May 5 – 7, 2014
Conrad Dubai
Dubai, United Arab Emirates

THE CONGRESS WILL FEATURE:
• EU Compliance Developments with Special Reports from CEE, MEA and India,
• A Focus on new Pharma Business Models Resulting in new Compliance and Ethics Challenges,
• An IFPMA Code Workshop and Ethical Promotion Roundtable on Sunday, May 4, 2014,
• And a Middle East/Africa (MEA) Regional Compliance Roundtable on the Morning of Monday, May 5, 2014 — Sponsored by IFPMA and Pharmaceutical Research and Manufacturers Association, Gulf (PHRMA/G)

THE FOLLOWING PLENARY SESSIONS:
• Congress Vision and Overview
• MEA Compliance Best Practices Overview
• India Compliance Best Practices Overview
• Global Transparency Regulatory Update Roundtable
• Communicating with Health Care Professionals re Participation in Transparency Programs
• The Perspectives of Leading NGOS re Pharma Ethical and Compliance Regimes
• Medical Device Compliance and Ethics Issues Update
• Emerging Compliance Issue: R&D, Clinical Trials, Post Marketing Studies and Publications
• Emerging Compliance: Market Access, Pricing, Reimbursement and Tendering
• Emerging Compliance Issue: Medical Education and the Thin Line between Information and Promotion
• Roundtable on Current Challenges and New National Anticorruption Initiatives
• The Role of Ethics in the Compliance Decision Making Process
• The Worldwide Enforcement Environment for Pharma and Medical Devices
• Transforming the Compliance Profession
• Global Compliance Code Update

AND THE FOLLOWING MINI-SUMMITS:
• Training on Compliance and Ethics Basics I
• Annual MEA Compliance and Ethics Update
• Global Compliance Auditing and Monitoring Best Practices
• R&D, Clinical Trials, Transparency, Post Marketing Studies and Publications
• Advanced Issues in Global Transparency, Disclosure and Aggregate Spend Compliance
• Training on Compliance and Ethics Basics II
• Indian Compliance Best Practices Roundtable
• Medical Education and the Thin Line between Information and Promotion
• Global Fair Market Value Update
• Congresses and the Realities of Cross-border Confluence
• Training on Compliance and Ethics Basics III
• Annual Central and Eastern Europe Compliance Update
• Lessons from the Global Medical Device Sector Compliance Issues
• Advanced Issues in Global Anticorruption Compliance
• Public Procurement, Tendering, Reimbursement and Pricing Update
• Managing the Compliance Function being both Small and Global
• Turkish Compliance Roundtable
• Using Data Analytics and Going Beyond Policy Compliance
• A Sustainable Approach to Meet EFPIA Transparency Requirements

CONTINUING EDUCATION CREDITS:
Compliance Professionals: Approved for up to 18.4 Compliance Certification Board CCB Credits.
Accounting Professionals: Approved for up to 19 NASBE CPE credits
Attorneys: The Congress is currently pending approval to offer California, Pennsylvania and Texas MCLE Credit.
The first international Pharmaceutical Compliance Congress and Best Practices Forum was held in Brussels 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 mainly developed by company compliance professionals around topics that they wanted to know more about, which is one of the great strengths of these conferences and continues to be one of their key features.

In addition to Brussels, other international conferences have been held in Paris (2008), Rome (2009), Berlin (2010), Istanbul (2011), Budapest (2012) and Madrid (2013). Over the years the international conference agendas have developed to focus particular streams on the European Union (EU), Central and Eastern Europe (CEE), and Middle East and Africa (MEA), in addition to plenary sessions on global topics. The 2014 conference continues this trend.

In 2014 the Eighth International Pharmaceutical Compliance Congress and Best Practices Forum will address the leading pharmaceutical and medical device ethics and compliance issues in the European Union (EU) and include updates from Central and Eastern Europe (CEE), the Middle East and Africa (MEA) and India. The Congress will focus on the following New Business Models and New Compliance Challenges:

- **Changing Business Models:**
  - Context:
    - Rising Costs
    - Decline of Blockbuster Model
    - Rise of Specialty Care/Biologics
  - Industry Trends:
    - Consolidation
    - Patent Cliff
    - Mature Markets
    - Growth of Emerging Markets
    - Diversification into Diagnostics and Devices, Generics and Consumer Health
  - More Partnerships, Collaborations, and Licensing Agreements
  - Old Model Centered on Company/HCP Relationship
  - New Model in US; ACA; Increased Governmental Funding and Negotiations with Insurers
  - New Model Globally; Negotiation with Government
  - Emerging of Comparative Effectiveness Research

- **New Ethics and Compliance Issues Arise around:**
  - Market Access; Affordability; Infrastructure and Knowledge in Emerging Markets; Limiting Health Care Systems
  - Managing Third Party Relations; Increased Risk; Less Transparency
  - Pricing and Reimbursement; Conditional upon Post Marketing Confirmation of Effectiveness
  - Tendering
  - R&D; Clinical Trials; Publications
  - Medical Education
  - New National Anticorruption Initiatives
  - Proliferation of Transparency Initiatives
  - The Role of Compliance Codes

In 2013 the new International Society of Healthcare Ethics and Compliance Professionals (ethics) has become the Congress sponsor and the Pharmaceutical Compliance Forum (PCF) has become the Congress 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),** www.pharmacomplianceforum.org, 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.

