4th Annual

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CONFERENCE

Pharmacovigilance & RMS Forum

Modernizing Drug Safety

September 27 - 28, 2017 – Washington D.C.

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TECHNOLOGY NETWORKS

Expert Speakers and Panelists

Cheryl Renz
Head of Risk Management, Global Pharmacovigilance
AbbVie

Cristina Damatarca
VP, Medical Affairs and Pharmacovigilance
Agility Clinical

Daniel Naranjo
Associate Medical Director
Takeda

Alexander Kluczka
Global Pharmacovigilance, Head TA Oncology - ICSR Processing
Bayer

Jay Ehrlich
VP, Global Patient Safety, VP, Global Pharmacovigilance and Medical Device Vigilance
Baxter

Debra Feldman
VP, Global Pharmacovigilance and Epidemiology
Bristol-Myers-Squibb

Ruth Namuyinga
Associate Director, Clinical Safety and Pharmacovigilance
Daichii Sankyo

Anupam Agarwal
Global Drug Safety, Pharmacovigilance and RM Executive, former Director of Cardiovascular & Respiratory, Drug Safety and Public Health
former Gilead Sciences

Gary Appio
Executive Director, Benefit Risk Management
Jazz Pharmaceuticals

Judy Hsiung
Senior Medical Director, Head of Safety Sciences
Halozyme

J.-P. Clement
Pharmacovigilance Expert
JP Clement Pharmacovigilance

Sameer Thapar
Assistant Professor & Advisor, Drug Safety and Pharmacovigilance
Rutgers University

Stephen A. Goldman
International Medical Product Safety Consultant and former Medical Director
Medwatch, FDA

Paul Beninger
VP, Global Patient Safety
Sanofi-Genzyme

Shaka Martin
Medical Director Benefit-Risk Management Vaccines
Seqirus – a CSL Company

Mariette Boerstoel-Streefland
SVP, Head of Global Drug Safety
Shire

Veronique Kugener
SVP, Head of Global Pharmacovigilance
Takeda

Donna Valencia
Pharmacovigilance and Medical Affairs
Mesoblast

Jens-Ulrich Stegmann
VP, Head of Clinical Safety and Pharmacovigilance
GSK

Gerrit-Jan Nijveldt
Senior Director Global Regulatory Affairs Labeling
Sanofi

Ed Tucker
SVP Medical Safety, Quality and Compliance
Acerta Pharma

Senior Representative (tbd)
Elsevier

Event Intro

At the 4th Pharmacovigilance and Risk Management Strategies (RMS) Forum, we will offer a broad picture of drug safety priorities across the product lifecycle and look into closing the long-existing loop in pre-marketing and post-marketing reporting. We invite you to explore the newest ways in facilitating modern pharmacovigilance and patient safety in Washington D.C.

This event is set up in an interactive discussion format with attendance of 100+ senior industry practitioners & advisors representing large and most progressive pharmaceutical companies, biotech firms and regulatory bodies. The layout sets up debates on real life practices over 2 intensive days.

Based on several years of experience with this event, we guarantee to provide you in September 2017 with the most up-to-date insight sharing, problem solving and networking opportunities.

Event Features

SPECIAL KEYNOTE:
Drug Safety Priorities Across the Product Lifecycle

20-MINUTE INSIGHT SESSION:
New Final Ruling on Combination Products and Safety Measures

IN-CONFERENCE CASE EXCERCISE:
Using a Hypothetic Drug Development Framework and Facilitating Decision Making

BESPOKE ROUNDTABLE DISCUSSIONS:
More In-depth Knowledge Sharing with Pharmacovigilance Experts

INTERACTIVE GROUP DISCUSSION:
Practical Implications of Safety Governance

HIGH LEVEL NETWORK & ENGAGING PARTICIPATION:
With Senior-Level Safety Decision Makers

Key Topics

- Drug safety across the product lifecycle
- Finalizing the post-marketing reporting rule
- New final ruling on combination products and safety measures
- Using a hypothetical product to demonstrate various benefit-risk activities, their purpose and key outputs
- Labeling as critical part of RMSs
- Different processes on how to handle safety signals
- Modern tech solutions to facilitate better pharmacovigilance
- Political impact on pharmacovigilance regulations under the new administration
- Medical devices vs. drug regulation – the key differences
- The secret of well-implemented partnerships
- Practical ways of organizing safety structures

Who Will Attend

C-Level Executives, EVPs, SVPs, VP, Directors, Heads & Other Senior Level Executives within

- ✓ **Pharmacovigilance**
- ✓ **Drug Safety**
- ✓ **Risk Management**
- ✓ Epidemiology
- ✓ Pharmacoepidemiology
- ✓ Drug / Product Safety
- ✓ Clinical Development
- ✓ Clinical Safety
- ✓ Patient/ Medical Safety
- ✓ Patient Engagement
- ✓ Signal Detection
- ✓ Safety Surveillance
- ✓ Pre- and Post-Marketing Studies
- ✓ Regulatory Affairs
- ✓ Medical Affairs

