Former Legal Director, Association of International Pharmaceutical Manufacturers (AIPM); Former Head of Legal Department, Kutafin Moscow State Law Academy, Moscow, Russia

**Agata Szeliga, LLM**, Partner, Soltysinski, Kawecki and Szelzak, Warsaw, Poland

**Daniela Fabian Masoch, Esq.**, Founder and Managing Director, Fabian Privacy Legal GmbH; Member and Chapter Co-Chair, International Privacy Professionals Association (IAPP); Former Global Head Data Privacy, Novartis International AG, Basel, Switzerland (Moderator)

12:00 pm Networking Luncheon

### MINI SUMMIT IX: IMPLEMENTATION OF COMPLIANCE PROGRAMS ACROSS DIFFERENT COUNTRIES — CULTURAL IMPLICATIONS

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

**David Hodgson** (Invited), Partner, Deloitte, London, UK

**Tomasz Kruk**, Head of Compliance, Vifor Pharma; Former Director International Compliance, Mallinckrodt Pharmaceuticals; Former Director Global Ethics and Compliance, Actavis plc (now Allergan plc), Zürich, Switzerland

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

**Ulf H. Grundmann, Esq.**, Partner, King & Spalding LLP, Frankfurt, Germany (Moderator)

12:00 pm Networking Luncheon

### MINI SUMMIT X: USING PREDICTIVE ANALYTICS TO ENHANCE RISK MANAGEMENT

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

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

**Elvan Sevi Firat, LLM, PhD**, Founding Partner, Firat - Izgi Attorney Partnership, Istanbul, Turkey

**Carl Judge**, Director, Fraud Investigation and Dispute Services, EY, London, UK

**Abdul Luheshi, MBA**, Director, Life Sciences Regulatory Compliance, KPMG; Former Vice President, Health Care Compliance, Johnson & Johnson, London, UK (Moderator)

12:00 pm Networking Luncheon

## DAY II: AFTERNOON PLENARY SESSION

1:15 pm



### WELCOME AND OVERVIEW

**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)

1:20 pm



### KEYNOTE: ETHICS AND THE CURRENT INDUSTRY-PHYSICIAN RELATIONSHIP MODEL — ARE THEY COMPATIBLE?

**Sadek Beloucif, MD, PhD**, Professor, Department of Anesthesiology and Critical Care Medicine, Avicenne University Hospital; Chairman, Ethics Committee of the Biomedicine Agency, Paris, France

1:50 pm



### EFPIA KEYNOTE: REFLECTIONS ON THE EVE OF TRANSPARENCY

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

### PERSPECTIVES ON TRANSPARENCY FROM THE LOCAL COUNTRY LEVEL: VOICES FROM POLAND

2:20 pm



### INTRODUCTORY COMMENTS

**Dr. Krzysztof Łanda**, Vice Minister of Health in Charge of Drug Policy, Polish Ministry of Health; Founder, Watch Health Care Foundation; Former President, Central & Eastern European, Society of Technology Assessment in Health Care, Warsaw, Poland

2:50 pm



### ROUNDTABLE DISCUSSION

**Dr. Adam Bodnar, JD, LLM** (Invited), Commissioner for Human Rights, Poland; Associate Professor, University of Warsaw, Warsaw, Poland



**Maciej Hamankiewicz** (Invited), President, Polish Chamber of Physicians and Dentists, Warsaw, Poland



**Professor Jacek Jassem**, Head of the Department of Oncology and Radiotherapy, Medical University of Gdańsk; Former President of the Polish Society of Oncology, Gdańsk, Poland



**Dr. Krzysztof Łanda**, Vice Minister of Health in Charge of Drug Policy, Polish Ministry of Health; Founder, Watch Health Care Foundation; Former President, Central and Eastern European Society of Technology Assessment in Health Care, Warsaw, Poland



**Dr. Grzegorz Makowski**, Director of the Public Integrity Program, Stefan Batory Foundation, the Local Partner with Transparency International in Poland, Warsaw, Poland



**Paweł Sztwertnia**, Director General, INFARMA; Former Undersecretary of State, Polish Ministry of Health, Warsaw, Poland



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

4:00 pm

### Break

## MINI SUMMITS ROUND III

### MINI SUMMIT XI: ADVANCED ISSUES IN THIRD PARTY RELATIONSHIPS: CROSS-BORDER ENGAGEMENTS, FAIR MARKET VALUE, MONITORING AND AUDITING OF ON-GOING RELATIONSHIPS

