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

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

CONFEERENCE CHAIR

Susan Welsh, Chief Safety Officer, CSL BEHRING

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
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

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

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker/Panelist</th>
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</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Registration and Continental Breakfast</td>
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<tr>
<td>9:15</td>
<td>Chair Opening Remarks</td>
<td>Susan Welsh, Chief Safety Officer, CSL BEHRING</td>
</tr>
<tr>
<td>9:30</td>
<td>Improve Product Safety With a Cohesive Company-Wide Approach</td>
<td>Stephen A. Goldman, Managing Member, STEPHEN A. GOLDMAN CONSULTING SERVICES; Former Medical Director, MEDWATCH, U.S. FOOD AND DRUG ADMINISTRATION</td>
</tr>
<tr>
<td>10:30</td>
<td>Improve Efficiency, Safety, and Compliance Through Strategic Selection, Management, and Oversight of Vendors</td>
<td>Judith Sills, Vice President and Head, Global Pharmacovigilance, THE MEDICINES COMPANY</td>
</tr>
<tr>
<td>11:15</td>
<td>Networking Break</td>
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</tbody>
</table>

#### Signal Management and Assessment

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker/Panelist</th>
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<tbody>
<tr>
<td>2:30</td>
<td>Networking Break</td>
<td></td>
</tr>
<tr>
<td>3:00</td>
<td>Improve Signal Management and Drug Safety by Preempting or Responding to Causes of AE in Manufacturing</td>
<td>Paul Beninger, Assistant Professor of Public Health and Community Medicine, TUFTS UNIVERSITY SCHOOL OF MEDICINE; Former Vice President, Global Patient Safety, GENZYME</td>
</tr>
<tr>
<td>3:45</td>
<td>Improve the Functions and Composition of Safety Management Teams</td>
<td>Michael von Forstner, Co-Chair, Pharmacovigilance Working Group, MEDICINES FOR EUROPE</td>
</tr>
<tr>
<td>4:30</td>
<td>Determine Your Global Signal Management Strategy</td>
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<tr>
<td>5:15</td>
<td>Conclusion of Day One</td>
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</tbody>
</table>
**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

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12:30 Luncheon

**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, OTSUCA

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
REGISTRATION FEES

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Register by October 20, 2017

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STANDARD PRICING

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ONSITE PRICING

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• Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event.

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