Advisory Board

DAY 1

September 27, 2017

8:00 Registration and Morning Coffee

8:30 Welcome Note from **Fleming.**

8:35 Opening Remarks from the Conference Chairman

Strengthening Drug Safety Initiatives

8:40 **SPECIAL KEYNOTE: Drug Safety Across the Product Lifecycle**

- Developing a systematic approach to pre-marketing safety assessments
- Enhancing pre-market drug reviews with digital tools
- Post-marketing pharmacovigilance
- Finalizing the post-marketing reporting rule and closing the drug safety loop

(Session reserved for the FDA)

9:10 **20-MINUTE INSIGHT SESSION: New Final Ruling on Combination Products and Safety Measures**

- In 2016 for the first time, a final rule issued by the FDA establishes post-market safety reporting requirements specifically for combination products
- How companies must meet safety requirements in relation to their combination products depending on the category of these products
- Main challenges and practical ways to approach safety measures

Daniel Naranjo, *Associate Medical Director*
Takeda

9:30 **SPOTLIGHT SESSION**

Senior Representative (tbd)
Elsevier

10:10 Networking & Energizer Break

10:50 **SPOTLIGHT SESSION: The Drug Label as a Critical Part of your Risk Management Strategy**

- Why the drug label is a critical risk management document
- Setting the stage for the afternoon: what is labeling's role in signal detection

Debra Feldman, *VP, Global Pharmacovigilance and Epidemiology,* **Bristol-Myers-Squibb**

Benefit-Risk Management, Decision Making and Labeling in RM

11:20 **CASE STUDY PRESENTATION WITH CASE EXERCISE: Benefit-Risk: The Lifecycle Approach**

- How to integrate safety, regulatory and benefit-risk activities to improve patient safety
- Using a process map to display when B/R assessments might be conducted at different time points during the product lifecycle
- Highlight the importance of utilizing the patient perspective in B/R decision making
- **CASE EXERCISE: Benefit-Risk Hypothetic Drug Development**

Cheryl Renz, *Head of Risk Management, Global Pharmacovigilance,* **AbbVie**

12:30 Networking Lunch

2:00 **SPOTLIGHT SESSION: Leveraging Synergies between Quality & Safety**

- How to build a PV group with QA/Compliance embedded into the organization
- Best examples of QA and PV working in alignment to overcome certain issues
- The importance of PV and QA alignment with regards to safety and product quality

Ed Tucker, *SVP Medical Safety, Quality and Compliance,* **Acerta Pharma**

DAY 1

September 27, 2017

Data Sources and Signal Detection Methods

2:30 **Integrating Data Sources into a Comprehensive Signal Detection System**

- Getting the best possible data
- Leveraging data beyond spontaneous reports
- Real world data or big data - What role they play?
- Integrating social media in daily lives of PV scientists

Sameer Thapar, *Assistant Professor & Advisor, Drug Safety and Pharmacovigilance*
Rutgers University

3:00 **SMART PANEL:**
How do Companies Handle Evolving Safety Concerns?

- Organizational processes and procedures on how to handle signals
- Variations of assessment techniques, pros and cons
- Use of standardized tools and systematic methodologies
- The global role of the EU QPPV in safety decisions

Moderated by:
Stephen A. Goldman, *Managing Member*
Stephen A. Goldman Consulting Services, LLC

Panelists:
Sameer Thapar, *Assistant Professor & Advisor, Drug Safety and Pharmacovigilance*
Rutgers University

Anupam Agarwal, *Global Drug Safety, Pharmacovigilance and RM Executive, former Director of Cardiovascular & Respiratory, Drug Safety and Public Health,* **Gilead Sciences**

3:30 Networking Coffee Break

4:00 **INTERACTIVE ROUNDTABLES**

ROUNDTABLE 1: What Matters: The Patients, the Providers, the Technology - Effective Risk Management

Cristina Damatarca, *VP, Medical Affairs and Pharmacovigilance,* **Agility Clinical**

ROUNDTABLE 2: Modernizing REMS – Innovative Approach to Benefit-Risk Management

Gary Appio, *Executive Director, Benefit Risk Management,* **Jazz Pharmaceuticals**

ROUNDTABLE 3: Strategizing Risk Management Plans – New Rules and Priorities

Judy Hsiung, *Senior Medical Director, Head of Safety Sciences,* **Halozyme**

ROUNDTABLE 4: How Safety and Risk Management Impacts Labeling - PV Inspection Impact on Labeling

Gerrit-Jan Nijveldt, *Senior Director Global Regulatory Affairs, Labeling,* **Sanofi**

ROUNDTABLE 5: *to be announced*

ROUNDTABLE 6: *to be announced*

5:40 Closing Remarks from the Conference Chairman

6:00 Speakers and Delegates are cordially invited to attend a Networking Cocktail Reception

Interactive Roundtables

Roundtable 1:

What Matters: The Patients, the Providers, the Technology - Effective Risk Management

Cristina Damatarca
VP, Medical Affairs and Pharmacovigilance
Agility Clinical

Roundtable 2:

Modernizing REMS – Innovative Approach to Benefit-Risk Management

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Roundtable 3:

Strategizing Risk Management Plans – New Rules and Priorities

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Roundtable 4:

How Safety and Risk Management Impacts Labeling - PV Inspection Impact on Labeling

