3rd
ADVERSE EVENTS REPORTING, SAFETY STRATEGIES and CAPA SUMMIT

December 5-6, 2016 | Sheraton Philadelphia University City Hotel | Philadelphia, PA

OUR ESTEEMED FACULTY INCLUDES:

Conference Chair:
Michael Forstner, Global Head of Pharmacovigilance, ACINO PHARMA

Keynote Speaker:
Mick Foy, Group Manager, Vigilance, Intelligence and Research Group, MHRA

Amy Sun, M.D., Ph.D., MBA, FACP, Senior Director, SANOFI

Zoe Hudson, BSc, MSc, Pharmacovigilance Scientist, Global Drug Safety, ROCHE PRODUCTS

Shaun Comfort, M.D., MBA, Associate Director and Senior SSL Safety Science IIDO, GENENTECH, A MEMBER OF THE ROCHE GROUP

Huiying Yang, M.D., Ph.D., Senior Director and Head of Epidemiology and Safety Analytics, PHARMACYCLICS, AN ABBVIE COMPANY

Stephen A. Goldman, M.D., FAPM, DFAPA, Managing Member, STEPHEN A. GOLDMAN CONSULTING SERVICES, L.L.C.; Former Medical Director, MEDWATCH, U.S. FOOD AND DRUG ADMINISTRATION

Israel Gutierrez, Vice President Drug Safety, EXELIXIS

New Cutting-Edge Topics for 2016:

- Safety Biomarkers and Their Utility in Clinical Development
- Risk Management Through the Use of Risk Assessment
- Social Media Integration and New Adverse Event Reporting Strategies
- Metrics and Benchmark Utilization for Improved CAPA Management
- Unification Across International Organizations and Electronic Health Records

Consumer Engagement
Premarketing/Postmarketing Marketing Safety Strategies
International Pharmacovigilance Affairs
Technology and Safety Must-Haves
GxP and Inspection Trends

“Excellent real-world issues. Real great example of industry collaboration, not just company focused.” —Senior Director, ABBVIE
Dear Colleague,

Life science organizations are always looking to improve safety through all aspects of a drug’s development and life cycle. As such, there are different strategies to consider when discussing patient safety. Reporting adverse events is one of the most important safety measures the pharmaceutical industry has. Regulatory agencies put immense effort into increasing adverse event reporting, but they rely on the accuracy of reports from the patients, doctors and drug companies. Accurate reports are crucial for creating the high-quality products that go to market for consumer use. However, there are many challenges that come with ensuring the safety of patients. An increase in reports doesn’t necessarily mean an increase in efficacy, and can end up slowing down the process, or even burying the correct information.

Because of safety concerns, it’s important to put together a signal detection, preventive action, corrective action and root cause analysis plan to review trends and understand when potential issues arise.

ExL Events is excited to announce that our 3rd Adverse Events Reporting, Safety Strategies and CAPA Summit will take place in Philadelphia, PA on December 5-6, 2016. This event will bring together pharmacovigilance, safety and CAPA thought leaders to discuss the industry’s most challenging issues. Join us for an exciting two days and leave with the knowledge needed to increase the efficiency and effectiveness of your safety process. Don’t miss this opportunity to hear from the leaders in this industry and gather all the tools your team needs to be successful.

WHO SHOULD ATTEND:

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- Pharmacovigilance
- Drug Safety
- Risk Management and Surveillance
- Quality Assurance/Control
- CAPA
- Medical Product Safety Assessment
- Pharmacoepidemiology
- Regulatory Affairs
- Safety Surveillance
- Signal Detection
- Clinical Safety
- Patient/Medical Safety
- Case Management/Review
- Data Management/Analysis
- Phase IV/Postmarketing Safety
- Research and Development
- Trial Optimization
- GCP Compliance
- Clinical Auditing
- Quality Systems/Processes
- Clinical Development

This conference is also of interest to:

- CRM/Data Management Software Vendors
- Adverse Event/Case Management Service Providers
- Regulatory/Healthcare/Pharmacovigilance Consultants
- Audit Tracking and Management Vendors
- Compliance/Quality Assurance/GCP Consultants
- CROs
- Technology Vendors/Portal Service Providers
- Healthcare Translation Agencies

Sheraton Philadelphia University City Center
3549 Chestnut St.
Philadelphia, PA 19104

If you require overnight accommodations please contact the hotel. ExL has reserved a block of rooms at a group rate. To make reservations, please call 1-888-627-7070 and request the group rate for ExL’s December Meetings. The group rate is available until November 14, 2016. Please book your room early, as rooms available at this rate are limited.