**REGISTRATION DISCOUNTS AVAILABLE TO ASSOCIATION MEMBERS:**
- International Society of Healthcare Ethics and Compliance Professionals (ethics)
- Pharmaceutical Compliance Forum (PCF)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Pharmaceutical Research and Manufacturers Association, Gulf (PhRMA)
- Organization of Pharmaceutical Producers of India (OPPI)
- US India Business Council (USIBC)

**PARTICIANTON OPTIONS**

**TRADITIONAL ONSITE ATTENDANCE**

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

**PROS:**
- Subject matter immersion;
- Professional networking opportunities;
- Faculty interaction.

**LIVE AND ARCHIVED INTERNET ATTENDANCE**

Watch the conference in live streaming video over the Internet and at your convenience at any time 24/7 for six months following the event. The archived conference includes speaker videos and coordinated PowerPoint presentations.

**PROS:**
- Live digital feed and 24/7 Internet access for the next six months; accessible in the office, at home or anywhere worldwide with Internet access; avoid travel expense and hassle; no time away from the office.
The International Pharma Congress will be preceded by two preconference events: IFPMA CODE WORKSHOP AND ETHICAL PROMOTION ROUNDTABLE and IFPMA/PhRMA MEA COMPLIANCE ROUNDTABLE. Please see insert for more information.

MONDAY, MAY 5, 2014

INTERNATIONAL PHARMA CONGRESS DAY I: OPENING PLENARY SESSION — NEW BUSINESS MODELS DRIVING NEW ETHICS AND COMPLIANCE CHALLENGES

1:00 pm Welcome
Nabil Daoud, MA, Vice President and Area Director, TMEA-CIS, Eli Lilly; Chair, MEA Regional Ethics Group (LERB), Dubai, United Arab Emirates

1:10 pm International Pharma Congress Vision and Overview: New Business Models and New Compliance Challenges

Changing Business Models:
- Context:
  - Rising Costs
  - Decline of Blockbuster Model
  - Rise of Specialty Care/Biologics
- Industry Trends:
  - Consolidation
  - Patent Cliff
  - Mature Markets
  - Growth of Emerging Markets
  - Diversification into Diagnostics and Devices, Generics and Consumer Health
  - More Partnerships, Collaborations, and Licensing Agreements
- Old Model Centered on Company/HCP Relationship
- New Model in US: ACA; Increased Governmental Funding and Negotiations with Insurers
- New Model Globally: Negotiation with Government
- Emerging of Comparative Effectiveness Research

New Ethics and Compliance Issues Arise around:
- Market Access; Affordability; Infrastructure and Knowledge in Emerging Markets; Limiting Health Care Systems
- Managing Third Party Relationships; Increased Risk; Less Transparency
- Pricing and Reimbursement; Conditional upon Post Marketing Confirmation of Effectiveness
- Tendering
- R&D; Clinical Trials; Publications
- Medical Education
- New National Anticorruption Initiatives
- Proliferation of Transparency Initiatives
- The Role of Compliance Codes

Overview
Brian Riewerts, Principal, Global Governance, Risk and Compliance Leader, Pharmaceutical and Life Sciences Advisory, PwC, Baltimore, MD, USA

Commentary
Ann Beasley Bacon, Senior Vice President and Chief Compliance Officer, Biogen Idec; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Zug, Switzerland (Co-chair)

Dr. Michael Bartke, Director, Compliance Management, DAICHI SANKYO EUROPE GmbH; Co-chair, EFPIA Compliance Workgroup, Munich, Germany (Co-chair)

Dominique Laymand, Vice President, Compliance and Ethics EMEA, (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb; President, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Paris, France (Co-chair)

Roeland Van Aelst, Vice President, Health Care Compliance, Medical Devices and Diagnostics, EMEA-C, HCB&P, Johnson & Johnson; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics); Chairman, EUCOMED Compliance Network, Brussels, Belgium (Co-chair)

Nabil Daoud, MA, Vice President and Area Director, TMEA-CIS, Eli Lilly; Chair, MEA Regional Ethics Group (LERB), Dubai, United Arab Emirates

2:15 pm MEA Compliance Best Practices Overview

(For greater detail please attend related Mini Summit II.)

Nabil Daoud, MA, Vice President and Area Director, TMEA-CIS, Eli Lilly; Chair, MEA Regional Ethics Group (LERB), Dubai, United Arab Emirates

2:45 pm India Compliance Best Practices Overview

(For greater detail please attend related Mini Summit VII.)

Lawrence Ganti, MBA, Country Director and General Manager, India, Merck Serono; Vice President and Chair, Working Group on Ethics and Compliance, Organization of Pharmaceutical Producers of India (OPPI), Mumbai, India

3:15 pm Break

3:45 pm Global Transparency Regulatory Update Roundtable (For greater detail please attend related Mini Summit V.)

EFFIA and EU Updates

EFPIA Code Update with Brief Reports on Austria, Belgium, Switzerland and Turkey

Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA); Former Director General, Lif Sweden, Brussels, Belgium

Carsten Blaesberg, Chief Consultant, LIF Denmark, The Danish Association of the Pharmaceutical Industry, Copenhagen, Denmark

France

Julie Bonhomme, Esq., Legal and Compliance Manager, Legal and Compliance Department, LEEM, Paris, France

Ingrid Gallies, LLM, PhD, Permanent Secretary of the CODEEM (the ethics committee of the pharmaceutical industry) French Code Authority, Leem, Paris, France

Germany

Holger Diener, PhD, Managing Director, Association of Voluntary Self-Regulation for the Pharmaceutical Industry (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.), Berlin, Germany

Spain

Jose F. Zamarriego Izquierdo, Director, Unidad de Supervision Deontologica, FARMAININDUSTRIA, Madrid, Spain

United Kingdom

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

Regional Reports: US Sunshine Act Update and Brief Reports on Asia Pacific and Latin American Transparency Initiatives