Gerrit-Jan Nijveldt
Senior Director Global Regulatory Affairs, Labeling
Sanofi

Roundtable 5:

to be announced

Roundtable 6:

to be announced

DAY 2

September 28, 2017

8:00 Registration and Morning Coffee

9:00 Recap of Day 1 and Opening Remarks from the Conference Chairman

Current Regulatory Frameworks in Key Markets

9:10 **KICKOFF PANEL:**
The Global Regulatory Environment and Aspects of Harmonization

- Ensuring compliance with national and international premarketing safety and postmarketing pharmacovigilance requirements
- Updates and advances in the regulatory systems of key markets
- How to cope with insufficient regulatory harmonization
- How to keep your safety department's focus and drivers patient-centric

Panelists:

Stephen A. Goldman, *International Medical Product Safety Consultant and former Medical Director,* **Medwatch, FDA**

9:50 **FEATURED PANEL:**
Political Impact on Global PhV Regulations under the New Administration

- Remarks on US regulations and the European perspective – Fearful or fertile ground for pharma?
- Different scenarios and predictions for the future
- Updates on the recently passed 21st Century Cures Act and implications for Regenerative Medicine

Moderated by:
Sameer Thapar, *Assistant Professor & Advisor, Drug Safety and Pharmacovigilance*
Rutgers University
Panelists:

Jens-Ulrich Stegmann, *VP, Head of Clinical Safety and Pharmacovigilance,* **GSK**

Donna Valencia, *Pharmacovigilance and Medical Affairs,* **Mesoblast**

10:30 Networking & Energizer Break

Inspection Readiness

11:00 **SMART PANEL: Creating Strong Compliance Frameworks with a Holistic Approach**

- Monitoring PV compliance – How patient-centric are we? Should PV monitor differently?
- PV inspection readiness: How ready we can be?
- PV compliance: PV is at the center but how it can mobilize internal and external stakeholders?

Moderated by:
Veronique Kugener, *SVP, Head of Global Pharmacovigilance,* **Takeda**

11:40 **SMART PANEL:**
Inspection Observations and Responses

- Pharmacovigilance inspections and their benefits
- Describing the inspection process from different angles
- How to plan and conduct a response to inspection observations
- How to interpret messaging in FDA Letters

Panelists:
Stephen A. Goldman
International Medical Product Safety Consultant and former Medical Director, **Medwatch, FDA**

Medical Device Updates

12:10 **Medical Device Regulation and Safety**

- Clarifying key factors when assessing the benefits and risks of submissions
- Establishing a common understanding on what information informs the benefit-risk assessment of a submission
- Facilitating the incorporation of evidence and knowledge from different domains—clinical, nonclinical and patient—to support a comprehensive, balanced decision-making approach

DAY 2

September 28, 2017

12:50 Networking Lunch

Implications of Safety Governance

2:00 **SPOTLIGHT SESSION: Viewing Partnerships Through A New Lens**

- Lessons learned from a recent outsourcing deal
- Financial, technological and human resources related factors
- Significant benefits of a well-implemented outsourcing
- How to build Safety Management Plans with vendors?

Jay Ehrlich, *VP, Global Patient Safety, VP, Global Pharmacovigilance and Medical Device Vigilance*
Baxter

2:30 **SMART PANEL: Differences in Organizing Safety Structures**

- Recruitment and retention for a global/local talent
- How to meet changing regulations
- Critical aspects of training and knowledge management
- How to ensure that resources are applied where they matter the most

Panelists:

Mariette Boerstoel-Streefland, *Senior Vice President, Head of Global Drug Safety,* **Shire**

Jens-Ulrich Stegmann, *VP, Head of Clinical Safety and Pharmacovigilance,* **GSK**

Jay Ehrlich, *VP, Global Patient Safety, VP, Global Pharmacovigilance and Medical Device Vigilance,* **Baxter**

3:10 **FEATURED GROUP DISCUSSION: Practical Implications of Safety Governance**

In this special final session each participant will be given a note and encouraged to write down challenges and concerns in their organization and post it to the wall we designed. Then participants will be divided in groups. Group discussions will be conducted on the above topic and the session will be concluded with a wrap-up panel.

Moderated by:

J.-P. Clement, *Pharmacovigilance Expert*
JP Clement Pharmacovigilance

4:00 Closing Remarks from the Conference Chairman

4:10 Wrap-Up Session with Farewell Drinks – Informal Open Floor Discussion with Speakers

I would like to thank everyone who has helped with the research and organization of this event - especially the advisory committee and the speakers for their commitment, time and support.