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AGENDA DAY ONE  MONDAY, DECEMBER 5, 2016

8:00  REGISTRATION AND CONTINENTAL BREAKFAST

9:00  CHAIRMAN’S OPENING REMARKS

CONSUMER ENGAGEMENT

9:15  ENHANCE PATIENT SUPPORT PROGRAMS THROUGH EFFECTIVE ADVERSE EVENT REPORTING
- Establish how to improve accurate data that is received through various media channels
- Differentiate the impact that solicited versus unsolicited data can have on safety operations
- Benchmark existing oversight programs and learn ways to improve them

10:15  TACKLING THE PROBLEMS POSED BY TERMINOLOGIES FROM DIFFERENT SOURCES INCLUDING SOCIAL MEDIA AND ELECTRONIC RECORDS PLATFORMS
- Define the terminologies used and the disconnect they cause
- Discuss the challenges for pharmacovigilance in handling real-world data
- Approach the possibility of a mapping tool that can cross over platforms
- Analyze ideas to help support signal detection
Mick Foy, Group Manager, Vigilance, Intelligence and Research Group, MHRA

11:15  NETWORKING BREAK

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12:00  RISK ASSESSMENT STRATEGIES AND THEIR ROLE IN RISK MANAGEMENT
- Determine how to optimize the benefit-risk balance for products through their entire life cycle
- Identify the nature and frequency of reported adverse events, and qualify their level of severity
- Build a large and comprehensive preapproval database to detect serious adverse events during drug development
Michael Forstner, Global Head of Pharmacovigilance, ACINO PHARMA

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12:45  LUNCHEON

2:00  OPTIMIZE SIGNAL DETECTION STRATEGIES TO IMPROVE ORGANIZATIONAL AWARENESS
- Understand that safety information can come from anywhere, and use it to its maximum potential
- Employ internal signals that come from aggregate reporting, data mining, ICSR and other methods of signal detection
- Ensure your system is robust and can address new types of signals to expedite corrective measures in the developmental phase
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2:15  THE IMPLEMENTATION OF POSTMARKETING SAFETY REPORTING FOR COMBINATION PRODUCTS
- Discuss the 2009 FDA draft guidance and its finalization
- Evaluate the impact of possible changes to combination products
- Utilize postmarketing safety reporting to ensure proper product management
Gay Steinbrick, Director, Global Clinical Safety and Pharmacovigilance, MERCK & CO., INC.

2:45  ENSURE VERIFICATION OF EFFECTIVENESS AND CAPA VALIDATION
- Analyze the process from start to finish to ensure effectiveness
- Review timelines to discover areas that need improvement
- Determine potentially problematic areas by looking across root causes
- Record the data received and utilize it to improve the CAPA system
Pramod Wable, Associate Director Inspection Management, PFIZER

3:30  NETWORKING BREAK

4:00  PANEL SESSION: INTERNATIONAL HARMONIZATION EFFORTS AND THE MOVE TOWARD CENTRALIZATION
- Consider methods for improving the efficiency of international companies dealing with different regulations in multiple areas
- Address the ICH and its guidelines moving forward in the interest of harmonization
- Understand CIOMS guidelines and methods of implementation by regulators
Israel Gutierrez, Vice President Drug Safety, EXELIXIS

5:00  CONCLUSION OF DAY ONE
9:00 CHAIRMAN’S RECAP OF DAY ONE

9:15 HOW EPIDEMIOLOGY CONTRIBUTES TO SAFETY EVALUATION AND RISK MANAGEMENT
- Evaluate the importance of having an epidemiologist as a strategic partner who can provide a population-focused perspective and analytical strengths to the evaluation of a safety signal
- Analyze the strengths and limitations of real-world data that can be used to address a safety question
- Discover what is in epidemiologists’ toolboxes: data sources and study designs, and their applications

Huiying Yang, M.D., Ph.D., Senior Director and Head of Epidemiology and Safety Analytics, PHARMACYCLICS, AN ABBVIE COMPANY