Evelyne Lemaire, Director, Global Pharmaceutical and Life Sciences, PwC, LLP, Zurich, Switzerland

Moderator
Diva Duong, Vice President Compliance EMEA, Cegedim Relationship Management, Paris, France
5:30 pm Communicating with Health Care Professionals regarding Participation in Transparency Programs

Michel Ballieu, Chief Executive Officer, European Cancer Organisation, Brussels, Belgium

Isabel Bardinet, Chief Executive Officer, European Society of Cardiology; Former Director and General Manager at SOCFI (Société d’Organisation de Congrès Français et Internationaux), Sophia Antipolis, France

Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA); Former Director General, LIF Sweden, Brussels, Belgium

Carin R. Smand, MSc, Managing Director, European Hematology Association, The Hague, The Netherlands

Michael Bartke, PhD, Director, Compliance Management, Daiichi Sankyo Europe GmbH; Co-chair, EFPIA Compliance Workgroup, Munich, Germany (Moderator)

6:30 pm ADJOURNMENT AND NETWORKING RECEPTION

TUESDAY, MAY 6, 2014

7:30 am Registration Commences

DAY II: MORNING PLENARY SESSION

8:00 am Co Chair Welcome and Overview

8:15 am The Perspectives of Leading NGOs regarding Appropriate Ethical and Compliance Regimes for the Global Pharmaceutical Sector

Jermyn P. Brooks, Board Member and Chair, Business Advisory Board, Transparency International; Chair, 10th Principle Working Group, United Nations Global Compact; Independent Chair, Global Network Initiative, Frankfurt Am Main, Germany

Prof. Dr. iur. Mark Pieth, Professor of Criminal Law and Criminology, University of Basel; Former Head of Section, Economic and Organised Crime, Swiss Federal Office of Justice; Former Chair, OECD Working Group on Bribery in International Business Transactions, Basel, Switzerland

Debra Christenson Forster, Esq., Global Compliance Officer, Novartis Pharma AG; Former Executive Director, Marketing and Sales Compliance, Boehringer Ingelheim, Basel, Switzerland (Moderator)

9:30 am Medical Device Compliance and Ethics Issues Update

(For greater detail please attend related Mini Summit III.)
Christine Sainvil, Compliance Officer, EthicalMedTech, Brussels, Belgium
Roeland Van Aelst, Vice President, Health Care Compliance, Medical Devices and Diagnostics, EMEA – C, HCC&P, Johnson & Johnson; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics); Chairman, EUcomed Compliance Network, Brussels, Belgium

10:00 am Break

10:30 am Emerging Compliance Issue Overviews

- R&D, Clinical Trials, Post Marketing Studies and Publications
  (For greater detail please attend related Mini Summit IV.)
  Daniel A. Kravos, Esq., Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC

- Market Access, Pricing, Reimbursement and Tendering
  (For greater detail please attend related Mini Summit XV.)
  Hein van den Bos, Esq., Counsel, Hogan Lovells International LLP, Amsterdam, Netherlands

- Medical Education and the Thin Line between Information and Promotion (US vs. EU Approaches)
  (For greater detail please attend related Mini Summit XIX.)
  Marc Eigner, MS, MBA, Partner and Co-founder, Polaris, New York, NY, USA

11:45 am Roundtable on Current Challenges and New National Anticorruption Initiatives

(For greater detail please attend related Mini Summit VIII.)
Gary F. Giampetruzzi, Esq., Vice President and Assistant General Counsel and Head of Government Investigations, Pfizer Inc., New York, NY, USA

Vivian Robinson, Esq., Partner, McGuireWoods; 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

Joseph B. Tompkins, Jr., Partner, Sidney Austin LLP; Former Deputy Chief of the Fraud Section, Criminal Division, United States Department of Justice, Washington, DC, USA

Ted Acosta, Esq., Principal, Fraud Investigation & Dispute Services, EY; Former Senior Counsel, Office of Inspector General, United States Department of Health and Human Services, New York, NY, USA and Paris, France (Moderator)

12:45 pm NETWORKING LUNCHEON

HOTEL INFORMATION/RESERVATIONS
The Conrad Dubai is the official hotel for the Eighth International Pharmaceutical Compliance Congress. A special group rate of AED 1,190.00 single/double per night (plus tax) has been arranged for Congress Attendees. Reservations can be made by calling the hotel at +971 4 444 7444 and asking for reservations. Please refer to the International Pharmaceutical Compliance Congress, Group Code: GINTA to receive the group rate. Information for making a reservation online can be found on the conference website at www.InternationalPharmaCongress.com at the Travel/Hotel page. Please refer to the International Pharmaceutical Compliance Congress/ May 5 to receive the group rate.

Reservations at the group rate will be accepted while rooms are available or until the cut-off date of Friday, April 4, 2014. After this, reservations will be accepted on a space-available basis at the prevailing rate.