Victoria Lambert, Senior Production Specialist
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Meet Our Expert Advisors And Speakers

Alexander Kluczka, Global Pharmacovigilance, Head TA Oncology - ICSR Processing, Bayer

Dr. Alexander Kluczka is Global Head of ICSR Processing Oncology at Bayer HealthCare, a company managing 500,000 Adverse Event case cycles per year. He leads an integrated team of 80 case processors and evaluators in USA, Germany, Brazil, and India. His organization receives oncology Adverse Event reports from all sources and takes them through global database entry, coding and single case evaluation. He previously led Bayer's global Post-Marketing Study organizations, a safety Risk Management Therapeutic Area and the UK affiliate's Drug Safety department, having started in the company as a safety Risk Management physician. He represented Bayer Pharmacovigilance in several European and US-Health Authority Inspections since the company's very first MHRA inspection in 2005. Alexander graduated from medical school and earned a PhD in Medicine at the Free University Berlin, Germany. He practiced hospital medicine as a licensed physician in Germany and the UK. He is a registered specialist in Pharmaceutical Medicine in the United Kingdom, and Member of the UK's Faculty of Pharmaceutical Medicine. Having moved to the US in 2012, he now lives in New Jersey with his wife and two children and works at one of Bayer's four Global Pharmacovigilance sites. 2007.

Jay Ehrlich, VP, Global Patient Safety, VP, Global Pharmacovigilance and Medical Device Vigilance, Baxter

Jay Ehrlich is Vice President, Global Patient Safety, responsible for the groups who monitor Baxter's drug, biologic, and medical device products for patient safety issues, communicating and minimizing any of those issues as they arise, as well as anticipating any potential safety issues as those drug and device products are developed. He is responsible for 140+ Safety employees globally and oversees the many aspects of PV, including Regional and Country PV, Safety Operations, PV Compliance, PV Risk Management and Epidemiology, Medical Safety Writing, Medical Review and Signal Detection and PV Technology. He also has responsibility Medical Device Vigilance, responsible for patient safety aspects of Baxter's medical devices. After practicing medicine until 2002, Jay began his career in Pharmacovigilance at Abbott Laboratories where he was responsible for Clinical Safety Evaluations, where his primary responsibility was Abbott's blockbuster anti-TNF alpha biological, Humira. In 2005, he joined Baxter Healthcare, Inc. as the Director of (PV) Safety Operations. He continued his career growth at Baxter in expanding roles, and in 2009, he was promoted to Vice President of the Global Pharmacovigilance function, when he began to integrate the various global PV affiliates into a single global PV organization. In Sept 2013, he was given additional responsibility for part of the Medical Device Safety Organization, where he has focused on creating a single approach for device safety, as well as moving from a reactive approach to a proactive one. Jay received his Bachelor of Arts degree in Biology from the University of Illinois at Champaign-Urbana in 1989. He received his Doctor of Medicine degree from the University of Chicago Pritzker School of Medicine in 1993. He completed his internship and residency in Internal Medicine at Rush-Presbyterian-St. Luke's Medical Center in Chicago. He practiced Internal Medicine from 1996-2002 in the suburbs of Chicago in both a hospital-owned multispecialty medicine practice and a smaller private practice. He received his American Board of Internal Medicine certification in 1996 and again in 2006 and 2015. He is also a Board Member of the Lake County Board of Health.

Debra Feldman, Bristol-Myers Squibb, Vice President, Global Pharmacovigilance and Epidemiology

Debra Feldman, MD is the Vice President and Head of Medical Safety Assessment for Specialty and Mature Products at Bristol Myers Squibb (BMS). Debra is board certified in Internal Medicine. She spent 14 years in clinical practice in academic/ teaching sites at the Medical College of Pennsylvania, and at Graduate Hospital as division chair of general internal medicine. Along with patient care, Debra co-directed medical ethics training for medical students, chaired the hospital ethics committee, published in the field of medical ethics and clinical skills, and served on the hospital Institutional Review Board. Debra joined the pharmaceutical industry in 2001 as a safety physician at Wyeth. While at Wyeth (now Pfizer), she was accountable for anti-inflammatory products for rheumatologic, skin and asthma therapies across all stages of development. Debra went on to become the global therapeutic area leader for these disease groups, managing a team of physicians and scientists. Additionally, Debra played a key role in delineating pharmacovigilance group support in clinical development projects, and in review of product quality issues in the context of product safety. Debra joined AstraZeneca in October of 2010 as senior director in Patient Safety, working on infection and rheumatologic products. In June 2011, Debra moved into the role of Therapeutic Area Medical Expert for Respiratory and Inflammation, working both indirectly and directly with AZ products and PS projects. Debra joined BMS in 2013 where she is accountable for safety activities for the Specialty and Mature product portfolio, as well as optimizing strategic approaches and regulatory compliance.

J.-P. Clement, Pharmacovigilance Expert, JP Clement Pharmacovigilance

Dr. Clement is an Executive PV Consultant for the pharmaceutical industry. He has worked in Drug Safety and Pharmacovigilance in multiple capacities, mostly with global responsibilities. In his last role, he was leading the PV activities for Cubist (now part of Merck) as Vice-President, Global Pharmacovigilance & Medical Risk Management. In his previous roles, he was VP for Drug Safety and Pharmacovigilance at Onyx/ Amgen, and prior to that assumed different leadership roles with Janssen, sanofi, Lipha-Merck Kga, Abbott and Janssen France. Dr. Clement graduated in Family Medicine from the Pierre and Marie Curie Medical University, Paris, France, and worked in clinical practice for 8 years before joining the pharmaceutical industry. He also studied Pharmacology at Faculties of Pierre & Marie Curie Paris 6, Lariboisiere Paris 5 and Claude Bernard Lyon, France.

