Pharmacovigilance
AUDIT & INSPECTIONS
CONFERENCE

Utilize Emerging Technologies and Innovative Methods to Improve Audit and Inspection Outcomes, Through Risk Assessment and Quality Assurance

March 26-27, 2018 | Sheraton Philadelphia University Hotel | Philadelphia, PA

CONFERENCE CHAIR

Susan Welsh
Chief Safety Officer
CSL BEHRING

FEATURED SPEAKERS

Paula Engle
Head of Global PV Compliance, Training and PV Network
GE HEALTHCARE

Rena Pandit
Director, Inspection Readiness Global Patient Safety and Epidemiology (GPSE)
ALLERGAN

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

Sameer Thapar
Assistant Professor, Drug Safety and PV
RUTGERS UNIVERSITY

Boris Videlov
Head PV Licensing
PFIZER

Richard Wolf
Senior Director Regions and Pv Operations, Global Clinical Safety and Pharmacovigilance
CSL BEHRING

ATTENDEE BENEFITS

- Examine best practices to improve your organization's audit and inspection performance and reporting
- Network and learn with over 50 of the best industry experts to learn the latest trends in PV audits
- Discuss the recently revised GVP guidelines as well as forward-thinking strategies
- Learn the best tools and techniques to overcome the top challenges, concerns, and obstacles to improve the quality of your PV System
- Identify best practices for using metrics and benchmarks to improve CAPA management

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DEAR COLLEAGUE,

Over the past several years due to the regulatory authority changes we have seen a **significant increase** in the regulations for pharmacovigilance audits and inspections. However, by using a risk-based approach to develop an audit and inspection strategy, companies can efficiently uphold these regulations. This will not only enable an organization to monitor issues with medications, products, and information more effectively, but also provide safer resources for their consumers.

With safety being of utmost concern for life science organizations and governing bodies worldwide, the goal of the **Pharmacovigilance Audit and Inspections Conference** is to address the recently revised guidelines as well as forward-thinking strategies and best practices to **strengthen the preparation and outcomes of your audit and inspections.**

Additionally, this conference will bring concrete answers and insights to educate professionals on **the latest innovative methods and technologies emerging in Pharmacovigilance**, and how they can effectively utilize them to improve organizational performance and reporting.

I look forward to welcoming you to Philadelphia in March!

Sincerely,

Bianca Dux
Conference Production Director
ExL Events, a division of Questex
bdux@exlevents.com

VENUE INFORMATION

Sheraton Philadelphia University City Hotel
3549 Chestnut Street
Philadelphia, PA 19104

To make reservations, please call 1-888-627-7071 and request the negotiated rate for ExL's March Meetings. The group rate is available until March 12, 2018. Please book your room early, as rooms available at this rate are limited.

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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 (QPPV)
- Pharmacovigilance Auditors
- Quality Assurance/Compliance
- Patient Safety
- Regulatory Affairs
- Drug/Product Safety
- Drug Development
- Risk Management
- Compliance
- Medical Information
- Information and Clinical Data Management
- Clinical Pharmacology/Safety
- Clinical Safety
- Research and Development
- Signal Detection
- Safety Surveillance
- Outcome Research
- Data Analysis
- Epidemiology
- Medical Affairs
- Regulatory Affairs and Compliance
- Information Technology

This conference is also of interest to:

- CRM/Data Management Software Vendors
- MLR Process Vendors and Facilitators
- Data Analysis Information Technology
- Regulatory Consultants
- Contract Manufacturing
- Sales and Marketing Clinical Trials and CROs

DAY ONE | Monday | March 26, 2018

8:00 Registration and Continental Breakfast

8:45 Chairperson's Welcome and Opening Remarks

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

9:00 **Data Integrity for PV in Preparation for Audits/Inspections**

- Translate GMP DI terms into GVP terms for a comparable data integrity assessment
- Ensure system requirements are fully met and adequately documented

Patrick Hoegen, *Associate Director, PV Quality and Compliance*, **ALKERMES, INC.**

10:15 **CASE STUDY: Allergan Audit/Inspection Readiness Program**

- Self-Audit (Self-Inspection Process)
- Analyze regulatory intelligence
- Audits Vs. inspections readiness tools and the process including a global perspective working with the affiliates
- Discuss overcoming challenges within your inspection readiness program

Rena Pandit, *Director, Inspection Readiness, Global Patient Safety and Epidemiology (GPSE)*, **ALLERGAN**

11:00 Networking Break

11:30 **CASE STUDY: Pharmacovigilance Exchange Through Pfizer's PvX**

- Explore how a web-based platform can replace the existing legacy PVA database and manage the PVA portfolio in a more advanced way
- Full breakdown of the information within the PVA, including ICSR exchange, RMPs, Aggregate Reports, Labeling (local and reference product information), Literature Searches (global and local), Safety Monitoring, actions taken for safety reasons, etc.
- Provision of various abilities for data mining, portfolio management, and various metrics
- Identify PVA responsibilities for individual partners and a single product across the PVA portfolio
- Compliance with the exchange of PVA deliverables with the partners is also tracked in PvX, allowing for the development and collection of metrics

Boris Videlov, *Head PV Licensing*, **PFIZER**

12:15 **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**

1:00 Luncheon

2:00 **Technological Advancements and Their Impact on Data Management**

- Discuss the introduction of artificial intelligence in pharmacovigilance
- Contrast between automation and artificial intelligence
- Analyze the emergence of social media and its impact on safety processes
- Understand the latest tools and technology used in PV systems