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DAILY MINI SUMMITS

MINI SUMMIT I: TRAINING ON COMPLIANCE AND ETHICS BASICS — PROGRAM BASICS
1:45 pm Introductions, Panel Discussion and Q&A
- The Basics of a Compliance Program: The Global Standard for Effective Programs
- The Role of Values Based Ethics in a Compliance Program
- The Role of Governance, Decision Making and Escalation
- The Roles and Responsibilities of the Compliance Officer

Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK (Co-moderator)
Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA (Co-moderator)
Piergiorgio Pepe, LLB, LLM, Office of Ethics and Compliance Regional Director, Eastern Europe-Middle East and Africa, AbbVie Pharmaceuticals Europe HQ, Rungis, France (Co-moderator)

3:00 pm Transition Break

MINI SUMMIT II: ANNUAL MEA COMPLIANCE AND ETHICS UPDATE
1:45 pm Introductions, Panel Discussion and Q&A
Joe Henein, President and Chief Executive Officer, NewBridge Pharmaceuticals; Former Regional Managing Director, Middle East and North Africa, Wyeth Pharmaceuticals, Dubai, United Arab Emirates
Saad Fahmy, Compliance Director, Middle East and Pakistan, Sanofi; Former Compliance Officer (Gulf, Saudi Arabia and Developing Markets), Merck, Dubai, United Arab Emirates
Pascale Feghal, Ethics and Compliance Director, Middle East and Egypt, Eli Lilly, Beirut, Lebanon
Meltem Ozker Gunduz, Legal Affairs and Compliance Director, Business Area Near East, Novo Nordisk, Istanbul, Turkey
Minal Patel, Compliance Officer, Pharmaceuticals and Consumer, South Africa and Sub Saharan Africa, Johnson & Johnson, Johannesburg Area, South Africa
Tahan (Tom) A. Thraya, Esq., Partner, Baker & McKenzie LLP, Abu Dhabi, UAE
Laura Nassar, Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon (Moderator)

3:00 pm Transition Break

MINI SUMMIT III: LESSONS FROM GLOBAL COMPLIANCE ISSUES AND INITIATIVES IN THE MEDICAL DEVICE SECTOR
1:45 pm Introductions, Panel Discussion and Q&A
Christine Sainvil, Compliance Officer, EthicalMedTech, Brussels, Belgium
Peter Diener, Esq., Partner, Clifford Chance, Düsseldorf, Germany
Roeland Van Aelst, Vice President, Health Care Compliance, Medical Devices and Diagnostics EMEA-C, HCC&IP, Johnson & Johnson; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics); Chairman, EUCOMED Compliance Network, Brussels, Belgium
Elisabethann Wright, Esq., Partner, Hogan Lovells, Former Senior Legal Officer and Hearing Officer, EFTA Surveillance Authority, Brussels, Belgium (Moderator)

3:00 pm Adjournment

MINI SUMMIT IV: R&D, CLINICAL TRIALS, TRANSPARENCY, POST MARKETING STUDIES AND PUBLICATIONS
1:45 pm Introductions, Panel Discussion and Q&A
Yogesh Bahl, MBA, Life Sciences Practice Lead, Financial Advisory Services, AlixPartners LLP, New York, NY
Kris L. Curry, Principal, Fraud Investigation & Dispute Services, EY, Philadelphia, PA, USA

Jade L. Shields, Chief Compliance Officer and Associate Vice President, Ferring Pharmaceuticals, Parsippany, NJ, USA
Magalie Treguer, Esq., Senior Director, Corporate Compliance and Regional Compliance Officer for Europe and Canada, Biogen Idec, International GmbH, Zürich, Switzerland
Daniel A. Kracov, Esq., Partner and Head, FDA and Healthcare Practice, Arnold & Porter, Washington, DC, USA (Moderator)

3:00 pm Transition Break

MINI SUMMIT V: ADVANCED ISSUES IN GLOBAL TRANSPARENCY, DISCLOSURE AND AGGREGATE SPEND COMPLIANCE
1:45 pm Introductions, Discussion and Q&A
George Fife, Executive Director, EMEA Compliance and Ethics, Bristol-Myers Squibb, Paris, France
Dr. Ima Parrondo, Health Care Compliance Lead Officer, Pharmaceuticals, EMEA-C, HCC&IP, Johnson & Johnson, Madrid, Spain
Dr. Gudula Petersen, Chief Compliance Officer, Europe and Australia, Grunenthal Pharma GmbH & Co. KG, Dortmund, Germany
Brian Sharkey, Esq., Counsel, Porzio, Bromberg & Newman; Director of Compliance and Legal Affairs, Porzio Governmental Affairs LLC, Morristown, NJ, USA (Moderator)
Christine Bradshaw, Esq., Counsel, Porzio, Bromberg & Newman; Director, Regulatory and Compliance Services, Porzio Life Sciences LLC, Morristown, NJ, USA (Moderator)

3:00 pm Transition Break

MINI SUMMIT VI: TRAINING ON COMPLIANCE AND ETHICS BASICS — ADDRESSING CORE COMPLIANCE RISKS
1:45 pm Introductions, Panel Discussion and Q&A
- The Basics of Anticorruption
- The Basics of Disclosure/Transparency
- The Basics of Pricing, Reimbursement Tendering and Public Procurement
- The Basics of Data Protection

Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK (Co-moderator)
Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA (Co-moderator)
Laura Nassar, Regional Pharma HCC Officer Emerging Markets, Johnson & Johnson, Beirut, Lebanon (Co-moderator)

4:30 pm Transition Break

MINI SUMMIT VII: INDIAN COMPLIANCE BEST PRACTICES ROUNDTABLE
3:15 pm Introductions, Panel Discussion and Q&A
Lawrence Ganti, MBA, Country Director and General Manager, India, Merck Serono; Vice President and Chair, Working Group on Ethics and Compliance, Organization of Pharmaceuticalal Producers of India (OPPI), Mumbai, India
Rajiv Malhotra, Senior Manager Compliance, Biogen Idec; Former Ethics and Compliance Officer, Eli Lilly and Company (India) Pvt Ltd., Gurgaon, India
Sandeep Seth, LLB, Director, Compliance, MSD Pharmaceuticals Pvt. Ltd. (Merck), Mumbai, India
Ramesh Varadarajan, Local Compliance Officer, AstraZeneca Pharma India Ltd., Bangalore, India
Yogesh Bahl, MBA, Life Sciences Practice Lead, Financial Advisory Services, AlixPartners LLP, New York, NY (Moderator)