Sameer Thapar, Assistant Professor & Advisor, Drug Safety and Pharmacovigilance, Rutgers University

Dr. Sameer Thapar is Oracle Health Science's Director of Global Pharmacovigilance and is currently on faculty as professor for the drug safety and pharmacovigilance track of the Masters in Clinical Trial Sciences program at Rutgers University. Dr. Thapar holds a doctorate of pharmacy and has extensive experience in operations within the pharmaceutical, biotech, and CRO industries, with cross-functional experience in medical, clinical, quality, and subject matter expertise in pharmacovigilance (PV) operations and compliance. He has built global PV departments and defended in successful FDA, MHRA, and EMA health authority inspections. He is an active as a speaker and panelist in numerous industry conferences. He is well versed in a multitude of therapeutic areas and PV-related databases. Dr. Thapar was previously chief principal in MedEsq LLC, a pharmacovigilance and risk management consulting firm and is currently on faculty as professor for the drug safety and pharmacovigilance track.

Meet Our Expert Advisors And Speakers

Paul Beninger, VP, Global Patient Safety, Sanofi-Genzyme

Dr. Beninger is a Therapeutic Area Head in Pharmacovigilance and Epidemiology at Genzyme, a Sanofi company, in Cambridge, Massachusetts. He began his career in drug development in 1987 at the US Food and Drug Administration, and then joined Merck & Company in 1995, before moving to Genzyme as vice-president of pharmacovigilance in 2006; Genzyme was acquired by Sanofi in 2011. Dr Beninger trained in internal medicine and infectious diseases. He received his MD from UC Davis, his BA from Claremont McKenna College in Claremont, California, his MBA from Saint Joseph's University in Philadelphia, Pennsylvania, and his graduate certificate in epidemiology from Tufts. He is a fellow of the American College of Physicians and the Infectious Disease Society of America. He is also the Director of a new Master's degree program in Development and Regulation of Medicines and Devices and the MD/MBA Program at Tufts University School of Medicine.

Mariette Boerstoel-Streefland, SVP, Head of Global Drug Safety, Shire

Mariette Boerstoel-Streefland, MD, MBA, MS(epi), has been in the pharmaceutical industry for 25 years, most recently as VP, Head of Global Drug Safety at Baxalta. She received her MD at the University of Utrecht in the Netherlands in 1986 and subsequently worked in clinical practice in pediatrics at Utrecht University Medical Centre. In 1989 she moved her career to the pharmaceutical industry, joining Organon, where she had a progressive career in drug safety for 16 yrs, and was Global Head/Vice President for Organon as of 1999. In 2002 she was re-located to New Jersey. In 2005 she joined Mayne Pharma in the position of VP Global Drug Safety and Medical Affairs. After Mayne Pharma's acquisition by Hospira in April 2007 she moved to Forest Research Institute, where she held the position of Chief Safety Officer and Vice President, Global Drug Safety, covering all of Forest safety functions for all Forest products as well as overseeing the Medical Information function. In 2014 she was recruited to establish and lead a new safety department and function for Baxalta (previously Baxter Bioscience). Mariette received her Masters degree in Pharmaco-Epidemiology from McGill University Montreal and the University of Utrecht in 2001, and her MBA from New York Institute of Technology/Ellis College in July 2007.

Stephen A. Goldman, International Medical Product Safety Consultant and former Medical Director, Medwatch, FDA

Dr. Goldman is an independent consultant with extensive experience in academic/clinical medicine, public health, federal medical product safety regulation, and the pharmaceutical industry. Since 2001, he has utilized this unique background and expertise to provide a wide range of medical product safety-related services to the regulated industry (including pharmaceutical and medical device companies), government, academia and associations worldwide. While at Knoll Pharmaceutical Company (Abbott Laboratories) he served as Director, Pharmacoepidemiology, with responsibility for developing pharmacoepidemiology safety research programs for both marketed and investigational products. This followed his initial tenure as Director, Corporate Drug Safety. Prior to working at Knoll, Dr. Goldman spent over six years at the U.S. Food and Drug Administration (FDA). After completing an FDA/Uniformed Services University of the Health Sciences (USUHS) fellowship in Clinical Pharmacology and Regulatory Drug Evaluation Sciences, he was Medical Director of MedWatch, the FDA postmarketing surveillance and medical product safety information program for several years. In this capacity, he was utilized by all Centers as an in-house medical product safety/ risk expert, and was an active member of the Task Force on Risk Management that wrote "Managing the Risks from Medical Product Use: Creating a Risk Management Framework" Report to the FDA Commissioner. Among the honors he received while at FDA were the FDA Commissioner's Special Citation/Harvey W. Wiley Medal and the Commendable Service Award. He holds an academic appointment as Adjunct Assistant Professor of Psychiatry at USUHS, and is a Fellow of the Academy of Psychosomatic Medicine (FAPM) and Distinguished Fellow of the American Psychiatric Association (DFAPA). He was a two time North America Chair of the Drug Information Association (DIA) CSP Special Interest Area Community, and was a 2005 DIA Outstanding Service Award recipient. Dr. Goldman served on the National Academy of Sciences/Institute of Medicine Food and Nutrition Board Committee on the Framework for Evaluating the Safety of Dietary Supplements, and was a member of the World Health Organization Uppsula Monitoring Centre's Signal Review Panel. In 2003 he was named Outstanding Alumnus by the Honors Tutorial College at Ohio University.

