4th

ADVERSE EVENTS REPORTING and SAFETY STRATEGIES SUMMIT

Ply Emerging Technologies and Effective SOPs to Enhance Regulatory Compliance and the Quality of Your Safety Program

December 4-5, 2017 | Sonesta Philadelphia Rittenhouse Square | Philadelphia, PA

Deepa Arora, *Vice President Pharmacovigilance, Global Head Drug Safety and Risk Management,* **LUPIN LIMITED**

Stephen A. Goldman, *Managing Member,* **STEPHEN A. GOLDMAN CONSULTING SERVICES;** *Former Medical Director,* **MEDWATCH, FDA**

Deanna Montes de Oca, *Associate Director, PV Operations Clinical Safety and Pharmacovigilance,* **OTSUKA**

Judith Sills, *Vice President and Head, Global Pharmacovigilance,* **THE MEDICINES COMPANY**

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

Michael von Forstner, *Co-Chair, Pharmacovigilance Working Group,* **MEDICINES FOR EUROPE**

CONFERENCE CHAIR

Susan Welsh,
Chief Safety Officer,
CSL BEHRING

KEY TAKEAWAYS

- Ensure compliance with new and pending regulations
- Synthesize signal detection from disparate sources to improve accuracy and management
- Improve safe drug use and evaluate impact of risk management interventions
- Improve efficacy by streamlining SOPs to handle signals and mitigate risk pre- and postmarketing
- Bolster the quality of your safety program using AI and other technologies

- **Case Management**
- **Signal Management and Assessment**
- **Technology**
- **Inspection Trends and Regulations**

"Great insight into ongoing issues and challenges in the pharmacovigilance world."

—*Associate Director, Global PV Operations,* **NOVARTIS**

4th ADVERSE EVENTS REPORTING and SAFETY STRATEGIES SUMMIT

WHO SHOULD ATTEND:

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

- Pharmacovigilance
- Drug Safety
- Risk Management
- Safety Research
- Epidemiology
- Pharmacoepidemiology
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Research
- Safety Surveillance
- Signal Detection
- Clinical Safety
- Medical Affairs
- Patient/Medical Safety
- Health Outcomes
- Phase IV/Postmarketing Studies

This conference is also of interest to:

- Adverse Event/Case Management Service Providers
- Safety Database Providers for Case Management
- CROs
- PV Services Providers and Consultants
- Healthcare/Pharmacovigilance Consultants
- Healthcare Translation Agencies
- Technology Vendors/Portal Service Providers

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Dear Colleague,

The complex work and ever-increasing regulations on drug safety are straining PV professionals to do more in less time. However, adverse event reporting systems can be costly and inefficient, and the varying rules of regulatory agencies in different areas of the world can cause significant slowdowns.

ExL Events is pleased to host the **4th Adverse Events Reporting and Safety Strategies Summit** in Philadelphia this December. This event will bring together pharmacovigilance thought leaders to discuss the industry's most challenging issues, such as enhancement strategies for reporting adverse events and safety protocols. The summit will illuminate how companies of varying sizes are working toward more efficient and effective risk management systems, preventive measures, and overall improvement of pharmacovigilance and drug safety strategies.

The exchange of ideas at this event is enhanced by the spectrum of elucidated viewpoints. Our speaking faculty and the attendees range from managers to VPs, not to mention a broad range of responsibilities.

Attendees, from seasoned to novice, will return to work with a better understanding of adverse event reporting systems in the context of benefit-risk assessments, utilizing aggregate data, signal detection, audit and inspection readiness,

I look forward to meeting and learning with you.

Best regards,

Brian

Brian L. Anderson
Senior Conference Producer

VENUE

Sonesta Philadelphia Rittenhouse Square
1800 Market Street
Philadelphia, PA 19103

To make reservations, please call 1-800-SONESTA and request the negotiated rate for **ExL's December Meetings**. You may also make reservations online at http://bit.ly/2wnElau.

The group rate is available until **November 14, 2017**. Please book your room early, as rooms available at this rate are limited.

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DAY ONE — MONDAY, DECEMBER 4, 2017

CASE MANAGEMENT

8:00 **Registration and Continental Breakfast**

9:15 **Chair Opening Remarks**

Susan Welsh, *Chief Safety Officer,* **CSL BEHRING**

9:30 **Improve Product Safety With a Cohesive Company-Wide Approach**

- Manage risk and signal assessment by creating cross-functional structures and procedures
- Determine and evaluate interventions to ensure safe use
- Apportion responsibilities among the representatives of the cross-functional team

Stephen A. Goldman, *Managing Member,* **STEPHEN A. GOLDMAN CONSULTING SERVICES;** *Former Medical Director,* **MEDWATCH, U.S. FOOD AND DRUG ADMINISTRATION**

10:30 **Improve Efficiency, Safety, and Compliance Through Strategic Selection, Management, and Oversight of Vendors**

- Ask clarifying questions and recognize red flags when selecting vendors
- Establish communication as an integral part of risk reduction
- Clarify expectations of vendors and hold them accountable to ensure compliance
- Institute routine and sound partnership governance practices to minimize risk
- Identify and address company-vendor relationship inefficiencies

Judith Sills, *Vice President and Head, Global Pharmacovigilance,* **THE MEDICINES COMPANY**