4:30 pm Transition Break
MINI SUMMIT VIII: ADVANCED ISSUES IN GLOBAL ANTICORRUPTION COMPLIANCE

3:15 pm  Introductions, Panel Discussion and Q&A
Karl Buch, Esq., Assistant General Counsel, Pfizer, New York, NY, USA
Vivian Robinson, Esq., Partner, McGuire Woods; Former General Counsel of the UK Serious Fraud Office; Former Head, QEB Hollis Whithman Chambers; Recorder of the Crown Court and Treasurer of Inner Temple, London, UK
Glenn T. Ware, JD, PPM, Principal, PwC; Former Chief Investigative Counselor, Institutional Integrity (anti-corruption enforcement), World Bank Group, McLean, VA, USA
Joseph B. Tompkins, Jr., Partner, Sidley Austin LLP; Former Deputy Chief of the Fraud Section, Criminal Division, United States Department of Justice, Washington, DC, USA (Moderator)

4:30 pm  Adjournment

MINI SUMMIT IX: GLOBAL COMPLIANCE AUDITING AND MONITORING BEST PRACTICES

3:15 pm  Introductions, Panel Discussion and Q&A
Peter Dieners, Esq., Partner, Clifford Chance, Düsseldorf, Germany
Liz MacGillivray, Compliance Director, Anti-Bribery, Country Support and Monitoring, Group Integrity and Compliance, Novartis International AG, Basel, Switzerland
Michele Tagliaferri, Esq., Partner, Sidley Austin LLP, Brussels, Belgium
Melissa Myatt, Director, Fraud Investigation & Dispute Services, EY, London, UK (Moderator)

4:30 pm  Transition Break

MINI SUMMIT X: CONGRESSES AND THE REALITIES OF CROSS-BORDER CONFLUENCE

• Practicalities of Cross-border Confluence,
• Complexities of Territorial Issues vs. Global Activities, and
• Mixing IFPMA/EFPIA Codes with Congress and Society Rules

3:15 pm  Introductions, Panel Discussion and Q&A
Piergiorgio Pepe, LLB, LLM, Office of Ethics and Compliance Regional Director, Eastern Europe-Middle East and Africa, AbbVie Pharmaceuticals Europe HQ, Rungis, France
Christian-Claus Roth, Head of Congresses and Conventions, Novartis Pharma; Co-President, International Pharmaceutical Congress Advisory Association (IPCAA), Berne, Switzerland
Jeff Rosenbaum, MBA, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Executive Director, Global Head of Ethics and Compliance, Novartis Oncology, Boston, MA, USA
Christine Sainvil, Compliance Officer, EthicalMedTech, Brussels, Belgium
Jose F. Zamarriego Izquierdo, Director, Spanish Code Surveillance Unit, FARMINDUSTRIA, Madrid, Spain
Ann Beasley Bacon, Senior Vice President and Chief Compliance Officer, Biogen Idec; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Zug, Switzerland (Moderator)

4:30 pm  Transition Break

MINI SUMMIT XI: TRAINING ON COMPLIANCE AND ETHICS BASICS — EVOLVING ISSUES, RISING EXPECTATIONS

4:45 pm  Introductions, Panel Discussion and Q&A
• Conducting Effective Third-Party Due Diligence
• Developing Effective Commercial/Medical Boundaries in Interactions with HCPS
• The Role of Analytics in Monitoring and Program Oversight
• Building Effective Relationships with the Business
Sue Egan, Director and Principal Consultant, Sue Egan Associates; Former Vice President Compliance, AstraZeneca, Great Missenden, Buckinghamshire, UK (Co-moderator)
Keith M. Korenchuk, JD, MPH, Partner, Arnold & Porter LLP, Washington, DC, USA (Co-moderator)
Pascale Feghali, Ethics and Compliance Director, Middle East and Egypt, Eli Lilly, Beirut, Lebanon (Co-moderator)

6:00 pm  Adjournment

MINI SUMMIT XII: ANNUAL CENTRAL AND EASTERN EUROPE COMPLIANCE UPDATE

4:45 pm  Introductions, Panel Discussion and Q&A
Rozalia Gyuial, Regional Compliance Manager, AbbVie; Former Regulatory Manager, Pfizer, Budapest, Hungary
Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia
Mariusz Witalis, CFE, CIA, Partner, Fraud Investigation & Dispute Services, EY, Warsaw, Poland (Moderator)

6:00 pm  Adjournment

MINI SUMMIT XIII: GLOBAL FAIR MARKET VALUE UPDATE

4:45 pm  Introductions, Panel Discussion and Q&A
Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY, USA
Swee Kheng Khor, MD, Associate Director, Office of Ethics and Compliance, Middle East and Pakistan, AbbVie BioPharmaceutical GmbH, Dubai, United Arab Emirates
Dr. Marcel Koerting, LLM, Senior Legal and Compliance Counsel, Novo Nordisk Health Care AG, Zurich, Switzerland
Dr. Gudula Petersen, Chief Compliance Officer Europe and Australia, Grunenthal Pharma GmbH & Co. KG, Dortmund, Germany
Marc Eigner, Partner and Co-founder, Polaris, New York, NY, USA (Moderator)

6:00 pm  Adjournment

MINI SUMMIT XIV: CONSIDERATIONS FOR IMPLEMENTING A SUSTAINABLE APPROACH TO MEET EFPIA TRANSPARENCY REQUIREMENTS

4:45 pm  Introductions, Panel Discussion and Q&A
Peter Dieners, Esq., Partner, Clifford Chance, Düsseldorf, Germany
David Wysocky, MBA, Partner, PwC, New York, NY (Moderator)

