Pharmacovigilance Audits and Inspections Summit

Align Global Data Collection and Analysis Systems • Ensure Cross-Functional Collaboration and Preparedness • Achieve Accurate and Timely Reporting

November 7, 2018 • Wyndham Philadelphia Historic District • Philadelphia, PA

Why This Conference? Why Now?

- The volume of audits and inspections is growing rapidly
- Audits and inspections currently consume an inordinate amount of PV’s time and attention
- Global PV regulations are incredibly detailed
- Managing, reviewing and sharing an increasing amount of data is tremendously complex
- Cross-functional cooperation and seamless collaboration with 3rd parties is critical

Examine these issues and more!

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CBI’s Pharmacovigilance Audits and Inspections Summit provides insights on the most pressing issues and challenges related to managing the growing volume and frequency of audits and inspections. This event has been specifically designed to provide timely and detailed guidance to busy Pharmacovigilance attendees in a single day. It examines complex subjects, such as facilitating cross-departmental PV engagement, identifying best practices for working with inspectors, developing and implementing effective PV agreements, handling large scale data sets (including social media signal data), developing comprehensive reports using automation tools and tracking evolving global regulations (with a focus on detailed European requirements).

Organizations that want to reach a continual state of PV audit and inspection readiness can’t afford to miss this chance to benchmark and learn from both colleagues and vendors that have successfully navigated these pathways.

ATTENDEE BENEFITS INCLUDE:

- Understand areas of regulatory focus related to PV audits and inspections
- Create internal processes and best practices for managing audits and inspections
- Benchmark with colleagues — Consider ways to work in partnership with regulatory affairs, quality, medical affairs, clinical development and manufacturing
- Examine ways to efficiently and effectively capture, manage and report on data
- Consider the future state of PV audits and inspections

BRING YOUR TEAM:

You will benefit from attending this event if you work at a life sciences company and have responsibilities or involvement in the following areas:

- Pharmacovigilance
- Drug Safety
- Signal Detection
- Regulatory Affairs
- Quality Assurance
- Patient Safety
- Risk Management
- Clinical Development
- Data Management
- Medical Affairs
- Outcomes Research
- Epidemiology
- Information Technology

This conference will also benefit consultants, technology vendors and companies providing services to the above audience.

A Great Place to Meet Your Market!

Maximize your access to decision-makers and align your brand with the life sciences industry’s premier thought-leaders and industry innovators. CBI’s custom sponsorship programs are designed to support your organization’s overall business development and marketing initiatives through meaningful prospect and customer interactions, brand assertion campaigns and content-rich thought-leadership opportunities. Capitalize on the life sciences community’s premier platform for peer-to-peer exchange, solution driven content and first-in-class networking opportunities. For more information on how to position your company as a sponsor or exhibitor, contact John Fosdick at 339 298 2142 or email john.fosdick@cbinet.com.
Wednesday, November 7, 2018

7:15  Registration and Continental Breakfast

8:15  Chairperson’s Welcome and Opening Remarks
Susan Welsh, Chief Safety Officer, CSL Behring

8:30  Examine Evolving Global Pharmacovigilance Regulations and the Impact on Audit and Inspection Readiness
As regulations are changing domestically and around the globe, it is important to keep up to date on the many different regulatory issues (including data integrity regulations) that affect your audits and inspections. During this session, learn more about current and pending regulatory developments that affect PV audits and inspections.
Shelley Gandhi, BSc (Hons). MSc, Strategic Advisor, NDA Group AB

9:15  Good Pharmacovigilance Practices for Inspections – The Canadian Perspective
This presentation informs participants about the following:
• How GVP inspections are organised in Canada
• What the most important documents are that can help companies prepare for Canadian GVP inspections
• What some of the differences are between Health Canada and other regulatory authorities
• Specifics of Canadian GVP inspections
Katarina Susnjar, Compliance Specialist, Health Canada (Toronto Office)

9:35  Quality Management Systems — What’s in it for Pharmacovigilance?
• Identify the essential quality management system elements that are in scope for pharmacovigilance audits and inspections
• Pharmacovigilance suppliers — Are they in, are they out?
  * are the contracted suppliers likely to be pulled in and looked at during audits and inspections?
  * how does this impact your audit preparedness?
• Insights into Health Canada specific requirements
Marissa Fernandez, M.D., Pharmacovigilance Manager, Baxter Corporation