Sameer Thapar, *Assistant Professor, Drug Safety and PV*, **RUTGERS UNIVERSITY**

2:45 Networking Break

3:30 **Pharmacovigilance (PV) Audits Through the Perspective of an Auditor and Auditee**

- Practical considerations to prepare for a PV audit
- Understand the Auditor Perspective — considering a career in PV auditing
- Recent hot topics in PV audits

Marissa Fernandez, *Pharmacovigilance Manager*, **BAXTER HEALTH CORPORATION**

4:15 **Successful Partner Change Management During Multiple Ongoing Development Programs — Best Practices and Lessons Learned**

- Understand internal and external resource needs in a rapidly changing environment
- Establish good pharmacovigilance standards, requirements, processes, and procedures
- When and how to make the decision to change vendors and how to manage successfully
- Reflect and learn from the past to improve, grow, and define a mixed model global pharmacovigilance team

Kevin P. Malobisky, *Senior Vice President Regulatory, Quality, and Pharmacovigilance*, **KARYOPHARM THERAPEUTICS**

5:00 End of Day One

DAY TWO | Tuesday | March 27, 2018

8:15 Registration and Continental Breakfast

9:00 Chairperson's Recap of Day One

Susan Welsh, *Chief Safety Officer*, CSL BEHRING

9:15 Session by UBC

10:00 **Support PV Inspections Activities That Come in Through the GMP Door**

- Ensure proper connectivity between PV and Site QA functions
- Ensure well defined roles for support of inspections across your enterprise
- Establish rules of the road for responding to inspector inquiries

Richard Wolf, *Senior Director Regions and Pv Operations, Global Clinical Safety and Pharmacovigilance*, CSL BEHRING

10:45 Networking Break

11:30 **Company Culture and the Impact on Pharmacovigilance Audit and Inspections**

- Why the culture affects audits and inspections
- What type of culture supports audits and inspections
- How to create a culture that seamlessly adapts to audits and inspections

Suzanne Elliot, *Director, Pharmacovigilance Quality Assurance Leader*, JAZZ PHARMACEUTICALS

12:15 **Oversight and Management of a Global PV Network**

- Explore Global PV compliance through oversight and management of a PV Network of staff responsible for performing local PV activities in every country/region where products are marketed. These PV responsible staff could consist of contractors, distributors, external partners or company regional employees.
- Analyze the importance that this vast PV network has product knowledge, local language skills, awareness of cultural sensitivities and relevant PV regulatory knowledge.
- Ensure effective and appropriate oversight across this PV Network by managing yearly PV training, exchange of adverse events reports and assist with inspection and audit readiness.

Paula Engle, *Head of Global PV Compliance, Training and PV Network*, GE HEALTHCARE

1:00 Luncheon

2:00 **Science and Art of Preparing Efficient CAPAs in Pharmacovigilance**

- Determine manner in which CAPAs are written and implemented reflects the Quality Systems of the company
- Implement root Cause Analysis (RCA) and subsequent efforts implemented for improving the systems are key to the success of efficient pharmacovigilance systems focusing on patient safety
- Focus on the importance of RCA, preparation, implementation, and evaluating the effectiveness of CAPA.

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

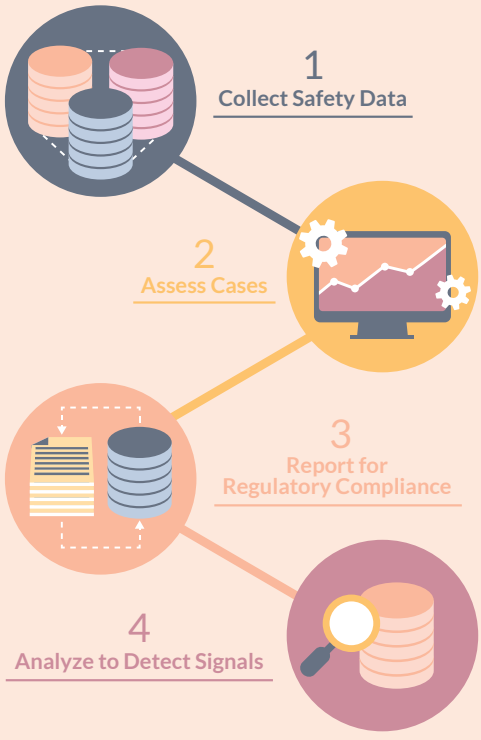
2:45 **Understand Top Corrective and Preventative Actions Through Risk Management**

- Understand why it is important to have a quality system in place to ensure data safety
- Communicate corrective actions implemented during the inspection
- Identify opportunities for improvement
- Maintain awareness of regulatory trends

Pedro Gomes, *PV QA Manager/Auditor*, VIFOR PHARMA

3:30 Conference Concludes

FLOW OF SAFETY INFORMATION



EXL EVENTS' TESTIMONIALS

"Very informative, relative for my current job to gain understanding of this area of PV."
—*Local Safety Officer*, UCB

"The event went beyond expectation. Impressed about new ideas about approaches/best practices."
—*Executive Director*, RETROPHIN, INC."

"I was pleasantly surprised with the usefulness of information presented over the two days."
—*Director, Promotion Compliance*, OTSUKA PHARMACEUTICALS

REGISTRATION
to register CLICK HERE or

Call: 201 871 0474
fax: 253 663 7224
email: register@pmaconference.com/
web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

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Register by Friday, February 9, 2018

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$2,095

Register After Friday, February 9, 2018

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