6:00 pm  Adjournment

MINI SUMMIT XV: EMERGING COMPLIANCE ISSUE: PUBLIC PROCUREMENT, TENDERING, REIMBURSEMENT AND PHARMA PRICING UPDATE

4:45 pm  Introductions, Panel Discussion and Q&A
Sacha D’Ecclesiis, Esq., Senior Associate, Hogan Lovells, Rome, Italy
Barbara Levi Mager, JD, LLM (Invited), Global Head, Legal TechOps, Primary Care, Established Medicines, Novartis Pharma AG, Basel Area, Switzerland
Nathalie Raynaud, Corporate Compliance Director, Global Compliance and Business Integrity Department, Sanofi, Paris, France
Hein van den Bos, Esq., Counsel, Hogan Lovells International LLP, Amsterdam, Netherlands (Moderator)

6:00 pm  Adjournment
DAY III: MORNING PLENARY SESSION

8:00 am
Co Chair Welcome and Introductions

8:15 am
The Role of Ethics in the Compliance Decision Making Process
Jean-Claude Najar, LLM, Member, Curtis, Mallet-Prevost, Colt & Mosle LLP; Lecturer, Sciences Po Law School and HEAD Law School; Former General Counsel EMEA, GE Medical Systems (now GE Healthcare), Paris, France

8:45 am
Evaluation of the Worldwide Enforcement Environment for Pharma and Medical Devices
Thomas A. Gunning, Esq., Senior Vice President and General Counsel, Prescription Medicines Division, Merck KGaA, Darmstadt, Germany
Michael K. Loucks, Esq., Partner, Skadden Arps LLP; Former First Assistant US Attorney, US Attorney's Office for the District of Massachusetts, Washington, DC, USA

9:15 am
Update on the Role of the International Society of Healthcare Ethics and Compliance Professionals (ETHICS) in Transforming the Compliance Profession
Arthur Muratyan, Esq., Secretary General, International Society of Healthcare Ethics and Compliance Professionals (ETHICS); Former Vice President-Head of Legal Corporate, and Global Compliance Officer, Sanofi, Paris, France

9:45 am
Global Compliance Code Update
IFPMA Code
Tamara Music, Manager, Influenza Vaccines and Code Compliance, IFPMA, Geneva, Switzerland
EFPIA Code
Dominique Laymand, Vice President, Compliance and Ethics EMEA, (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb; President, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS), Paris, France

Russian and Eastern European Codes
Paul J. Melling, Esq., Founding Partner, Baker & McKenzie - CIS, Limited, Moscow, Russia

MEA Codes
Laura Nassar, Regional Pharma HCC Officer, Emerging Markets, Johnson & Johnson, Beirut, Lebanon

Turkish Code Update
Bulent Becan, Managing Partner, Atuva Management Consultancy and Trade Ltd.; Consultant in Ethics Issues, Turkish Research Based Pharmaceutical Companies Association (AIFD), Istanbul, Turkey

India Code Update
Rajiv Malhotra, Senior Manager, Compliance, Biogen Idec; Former Ethics and Compliance Officer, Eli Lilly and Company (India) Pvt Ltd., Gurgaon, India

Asia Pacific Codes
Abdul Luqehshi, MBA, Vice President, Health Care Compliance, Johnson & Johnson; Former Co-chair, Asia Pacific Pharma Congress, London, UK

Latin American Codes
Clivetty Martinez, PhD (Invited), Regional Vice President, Latin America, Office of Healthcare Compliance and Privacy, Johnson & Johnson International, Inc.; Chair, Latin American Ethics and Compliance Network, Miami, FL, USA

Moderator
Antoinette Gutierrez-Crespin, Partner, Fraud Investigation & Dispute Services, EY, Paris, France

11:00 am
Break
MINI SUMMIT XVI: PRACTICAL APPROACHES TO MANAGING THE COMPLIANCE FUNCTION BEING BOTH SMALL AND GLOBAL

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

Gary F. Giampetruzzi, Esq., Vice President and Assistant General Counsel and Head of Government Investigations, Pfizer Inc., New York, NY, USA

Jeff Rosenbaum, MBA, Vice President, Chief Compliance Officer, Vertex Pharmaceuticals; Former Executive Director, Global Head of Ethics and Compliance, Novartis Oncology, Boston, MA, USA

Timothy S. Ayers, Esq., Principal, Porzio, Bromberg & Newman, PC; Vice President, Porzio Life Sciences; Former Vice President and Chief Compliance Officer, Dendreon Corporation, Morristown, NJ, USA (Moderator)

12:30 pm ADJOURNMENT

MINI SUMMIT XVII: TURKISH COMPLIANCE ROUNDTABLE

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

Hulya Baran, Director, Ethics and Compliance TMEA – CIS, Eli Lilly and Company, Istanbul, Turkey

Rıfat Bozacioglu, Deputy Compliance Officer, Compliance Business Partner, MEA Pharma Compliance, GlaxoSmithKline, Istanbul, Turkey

Meltem Ozker Gunduz, Legal Affairs and Compliance Director, Business Area Near East, Novo Nordisk, Istanbul, Turkey

Jean-Claude Najar, LLM, Member, Curtis, Mallet-Prevost, Colt & Mosle LLP; Lecturer, Sciences Po Law School and HEAD Law School; Former General Counsel EMEA, GE Medical Systems (now GE Healthcare), Paris, France

Bulent Becan, Managing Partner, Atuva Management Consultancy and Trade Ltd.; Consultant in Ethics Issues, Turkish Research Based Pharmaceutical Companies Association (AIFD), Istanbul, Turkey (Moderator)