11:15 **Networking Break**

11:45 **Implement an Effective CAPA System in Pharmacovigilance**

- Establish relevant metrics and criteria to identify the need for CAPA
- Ply Root Cause Analysis to identify problematic areas and corrections required
- Evaluate effectiveness of CAPA implemented
- Discuss case examples of the CAPA planning and implementation process

Deepa Arora, *VP Pharmacovigilance and Global Head Drug Safety and Risk Management,* **LUPIN LIMITED**

12:30 **Luncheon**

1:45 **Ascertain Hidden SAEs/SUSARs in Endpoint Reports by Systematizing and Standardizing a Process**

- Discuss the implications of AE commonly missed as a result of endpoint adjudication
- Examine the clinical events that do not meet endpoint criteria
- Identify processes required within systems to comprehensively review endpoint reports
- Address the limits of reconciliation and tactics for reducing the burden on sites
- Avoid missing SUSARs with a system that includes safeguards from reconciliation to redundant checking mechanisms

Ghazala Haque, *Safety Surveillance Manager,* **DUKE UNIVERSITY MEDICAL CENTER**

SIGNAL MANAGEMENT AND ASSESSMENT

2:30 **Networking Break**

3:00 **Improve Signal Management and Drug Safety by Preempting or Responding to Causes of AE in Manufacturing**

- Learn manufacturing pitfalls resulting from lack and clarity of regulations
- Determine and address possible causes of AE from the manufacturer to the patient
- Review procurement contracts, outsourcing relationships and QA practices that may advance or impede drug safety
- Understand regulations related to the role of manufacturing in signal detection and AE reporting
- Inspect historical case examples of adverse events caused by poor manufacturing practices

Paul Beninger, *Assistant Professor of Public Health and Community Medicine,* **TUFTS UNIVERSITY SCHOOL OF MEDICINE;** *Former Vice President, Global Patient Safety,* **GENZYME**

3:45 **Improve the Functions and Composition of Safety Management Teams**

- Define their role in signal detection, assessment and management
- Ensure their balanced focus is on clinical development and postmarketing stages
- Discuss when SMT should get involved in risk management programs

4:30 **Determine Your Global Signal Management Strategy**

- Avoid pitfalls and hear pain points for managing safety signals from identification through evaluation
- Learn practical considerations for an end-to-end signal management process
- Discuss key messages from EU GVP Module IX

Michael von Forstner, *Co-Chair, Pharmacovigilance Working Group,* **MEDICINES FOR EUROPE**

5:15 **Conclusion of Day One**

DAY TWO — TUESDAY, DECEMBER 5, 2017

DATA SCIENCE AND TECHNOLOGY

8:00 **Continental Breakfast**

9:15 **Chair Recap of Day One**

Susan Welsh, *Chief Safety Officer,* **CSL BEHRING**

9:30 **Automation of Adverse Events Reporting and Artificial Intelligence Application**

- Look at how AI has been applied in health sciences and epidemiology
- Assess the significance of AI to PV
- Advance AI from signal assessment to providing possible solutions and beyond

Israel Gutierrez, *Senior Director Drug Safety and Pharmacovigilance,* **PHARMACYCLICS**

10:15 **Panel: Harness New Technologies for PV**

- Incorporate social media platforms such as Facebook and Twitter
- Utilize mobile apps for AE reporting
- Leverage technology to enhance interactive connections with patients
- Hear the barriers to external interoperability and challenges of eliminating silos internally
- Discuss the rise of automation and machine learning in PV

Panelists

Israel Gutierrez, *Senior Director Drug Safety and Pharmacovigilance,* **PHARMACYCLICS**

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

11:15 **Networking Break**

11:45 **Use AI to Enhance Safety and Make Decisions Faster and With Improved Accuracy**

- Discuss the merits and functional limitations of AI technology
- Understand the "learning" capacity associated with cognitive computing
- Assess your preparedness by evaluating prerequisites of AI implementation
- Look to the future of AI to secure the future of your company

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

12:30 **Luncheon**

> ***"These were all very relevant topics to PV. All speakers presented very well and were very knowledgeable about topic of presentation."***
>
> —*Safety Surveillance Officer,* **EMERGENT BIOSOLUTIONS**

AUDITS AND INSPECTION TRENDS

1:30 **Ensure Inspection Readiness Through Mock Inspections**

- Build a Pharmacovigilance inspection readiness team to conduct mock inspections
- Vet and develop tools and metrics that correlate with regulatory expectations
- Determine type(s) of interventions needed
- Examine strategies and rationale for involving vendors in mock inspections
- Utilize audits to determine if there are any underlying systemic issues
- Review CAPA documentation to ensure inspection readiness

Deanna Montes de Oca, *Associate Director, PV Operations Clinical Safety and Pharmacovigilance,* **OTSUKA**

2:15 **Comply With the FDA's June 2018 Deadline for Combination Product Safety Reporting**

- Get clarification and perspective on the FDA's December 2016 final guidance
- Evaluate the impact of changes to combination products
- Review impediments and solutions to meeting the FDA's 2018 deadlines
- Formulate an action plan for implementation beginning
- Identify necessary resources including finding and recruiting candidates
- Utilize postmarketing safety reporting to ensure proper product management

3:00 **Chair Closing Remarks**

Susan Welsh, *Chief Safety Officer,* **CSL BEHRING**

3:15 **Conclusion of Conference**

> **"Great, practical presentations; knowledgeable presenters. Great interaction/discussions with group."**
>
> —*Associate Director,* **PROGENICS PHARMACEUTICALS**

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