10:15  Networking and Refreshment Break

This session outlines small details that are often forgotten and can then turn into larger issues for many types of audits/inspections, including planned/unplanned visits whether they are “routine” or “for cause.” Mobilizing staff effectively, having a keen eye to detail and understanding the correct jargon are incredibly important to having a successful inspection.
• Review management of inspection preparation and close out
• Examine best practices for audit conduct
• Discuss different ways to work with staff to create better organization of systems, documents and technology
Amanda B. Parrish, Ph.D., RAC, Director of Regulatory Affairs and Quality, Duke University School of Medicine

11:30  ROUNDTABLE DISCUSSIONS
Design Internal Collaboration Strategies to Overcome Barriers to Audit and Inspection Preparation
It is vital that those responsible for audits and inspections are able to collaborate effectively and efficiently cross-departmentally, ensure that they will meet deadlines and communicate clearly and accurately. In this roundtable discussion, attendees break into groups and consider the aforementioned challenges
for the following departments / organizations (one roundtable per functional area). Roundtable leaders report back to the group on what they see as best practices, key information required from each functional area and practical ways for each functional area to collaborate on audits/inspections.

- Regulatory Affairs
- Clinical Development
- Quality
- Country-level Organizations
- Medical Affairs
- Manufacturing

**Facilitator**

Susan Welsh, Chief Safety Officer, CSL Behring

**Networking Luncheon**

12:15

**1:30**

**Overcome the Challenge of Managing PV Agreements Across the Enterprise and Between Third Parties**

- Explore key considerations and challenges
  - findings from latest inspections/audits
  - regulatory requirements and guidance translated into company standards, terms, templates — one size fits all?
  - classification of PV-relevant activities (e.g., licensees, distributors, collaborations, other service providers)
  - contract structure — how to cover local contract law
  - managing the agreement lifecycle; monitoring of compliance
- Approach to process improvement and technical solutions
  - benchmarking
  - document management is different than data management

Janet Auerbach, Safety Systems Project Manager, CSL Behring
Andrew Bond, Global PV Excellence and Compliance Specialist, Global Clinical Safety & Pharmacovigilance (GCSP), CSL Behring

**2:15**

**Standardize Processes for Sourcing and Managing Social Media Signal Data in Preparation for Audits**

Twitter, Instagram, Facebook, Snapchat and other social media sites are all becoming part of real world evidence readiness reporting that is being looked at across pharmacovigilance audits and inspections. Being ready and able to report on these signals is vital to keeping up with the technological and interconnected world we live in today.

- How do you comply with patient reporting related to digital media?
- How do you collect adverse events on social media platforms?
- Do you have a digital listening company, and how do you effectively and compliantly use it?
- Gather insights on how to develop templates for data reporting

Jaylaxmi Nalawade, Associate Director - Pharmacovigilance and REMS, Lupin Pharmaceuticals

**2:45**

**Networking and Refreshment Break**

**3:15**

**Ensure Inspection Readiness Through Mock Inspections**

- Form a common understanding on inspection terminology, goals and what leads to successful outcomes
- Understand inspection variances among regulatory agencies
- Examine strategies and rationale for involving vendors in mock inspections
- Build a Pharmacovigilance inspection readiness team to conduct mock inspections
- Utilize audits to determine if there are any underlying systemic issues
- Determine type(s) of interventions needed
- Review CAPA documentation to ensure inspection readiness

Deanna Montes de Oca, Pharm.D., Director, PV Operations, Clinical Safety and Pharmacovigilance, Otsuka Pharmaceutical Development and Commercialization, Inc.
4:00  Global Manufacturing Pharmacovigilance — Creating A Systematic Interface Between Pharmacovigilance and Quality Assurance to Address Inspection Requirements

- Examine the emerging landscape of Health Authority expectations towards the interface between patient safety and quality management
- Improve the inspection experience — GMP inspections and pharmacovigilance
- Effectively address inspection observations on the threshold of product quality and pharmacovigilance

Christoph Hoeck, Ph.D., Global Manufacturing Site Pharmacovigilance Representative, CSL Behring

4:45  Chairperson’s Closing Remarks and Summary

Susan Welsh, Chief Safety Officer, CSL Behring

5:00  Close of Conference
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Register by October 5, 2018 and SAVE $200. Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Credit Card (Visa, MC, AMEX, Discover) or checks accepted. Please make checks (in U.S. funds drawn on a U.S. bank) payable to: CBI. (No personal checks accepted.) PLEASE NOTE: All advertised discounts are taken from the full, Standard Rate.

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