12:30 pm ADJOURNMENT

MINI SUMMIT XVIII: ADVANCED ISSUES IN COMPLIANCE MONITORING: USING DATA ANALYTICS AND GOING BEYOND POLICY COMPLIANCE

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

Vincent M. Walden, CFE, CITP, Partner, Fraud Investigation & Dispute Services, EY, New York, NY, USA

12:30 pm ADJOURNMENT

MINI SUMMIT XIX: MEDICAL EDUCATION AND THE THIN LINE BETWEEN INFORMATION AND PROMOTION

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

Marc Eigner, MS, MBA, Partner and Co-founder, Polaris, New York, NY, USA

Swee Kheng Khor, MD, Associate Director, Office of Ethics and Compliance, Middle East and Pakistan, AbbVie BioPharmaceutical GmbH, Dubai, United Arab Emirates

Dr. Ima Parrondo, Health Care Compliance Officer, EMEA Pharmaceutical Sector, Johnson & Johnson, Madrid, Spain

Peter Dieners, Esq., Partner, Clifford Chance, Düsseldorf, Germany (Moderator)

12:30 pm ADJOURNMENT

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July 29 – 31 • Mexico City, Mexico
www.LatinAmericanPharmaCongress.com


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Felipe Coronel, Esq., Head, Legal and Compliance Latin America, Grünenthal, Panama City, Panama
Clivetty Martinez, PhD, Regional Vice President, Latin America, Office of Healthcare Compliance and Privacy, Johnson & Johnson International, Inc.; Chair, Latin American Ethics and Compliance Network, Miami, FL, USA

FOURTH ASIA PACIFIC PHARMACEUTICAL COMPLIANCE CONGRESS

September 16 – 18 • Shanghai, China
www.AsianPharmaCongress.com

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Karen Eryou, Director and Head, Quality and Compliance, UCB Pharma – Greater China and SE Asia, Shanghai, China
Gareth Lee, Esq., General Counsel and Head of Compliance, Asia Pacific, Allergan Inc., Singapore
Maria “Maru” Quindimil, MBA, Executive Director, Regional Compliance Officer, Asia Pacific and India, Merck Sharp and Dhome (Asia Ltd.), Manila, Philippines

FIFTEENTH PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS

November 3 – 5 • Washington, DC
www.PharmaCongress.com

SPONSORED BY Pharmaceutical Compliance Forum

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Kelly B. Freeman, PhD, Senior Director, Ethics and Compliance, Eli Lilly and Company, Indianapolis, IN
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REGISTER FOR IFPMA CODE WORKSHOP AND ETHICAL PROMOTION ROUNDTABLE
Sponsored by The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

☐ Sunday, May 4: IFPMA Workshop

Note that this workshop is an independent activity of IFPMA. The Congress is collecting registration fees on behalf of IFPMA. This workshop is open to pharmaceutical industry representatives only, which includes company compliance professionals, in-house counsel and related staff. This session will not be included in the online broadcast and archive.

REGISTER FOR THE MIDDLE EAST/AFRICA (MEA) REGIONAL COMPLIANCE ROUNDTABLE
Sponsored by IFPMA and Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG)

☐ Morning of Monday, May 5: MEA Roundtable

Complimentary — No cost
Note that this workshop is an independent activity of IFPMA and PhRMAG. Attendance is open and complimentary. The Congress is collecting registration information to pass on to IFPMA and PhRMAG. This session will not be included in the online broadcast and archive.

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Onsite conference registration includes onsite attendance, professional networking, and live interaction with the faculty, plus a conference materials CD.

CONFERENCE

Standard Rate:

☐ Through Friday, March 14, 2014

☐ Through Friday, April 11, 2014

☐ After Friday, April 11, 2014

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☐ Through Friday, March 14, 2014*

☐ Through Friday, April 11, 2014*

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☐ Flash Drive ($129 + $30 shipping) €159

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

TUESDAY, MAY 6

ROUND I – 1:45 pm

☐ Training in Compliance & Ethics Basics

☐ Annual MEA/Compliance & Ethics Update

☐ Lessons from the Medical Device Sector

☐ IV & ID, Clinical Trials, Transparency, Post Marketing...

☐ Advanced Issues in Global Transparency...

ROUND II – 3:15 pm

☐ Training in Compliance & Ethics Basics

☐ Indian Compliance...

☐ Advanced Issues in Global Anticorruption Compliance

☐ Global Compliance Auditing & Monitoring Best Practices

☐ Conferences & the Realities of Cross-Border Confluence

ROUND III – 4:45 pm

☐ Training in Compliance & Ethics Basics

☐ Annual Central & Eastern European Compliance Update

☐ Global Fair Market Value Update

☐ Considerations for Implementing a Sustainable Approach...

☐ Emerging Compliance Issues: Public Procurement, Tenders...

WEDNESDAY, MAY 7

ROUND IV – 11:15 am

☐ XP: Practical Approaches to Managing the Compliance Function...

☐ Turkish Compliance Roundtable

☐ Advanced Issues in Compliance Monitoring...

☐ Medical Education & the Thin Line...

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ConfERENCE:

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You may also register online at www.InternationalPharmaCongress.com.

☐ Bank transfer (bank information provided upon receipt of form)

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The Eighth International Pharmaceutical Compliance Congress and Best Practices Forum

May 5 – 7, 2014
Conrad Dubai
Dubai, United Arab Emirates
IFPMA is pleased to organize this workshop in conjunction with the Eighth International Pharmaceutical Compliance Congress, May 5 – 7, 2014: http://www.internationalpharmacongress.com/index.html
IFPMA Code Workshop Registration at: http://www.internationalpharmacongress.com/registration.php

WORKSHOP FEE
• In an effort to cover organizational expenses IFPMA is charging a small fee of €145 per participant.