Veronique Kugener, SVP, Head of Global Pharmacovigilance, Takeda

Dr Veronique Kugener, MD, MsC, MBA was appointed as Senior Vice President and Head Global Pharmacovigilance at Takeda in 2013. Veronique joined legacy Millennium, The Takeda Oncology Company, as Vice President and Head of Pharmacovigilance in 2007. Veronique has over 20 years of experience in clinical drug safety and Pharmacovigilance in the pharmaceutical industry both in Europe and in the USA. Veronique started her career in Global Pharmacovigilance in 1991 at Rhone-Poulenc Rorer and has held positions in clinical drug safety and pharmacovigilance at Aventis, Biogen Idec and Bristol-Myers Squibb. Veronique received her medical training and earned her medical degree in France . Veronique received her master degree in advanced studies (DEA) in Epidemiology from the University of Medicine, Victor Segalen in Bordeaux, France and her master degree in Pharmacology from the University of Medicine, Paris VII, France. She is a graduate of the Masters in Business Administration (MBA) from the "Institut of Administration des Entreprises" (IAE) at the University of Bordeaux, France. Veronique and her family reside in the Boston area.

Ruth Namuyinga, Associate Director, Clinical Safety and Pharmacovigilance, Daichii Sankyo

Ruth Namuyinga, MD MPH is board certified in Public Health and General Preventive Medicine. She completed her residency training at the Johns Hopkins Bloomberg School of Public Health in 2014 and fellowship in Epidemiology as an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention in 2016. Ruth then joined the pharmaceutical industry as Associate Director of Clinical Safety and Pharmacovigilance at Daiichi Sankyo Pharma Development. She is responsible for safety of both investigational medicinal compounds and marketed drugs. Among other roles, Ruth leads aggregate signal detection and the safety monitoring plan for assigned products.

Meet Our Expert Advisors And Speakers

Donna Valencia, Pharmacovigilance and Medical Affairs, Mesoblast

Donna Valencia has over 10 years of relevant Drug Safety, Pharmacovigilance and Medical Affairs experience in the Pharma and Biotech industries at companies such as Ikaria, Pfizer and currently at Mesoblast. Her experience in medicinal products, medical devices and advanced therapy medicinal products including allogeneic mesenchymal precursor and stem cells includes PV operations, signal detection and surveillance, risk management/RMPs, medical writing, aggregate reports, CRO management, Sponsor transfer of clinical trials and Immunogenicity. Prior to industry, Donna worked as a Pharmacist for a few years. She has her BS in Physiology and Neurobiology and PharmD/MBA from the University of Maryland.

Judy Hsiung, Senior Medical Director, Head of Safety Sciences, Halozyme

Dr. Judy Hsiung is currently Senior Medical Director, Global Pharmacovigilance and Risk Management at Halozyme Therapeutics, where she is Head of Safety Sciences and responsible for leading a team charged with signal detection, aggregate safety reports and risk management for all compounds, both in development and marketed in the organization. She has extensive experience with worldwide regulatory agencies. Previously, she was Acting Head of Global Medical Safety at Otsuka Pharmaceuticals as well as Director of Risk Management at CSL Behring Inc. As Global Safety Leader at Bayer Schering Pharma, she led Safety submission strategy for a key indication of a novel oral anticoagulant, now marketed for several indications worldwide. While at BSP, she also was a facilitator and a key member of the Core Management Team in developing strategy for ideal benefit-risk lifecycle product management as well as risk management planning for EU and Core RMPs for multiple compounds in indications including Oncology and CV-Hematology. Dr. Hsiung started her 17 year career in Pharmavigilance/Risk Management as a Senior Drug Safety Associate at Hoffmann La Roche, where she primarily worked with a team of epidemiologists oon risk management for Accutane. She also collaborated on the AVDAC for an anti-infectives compound, now marketed for Hepatitis C. Later in her career, she served as a Senior Clinical Safety Scientist at Bristol Myers Squibb, where she authored aggregate safety reports for all products in the Oncology TA.

Gerrit-Jan Nijveldt, Senior Director Global Regulatory Affairs Labeling, Sanofi

Gerrit Nijveldt is currently Senior Director Global Regulatory Affairs Labeling for the therapeutic area Diabetes and Devices for Sanofi in Bridgewater NJ. Gerrit has more than 18 years of experience in Global labeling. He has a broad experience in developing and maintaining Company Core Data Sheets, US Prescribing Information and EU Summary of Product Characterisation, including the labeling for multiple development products (early phase to approval). Gerrit has experience with information management tools, SPL, agency inspections and setting up end-toend labeling process. Gerrit is also an associate adjunct professor for Temple University School of Pharmacy teaching Global Labeling in the Quality Assurance and Regulatory Affairs Master's Program and is part of the DIA Labeling Steering Committee. Gerrit earned his MSc in Medical Biology from University of Utrecht in the Netherlands and started working in pharmaceutical industry in 1991, in the Netherlands, in Regulatory Affairs and Medical Information department.