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

**Ela Bochenek, Esq.**, Vice President, Global Compliance, Insmed Incorporated, Bridgewater, NJ, USA

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

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

**Mirjam Weiss, Esq.**, Senior Director, Head of Compliance EMEA, Merz Pharma GmbH & Co. KGaA, Frankfurt, Germany

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

#### 5:45 pm Adjournment

### MINI SUMMIT XII: NEW ETHICS-BASED APPROACHES TO POLICIES AND TRAINING

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

**Suzana Junaci, MD**, Ethics and Compliance Officer, Eli Lilly and Company, Zagreb, Croatia

**Edoardo Lazzarini, PhD**, Europe and Canada Compliance Initiative Director, Takeda Pharmaceuticals; Former Compliance Officer EMEA, Biomet; Former Vice-chair of Compliance, Network Steering Committee, Eucomed, Milan, Italy

**Piergiorgio Pepe, LLM**, EMEA Compliance Area Director, Office of Ethics and Compliance, AbbVie; Former Director, Compliance and Ethics, EMEA, Bristol-Myers Squibb, Paris, France

**Ben Shoshan**, Director/Owner, Consultant and Executive Coach, Open Water, London, UK

**Christine Longawa, CPA, CFE**, Associate Director, Healthcare and Life Sciences Disputes, Regulatory, Compliance and Investigations, Navigant Consulting, Inc., Chicago, IL, USA (Moderator)

#### 5:45 pm Adjournment

### MINI SUMMIT XIII: MEDICAL DEVICES: THE CHANGING ENFORCEMENT LANDSCAPE

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

**John Brennan** (Invited), Director Regulatory and Technical Affairs, Eucomed, Brussels, Belgium

**Theresa Jeary, MSc** (Invited), Technical Manager, Lloyds Register Quality Assurance, Coventry, UK

**Roeland Van Aelst**, Regional Vice President, HCCO MD&D EMEA and Canada, Office of 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 (Co-chair)

**Saul Helman, MD, MBA**, Managing Director and Life Sciences Practice Leader, Navigant Consulting, Inc., Indianapolis, IN, USA

**Maurits J.F. Lugard, MA, JD, LLM**, Partner and Lead, EU Life Sciences Regulatory Team, Sidley Austin LLP; Former Member, European Commission's Legal Service, Brussels, Belgium (Moderator)

#### 5:45 pm Adjournment

### MINI SUMMIT XIV: R&D COMPLIANCE — CASE STUDY ON CLINICAL TRIAL DATA DISCLOSURES

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

**Yogesh Bahl, CPA, MBA**, Managing Director, Alix Partners, New York, NY

**Laurence Labey**, Research and Development Compliance, Sanofi, Paris, France

**George K. Ng, Esq.**, Executive Vice President and Chief Legal Officer, Sorrento Therapeutics, Inc., San Diego, CA, USA

**Ima Parrondo** (Invited), Health Care Compliance Officer EMEA-C, Janssen Pharmaceutical Companies of Johnson & Johnson, Madrid, Spain

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

#### 5:45 pm Adjournment

Round III Mini Summits Continued on Next Page

## MINI SUMMIT XV: ADVANCED ISSUES IN APPLYING ANALYTICS — USING THE DATA TO PROVIDE VALUE AND PARTNER WITH THE BUSINESS

### 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

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

**Evelyne Lemaire**, Head of Compliance, Europe and Canada, Takeda Pharmaceuticals International GmbH, Zurich, Switzerland

**John Patrick Oroho, Esq.**, Executive Vice President and Chief Strategy Officer, Porzio Life Sciences, LLC, Principal, Porzio, Bromberg & Newman PC, Morristown, NJ, USA (Moderator)

### 5:45 pm Adjournment

## THURSDAY, MAY 12, 2016

### 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 and Canada, Office of 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 KEYNOTE ADDRESS



**Eric Cornut, LL.M, PhD**, Chief Ethics, Compliance and Policy Officer, Novartis; Former Chief Commercial Officer, Novartis, Basel, Switzerland

### 9:10 am GLOBAL COMPLIANCE OFFICER ROUNDTABLE: KEY RISKS FOR THE INDUSTRY AND THE FUTURE OF ETHICS AND COMPLIANCE PROGRAMS



**Dante Beccaria**, Vice President Global Compliance, Sanofi, Paris Area, France



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



**Marc-Olivier Lamaro**, Chief Compliance Officer, Sanofi Pasteur MSD; Former Director, Compliance Officer, Johnson & Johnson, Lyon, France