10:00 ADVERSE EVENT REPORTING AND PROBLEM RESOLUTION IN THE GLOBAL ARENA
- Understand adverse event reporting in the various regulatory environments around the world
- Utilize adverse event reports to resolve issues on a global scale
- Target bottlenecks that slow down turnaround times for problem resolution
- Plan ahead for company-vendor partnership inefficiencies

Marissa Fernandez, Pharmacovigilance Manager, BAXTER

10:45 NETWORKING BREAK

11:15 TECHNOLOGICAL ADVANCEMENTS AND THEIR IMPACT ON DATA MANAGEMENT
- Discuss how increases in speed and storage capacity affect data aggregation
- Examine how electronic healthcare records can enhance effectiveness and data management
- Manage shorter timelines, increases in workflow and larger amounts of information through the use of technology

Sameer Thapar, Assistant Professor, Drug Safety and Pharmacovigilance, RUTGERS UNIVERSITY

12:00 CASE STUDY: CAUSALITY ASSESSMENT IN PREMARKETING DRUG CLINICAL TRIALS
- Understand how causality assessment of serious adverse events in premarketing drug clinical trials has undergone a regulatory evolution
- Discuss how determining a “reasonable possibility” of causality encompasses the use of cumulative safety information about an investigational drug
- Explain how current premarketing regulatory standards for expedited reporting do not preclude a cautious approach to causality assessment for investigational drugs

Stephen A. Goldman, M.D., FAPM, DFAPA, Managing Member, STEPHEN A. GOLDMAN CONSULTING SERVICES, L.L.C.; Former Medical Director, MEDWATCH, U.S. FOOD AND DRUG ADMINISTRATION

12:45 LUNCHEON

1:45 CASE STUDY: EMBARK ON THE CHALLENGE OF SOCIAL MEDIA USAGE FOR ADVERSE EVENT (SMAE) EVALUATION AT ROCHE
- Review the pharma digital media landscape, including the volume and type of information Roche and other companies are currently receiving
- Conduct an examination of what could occur in the future (e.g., the “Data Tsunami”)
- Take a quick tour of the current global regulatory environment, particularly guidelines from the US (FDA), EU (EMA and EphMRA), UK (MHRA and ABPI), and CIOMS and ICH
- Describe PV monitoring activities Roche is conducting (broadcasting websites, engaging websites and social media, and listening activities) and the challenges global safety encounters
- Address the grand challenge: How do we scale and process increasing data in an era of constrained resources?
- Review the rise of automation and machine learning in PV — the Pharmaco-Intelligent System

Shaun Comfort, M.D., MBA, Associate Director and Senior SSL Safety Science IIIO, GENENTECH, A MEMBER OF THE ROCHE GROUP
Zoe Hudson, BSc, MSc, Pharmacovigilance Scientist, Global Drug Safety, ROCHE PRODUCTS

GXP AND INSPECTION TRENDS

2:30 BEST PRACTICES FOR MAINTAINING GXP IN THE CAPA LANDSCAPE
- Teach GxP mindset across your organization to encourage vigilance
- Pinpoint constantly problematic areas to hinder future noncompliance
- Focus on root cause analysis to ensure you are not only addressing the symptoms of the problem

Julii Lindquist, Vice President of Quality and Regulatory, WESTERN ENTERPRISES

3:15 PANEL SESSION: PHARMACOVIGILANCE PREPARATIONS PRIOR TO REGULATORY INSPECTION
- Manage risk and adhere to global Good Clinical Practice standards
- Utilize audits to determine if there are any underlying systemic or non-systemic issues
- Review CAPA documentation to ensure inspection readiness

Israel Gutierrez, Vice President Drug Safety, EXELIXIS
Katie Alberta, BSN, Global Head CQA, ALKERMES
Sameer Thapar, Assistant Professor, Drug Safety and Pharmacovigilance, RUTGERS UNIVERSITY

4:00 CONCLUSION OF SUMMIT

“Great ‘insider’ info. Perfect amount of history from FDA and information going forward. GREAT presentation!” — Director of Pharmacovigilance, PFIZER
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$2,095

**Onsite Pricing**

$2,195
☐ YES! Register me for this conference!

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