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VIGILARE

Vigilare International (Vigilare), a Delaware USA (private) corporation, is a safety services organization established to provide biopharmaceutical and medical device companies with a full range of product vigilance services including consulting, QA services, inspection readiness, drug safety case processing, risk management, signal detection and supporting tools. Our company is based in Conshohocken, PA (Greater Philadelphia area). The combination of unparalleled leadership and operational expertise provides an ideal environment to capitalize not only on pharmacovigilance and product vigilance but also on the experience our teams bring to bear in service areas such as IT, consulting and quality. Vigilare's pharmacovigilance staff is made up of highly educated, qualified and experienced healthcare professionals. All of these elements come together to deliver end to end safety services and support in accordance with global regulations and standards.

PRIMEVIGILANCE
PHARMACOVIGILANCE & MEDICAL INFORMATION

PrimeVigilance is focused on providing high quality pharmacovigilance, medical information and regulatory services. We support pharmaceutical, biotechnology and generics companies in managing the global safety of their products from early clinical trial development through full post marketing activities. We have proven expertise and the international presence to assure clients that patients and products will be adequately protected. We have over 350 experienced professionals across all our offices in the USA, UK and Europe.

sciformix
Trusted Services. Built on Science

Sciformix Corporation is a leading global scientific process organization (SPO) that partners with life science companies to develop, launch and sustain medical products that improve the quality of healthcare worldwide. We collaborate with clients to support niche or end-to-end Safety & Risk Management initiatives including call center, case processing, medical review, aggregate reporting, and signal detection & risk management. Visit www.sciformix.com.

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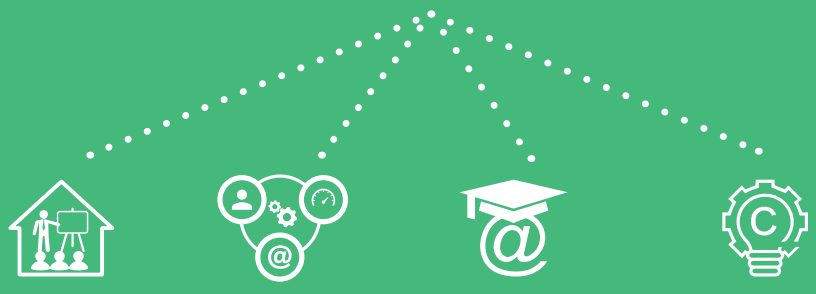
Complex Learning Experience

Why to choose our corporate learning programs

- ✓ **APPLY!** Get the real ROI by achieving the highest implementation rate of your learning
- ✓ **CUSTOMIZE!** Enjoy the benefits of a fully tailor-made training in the privacy of your organization
- ✓ **ENGAGE!** Make your onboarding and training count with our interactive e-learning programs

CORPORATE LEARNING



In-house Training | **Blended Learning** | **e-Learning** | **Custom Content e- Learning**

CONTACT US TO GET STARTED

Darius Slavik | MD, Corporate Learning Programs
darius.slavik@fleming.events
T: +421 257 272 180 | M: +421 918 447 166
http://corporate-learning.fleming.events/

Fleming.

4th Annual Pharmacovigilance & risk management strategies forum

September 27 - 28, 2017 – Washington D.C.

Code: AL LS 30 M

PLEASE COMPLETE THIS FORM AND SEND IT BACK TO:

PHONE: 312 582 4277

E-MAIL TO: isaac.mcnulty@fleming.events

OR FAX: 312 674 7304

Client Identification Details

(Details to be used on name badges)

☐ Ms ☐ Mrs ☐ Mr

Name: _____

Job Title: _____

Email: _____

☐ Ms ☐ Mrs ☐ Mr

Name: _____

Job Title: _____

Email: _____

☐ Ms ☐ Mrs ☐ Mr

Name: _____

Job Title: _____

Email: _____

Company / Organization Details

Name: _____

Contact person: _____

Email: _____

Address: _____

City: _____

State / County: _____

Country: _____

Phone: _____

Payment Method

Please debit my

Mastercard ☐ Visa ☐ Amex ☐ Discover ☐

Card Billing Address: _____

Street: _____

City / State: _____

Post/Zip Code

Card Holder´s Name: _____

Card Holder´s Signature: _____

Card Number:

Visa CVC Number or Mastercard CVV Number or Amex DBC

3 or 4 digit code on the back or front of the card | | | | |

Valid from | | / | | | Expiry Date | | / | | |

_____

I agree to AL Conference Production Ltd. terms and Conditions and AL Conference Production Ltd. debiting my card.