**Uffe Kåre Rasmussen, MSc**, Senior Director and Chief Compliance Officer, H. Lundbeck A/S, Copenhagen, Denmark



**Ilya Yuffa, MBA**, Vice President, Global Ethics and Compliance Officer, Eli Lilly and Company, Indianapolis, IN, USA



**Kip Ebel, MBA**, Principal, Fraud Investigation and Dispute Services, EY, New York, NY, USA (Moderator)

### 10:30 am Networking Break

10:45 am



## KEYNOTE: REPORT FROM A COMPLIANCE SURVEY COMMISSIONED BY ETHICS

**Marc Bartel, LL.M, MBA**, Managing Partner France, Partner, Legal and Board Practices, Heidrick & Struggles, Paris, France



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

11:15 am



## PANEL DISCUSSION OF THE SURVEY RESULTS

**Ann Beasley**, Chief Compliance Officer, Biogen; Former Global Compliance Officer, Novartis Pharma AG; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Cambridge, MA, USA (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 and Compliance Western Europe-Israel and Canada, AbbVie; Former Director, Ethics and Compliance Officer, Eli Lilly and Company, Paris, France (Co-chair)



**Roeland Van Aelst**, Regional Vice President, HCCO MD&D EMEA and Canada, Office of 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 (Co-chair)



**Olivier Chaduteau, MA**, Managing and Founding Partner, Day One Board Member, Cognacs Camus; Mentor for Entrepreneurs at the IME (French Chamber of Commerce), Paris, France (Moderator)

12:00 pm



## UPDATES ON GLOBAL CODES

MEA Code

**Laura Nassar**, Head of Compliance, Middle East, Hoffmann-La Roche Ltd., Dubai, UAE



EUCOMED and EMA Code

**Roeland Van Aelst**, Regional Vice President, HCCO MD&D EMEA and Canada, Office of 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)



EFPIA Code

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



**Jose F. Zamarriego Izquierdo, PhD**, Director Unidad de Supervision Deontologica, FARMAINDUSTRIA, Madrid, Spain



IFPMA Code

**Brendan Shaw, PhD** (Invited), Assistant Director General, International Federation of Pharmaceutical, Manufacturers and Associations (IFPMA); Former Chief Executive, Medicines Australia, Geneva, Switzerland



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



Moderator

**David Andersen**, Partner, Pharmaceuticals and Life Sciences, PwC, London, UK

1:00 pm

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7. Please describe briefly your function and reporting line:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

8. What is your level of Seniority in your current position?

\_\_\_\_\_

\_\_\_\_\_

9. What is your level of Seniority within the Compliance/Ethics functions?

\_\_\_\_\_

\_\_\_\_\_

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#### ROUND I – Tuesday, May 10, 4:45 pm

☐ I: Anti-Corruption Case Study:  
Examining a Hypothetical  
Investigation ...  
☐ II: Annual CEE Compliance Update ...  
☐ III: Ethics and Compliance Programs  
of the Future ...  
☐ IV: Patient Programs ...  
☐ V: Annual MEA Compliance Update ...

#### ROUND II – Wednesday, May 11, 10:30 am

☐ VI: Anti-Corruption Case Study:  
Contracting with Third Parties ...  
☐ VII: New Marketplace Case Study ...  
☐ VIII: Data Privacy Case Study ...  
☐ IX: Implementation of  
Compliance Programs across  
Different Countries ...  
☐ X: Using Predictive Analytics ...

#### ROUND III – Wednesday, May 11, 4:45 pm

☐ XI: Advanced Issues in  
Third Party Relationships ...  
☐ XII: New Ethics-Based Approaches ...  
☐ XIII: Medical Devices ...  
☐ XIV: R&D Compliance ...  
☐ XV: Advanced Issues In  
Applying Analytics ...

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\*\*\* To qualify for the ETHICS/PCF/IFPMA/EFPIA/PhRMAG/OPPI/USIBC member rate an individual must be an individual member or an employee of a member company of the International Society of Healthcare Ethics and Compliance Professionals (ethics), the Pharmaceutical Compliance Forum (PCF), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG) or the Organization of Pharmaceutical Producers of India (OPPI) or the US India Business Council (USIBC).

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Registration (whether online or by this form) constitutes a contract and all of these terms and conditions are binding on the parties. In particular, these terms and conditions shall apply in the case of any credit/debit card dispute. For Webcast and onsite registrants there will be no refunds for "no-shows" or cancellations.

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