WORKSHOP AIMS
The workshop has been designed to provide “business case” exposure to individuals responsible:
• for day-to-day commissioning and creation of promotional material and to those writing and approving copy and artwork
• for determining promotional methods including professional representation, hospitality to doctors and the use of audio-visual and related communications technology in the organization of international educational events
The workshop will be based on the global IFPMA Code of Practices (2012) which forms the basis for national codes of practice within the Middle-East and Africa region and world-wide.

WHO SHOULD ATTEND?
• Representatives from biopharmaceutical companies and national pharmaceutical trade associations
• Compliance professionals
• Personnel responsible for the development and certification of promotional materials
• Sales and Marketing representatives
• General Managers
• In-house counsel and other related staff

CAPACITY
• Workshop capacity is limited and registration confirmation will be on a first-come, first-served basis. Therefore, please make sure to register early in order to secure a place in the workshop.

REGISTRATION
• Online registration via the PCF Congress website is now open at: http://www.internationalpharmacongress.com/registration.php
• Registration deadline: May 1. 2014 (since workshop capacity is limited, we encourage early registration to secure a spot).

CERTIFICATE
A certificate of participation will be awarded upon the completion of the workshop.

If you have any questions please contact the IFPMA Secretariat at ccn-registration@ifpma.org

SUNDAY, MAY 4, 2014

8:30 am Welcome and Introduction
Tamara Music, Manager, Influenza Vaccines and Code Compliance, IFPMA, Geneva, Switzerland

8:40 am Setting the Scene — The Future of Marketing, Compliance and Ethics: The Expanding Role of the Compliance Officer
Abdul Luheishi, MBA, Vice President, Health Care Compliance, Johnson & Johnson; Former Co-chair, Asia Pacific Pharma Congress, London, UK

9:15 am The Spirit of the Code: Our Values and Principles
Roeland Van Aelst, Vice President, Health Care Compliance, Medical Devices and Diagnostics, EMEA-C, HCC&P, Johnson & Johnson; Board Member and Co-chair, Strategic Committee, International Society of Healthcare, Ethics and Compliance Professionals (ethics); Chairman, EUROMED Compliance Network, Brussels, Belgium

9:45 am Defining Promotion: Supporting Patient Programs
Heather Simmonds, Director, Prescription Medicines Code of Practice Authority, London, UK

10:30 am Coffee Break

10:45 am Part 1 — Interactions with HCPs: Meetings, Sponsorship and Fees for Service
Cécile Gousset, AVP, Compliance Risk Assessment, Education and Monitoring, Global Compliance, Sanofi, Paris, France

11:00 am Part 2 — Interactions with HCPs: Gifts and Other Items
Dominique Laymand, Vice President, Compliance and Ethics EMEA, (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb; President, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Paris, France

11:30 am Part 2 — Interactions with HCPs: Patient Programs
Dominique Laymand, Vice President, Compliance and Ethics EMEA, (Europe, Middle-East, Africa, Russia and Turkey), Bristol-Myers Squibb; President, International Society of Healthcare, Ethics and Compliance Professionals (ethics), Paris, France

12:00 pm Networking Lunch

1:15 pm Business Simulation Compliance Game: Fees for Service
ISMS

3:00 pm Congress Organization: How to Interact and Practical Cases
Jose F. Zamarriego Izquierdo, Director Unidad de Supervision deontologica, FARMAINDUSTRIA, Madrid, Spain

4:15 pm Thermometer Game: How Hot is this issue?
Jan Oliver Huber, Secretary General, PHARMIG (Association of the Austrian Pharmaceutical Industry); Member, IFPMA Code Compliance Network, Vienna, Austria

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

5:30 pm Interactive Discussion and Q&A
Rıfat Bozacıoglu, Deputy Compliance Officer, Compliance Business Partner, MEA Pharma Compliance, GlaxoSmithKline, Istanbul, Turkey

6:00 pm Adjournment
MONDAY, MAY 5, 2014

7:30 am  Registration Opens

MEA COMPLIANCE ROUNDTABLE

Sponsored by International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG)

8:45 am  Welcome and Introductions

Dr. Yacoub Haddad, Chair, Pharmaceutical Research and Manufacturers Association, Gulf (PhRMAG); Government Affairs Director MEAP Region, Abbvie, Dubai, UAE (Co-moderator)

Tamara Music, Manager, Influenza Vaccines and Code Compliance, IFPMA, Geneva, Switzerland (Co-moderator)

9:00 am  Opening Presentation

Dr. Amin Al Amiri, Assistant Undersecretary, Medical Practice and Licenses, Ministry of Health, UAE, Dubai, UAE

9:15 am  UAE National Code and Government Enforcement of Ethical Promotional Practices

To be Announced

9:30 am  Compliance Case Study: Saudi Arabia, the First MEA Country to Launch a National Code, and the Biggest MEA Market

Abdulrahman Al Sultan, Executive Director of Communication and Awareness, Saudi Food & Drug Authority, Riyadh, Saudi Arabia

10:15 am  Our Ethical Business Practices: IFPMA Code and MEA Code Highlights (Video)

Tamara Music, Manager, Influenza Vaccines and Code Compliance, IFPMA, Geneva, Switzerland

11:00 am  Private/Public Partnership Best Practice: UK ABPI Code

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

11:20 am  Open Discussion

Noon  Adjournment and Lunch on your Own

Held in Conjunction with
THE EIGHTH INTERNATIONAL PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

May 5 – 7, 2014 • Dubai, United Arab Emirates