Authorization and Acceptance of Sales Contract & Terms & Conditions

I hereby declare i am authorized to sign this contract and terms & conditions in the name of the company/organization:

_____

Name: _____

Date: _____

Signature: _____

Booking is invalid without a signature

Agreed Price of the Service

Industry Professional ☐ **$ 2496** per delegate

Solution Provider ☐ **$ 3099** per delegate

23 USD administration charge and any applicable withholding or any other tax or fee will be applied

Payment is required within 7 working days

Terms and Conditions:

1. PAYMENT TERMS: **AL Conference Production Ltd.** (AL) **requires the full payment of the invoiced amount within 7 working days from the issue date of the invoice.** AL reserves the right to refuse entry to any client who has not paid its invoice. The registration fee includes: conference documentation, admission to all conference sessions, lunches and refreshments, admission to networking social events. The registration fee does not include: travel, hotel accommodation, transfers or insurance.
2. HOTEL ACCOMMODATION: Overnight accommodation is not included in the registration fee. A reduced rate may be available at the hotel hosting the event. The reservation form will be sent to the client after the venue has beenc onfirmed, but no later than one month before the event begins.
3. CANCELLATION BY CLIENT: The client has the right to cancel his/her participation in the event. Cancellation must be received by AL in writing, either by mail or fax. If the client cancels with more than one month's advance notice before the start of the event, AL shall be entitled to retain and charge 50% of the amount payable for participation in the event. If the client cancels with one month's (or less) advance notice, or fails to attend the event, then the client shall not be entitled to any refund. Failure to attend an event shall not excuse a client from owing the full amount of the registration fee. A copy of the conference notes from the event will be sent to the client after the event is over in case of cancellation by the client.
4. CANCELLATION BY AL: While every reasonable effort is made to adhere to the advertised program, circumstances can arise which may cause changes in the program, including but not limited to changes in the content, date(s), location or venue, or special features of the planned event. Such circumstances include but are not limited to acts of terrorism, war, extreme weather conditions, compliance with government requests, orders and legal requirements, failure of third party suppliers to timely deliver, and failure to register the minimum target amount of attendees for a given event. AL reserves the right to change the content, date(s), location or venue and /or special features of an event, to merge the event with another event, or to postpone it or cancel it entirely as appropriate under the circumstances. Client agrees that AL shall not be liable for any cost, damage or expense which may be incurred by client as a consequence of the event being so changed, merged, postponed or cancelled and client agrees to hold AL harmless and to indemnify AL in case of liability caused by any such changes, mergers, postponements or cancellations.
5. CANCELLATION OF THE EVENT: In case AL cancels an event, then AL may offer the client a full credit up to the amount actually paid by the client to AL. This credit shall be valid for up to one year from the issue date of the invoice to attend any AL-sponsored events. The client shall not be entitled to this credit as a contractual right.
6. CLIENT'S IDENTIFICATION INFORMATION. By signing of this sales contract and these terms and conditions the client gives full right to AL to share the client's identification information such as, but not limited to, client's name, address, email addresses, phone numbers and names of representatives with third parties, which participated on the same event as the client.
7. JURISDICTION: This contract shall be governed and construed in accordance with Illinois Law (not including its conflict of laws provisions AL and the client agree that, any dispute in any way arising out of or relating to this contract will be resolved by arbitration using one arbitrator before JAMS or American Arbitration Association in Chicago, Illinois, USA. The parties to this agreement agree that in any arbitration proceeding they may conduct reasonable discovery pursuant to the arbitration rules, that he law of the state Illinois will be the governing law, and any arbitration award will be enforceable in state or federal court.
8. DISPUTES INVOLVING CREDIT CARD PAYMENTS: As a condition of AL agreeing to accept your credit card as a approved form of payment, you especially agree to waive any rights you may have under applicable state and federal truth in lending laws or otherwise (including, but not limited to, under your credit's card issuer's procedures for resolving such disputed) to receive a temporary credit from your credit card issuer for disputed charges arising from your credit card transaction with AL (commonly referred to as a "charge back"). You agree that any dispute that may arise with respect to any credit card transaction must be addressed directly between you and us and to work in good faith to resolve any such disputed invoices in timely manner. Any dispute that can not be timely resolved to the mutual satisfaction of the parties shall be resolved in accordance with the dispute resolution provisions as contained in this Agreement.
9. COLLECTION/ATTORNEY'S FEES: The parties agree that in the event that any dispute arises in any way relating to or arising out of this Agreement, the prevailing party in any arbitration or court proceeding will be entitled to recover an award of its attorney's fees and costs, plus pre and post judgment interest. If we retain the services of a collection agency or attorney to assist in the collection of any amounts due to us under this Agreement, you will pay all expenses incurred by us in such collection efforts.
10. INDEMNIFICATION: To the fullest extent permitted by the law, you agree to protect, indemnify, defend and hold harmless AL, its owners, managers, partners, subsidiaries, affiliates, officers, directors, employees and agents, from and against any and all claims, losses or damages to persons or property, governmental charges or fines, penalties, and costs (including reasonable attorney's fees) (collectively "the Claims"), in any way arising out of or relating to the event that is the subject of this contract, and regardless of negligence, included but not limited to, Claims arising out of the negligence, gross negligence or intentional misconduct of AL employees, agents, contractors, and attendees; provided, however, that nothing in this indemnification shall require you to indemnify AL Indemnified parties for that portion of any Claim arising out of the sole negligence, gross negligence or intentional misconduct of the AL parties.
11. OTHER CONDITIONS: Any terms or conditions contained in the client's acceptance which contradict or are different from the terms and conditions of this registration document shall not become part of the contract unless individually negotiated with AL and expressly accepted by AL.