Key Speakers Include

DEREK ROY
Resident Agent in Charge
FDA, Office of Criminal Investigations (FDA OCI)

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

TEGINDER SINGH
Senior Director Global Regulatory Affairs
Johnson & Johnson

ALEXANDRE KIAZAND
Global Head Safety Science
AstraZeneca

RICHARD WOLF
Head of GCSP Regions & PV Operations
CSL Behring

MICK FOY
Group Manager
MHRA (UK)

DEEPA ARORA
Vice President - Pharmacovigilance & Global Head-Drug Safety & Risk Management
Lupin (India)

KHAUDEJA BANO
Senior Medical Director Medical Affairs
Abbott

DOUG COFFMAN
Chief of Staff/Senior Director, Strategy & Business Planning - Global Patient Safety Evaluation
Takeda Pharmaceuticals

MATTHEW MELDORF
Senior Group Medical Director, Safety Science
Genentech

ANAND ANANTHAKRISHNAN
Director, Pharmacovigilance Safety System Operations
Fresenius Medical Centre

WILLIAM BLUMENTALS
Sr. Director, Pharmacoepidemiology Team Lead
Sanofi Genzyme

PEDRO L. OYUELA
Medical Director, Global Patient Safety
Amgen

ANANYA BHATTACHARYA
Director Global IO Implementation Lead
Bristol-Myers Squibb

KIMBERLEY MCKINNELL-MARCOPUL
Director, Safety Signaling and Aggregate Reporting
Alkermes

DAVID CHONZI
Vice President- Head of Patient Safety and Pharmacovigilance
Kite Pharma, A Gilead Company

ANKA G. EHRHARDT
Director, Clinical Research
CHDI Foundation

DAVID HUTCHINSON
Founder
Brookwood International Academy

SUZANNE SCHRANTZ
Director, Patient Engagement
Arthritis Foundation

MELVA T. COVINGTON
Principal
AGAPE Strategic Solutions

SHEILA WEISS
Senior Research Leader
Evidera

SHEETAL KHEDKAR
Senior Director, Regulatory Science
Sarah Cannon Development Innovations

BEN LOCWIN
President
Healthcare Science Advisors

STEPHEN F. AMATO
Faculty Director Graduate Regulatory Affairs, Market Access and Life Sciences
Northeastern University

Plus many more COMING SOON.....

WHO ATTENDS?

30+ Speakers
70% Pharma / Biotech
6+ Hours of Networking
3 Days
1 Golden Opportunity

www.virtueinsight.com
"Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management"

02nd – 04th October 2018,
Double Tree Suites By Hilton Boston,
Cambridge, Massachusetts, USA

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:

Global Pharmacovigilance Market expected to Reach US$6.1 bn by 2020 expanding at a CAGR of 14.2% from 2015 to 2020 and also expected to reach a market size of $8.23 billion by 2022. By 2020, the size of the global pharmaceutical market is anticipated to grow to USD 1.3 trillion, with the E7 countries – Brazil, China, India, Indonesia, Mexico, Russia and Turkey.

16th Pharmacovigilance 2018 will bring together top pharmaceutical, biotechnology and regulatory representatives under one roof that will address the key issues of the industry. The entire program will cover the detection, analysis and prevention of adverse drug reactions. It will be studied with the help of case studies and industry experiences. This conference will help the drug safety representatives from the pharmaceutical industry and academic and quality research organizations who wish to understand how to avoid common deficiencies in inspections by learning from the experiences of others; to gain a greater understanding of new and existing pv requirements, and to improve their organizations’ compliance with pv requirements. Also it can help you control your product’s lifecycle, your patient’s trust, and your revenue. Hence, this conference will provide an important platform for pharmacovigilance stakeholders to discuss and share best practices in expediting Pv development. What does the future hold for pv? Find out at our conference on opportunities and activities shaping pv to 2020 with respect to regulations, technologies and services. Learn and know on what are drug producers and service providers doing? What regulations and technologies influence the current PV field? You can also discover at 16th Pharmacovigilance 2018 on spending forecasts for PV (US, the EU and Asia).

It gives me great pleasure in welcoming all of you to the Virtue Insight’s 16th Pharmacovigilance 2018. I wish and pray that all our efforts will be beneficial to our industries and to our country at large.

KEY THEMES DISCUSSED IN THIS CONFERENCE:

• Pharmacovigilance in the US: What comes next for the industry?
• Recent developments – legislation, policies, systems, technology, communication strategies and best practice in PV
• Optimising the overall PV ecosystem - Challenges and Opportunities
• Why does pharmacovigilance sometimes fail and where could the fault lie?
• Pharmacovigilance and healthcare system
• Technology Impact - Cloud – Big data – Analytics – AI – Machine learning
• Updates to PSUR, PBFRs, DSUR, PASS
• Good Clinical Practices and Good Pharmacovigilance practices
• Future of outsourced phase I, II and III trials and post-marketing studies,
• Data quality management and analysis – analyzing the new guidelines
• Strategies to improve clinical trials and PV
• Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients
• Patient centric approach to help improve patient safety
• Outsourcing activities - Choosing your right vendor and setting the path right
• PV Audit & inspections - preparation, implementation and lessons to be learnt
• Discover approaches for collecting, integrating and analyzing all of the safety data generated from preclinical models
• Current regulations and guidelines - USA, EU and RoW
• The developing regulatory framework in advanced and developing markets
• Be part of a major networking opportunity

WHO WILL YOU MEET

CEOs, CTO’s, CIO’s, Presidents, VPs, Directors, Heads, Managers, Scientific Advisors, Consultants of:

AN EVENT TO VOW

16th Pharmacovigilance 2018 – “Uniting “Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management”

Get more from the event, with a broader scope bringing the whole communications value chain together. Enjoy and make the best out of our dedicated networking drinks time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition. Expand your knowledge of the latest business models and strategies in the high-level conference. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margins.

WHY EXHIBIT?

Make Sales
Debut new products
Profile your brand
Meet new business partners
Develop key relationships
Educate pharma and biotech companies

Organized by
DAY ONE - 02nd October 2018

WORKSHOP - SUMMARY

New European Regulations impacting global clinical trials

Radical changes to the way trials will be authorized and performed in Europe will have a major effect on sponsors undertaking clinical trials in Europe. Add to this strict new EU data protection laws which affect data transfers to the USA - you need to be aware!

This must attend half day session – with interactive Q&A’s using keypads – will be delivered by globally renowned clinical research and GCP trainer, Prof Dr David Hutchinson. It will provide key facts on the new requirements and allow participants to make sure that they are prepared for the changes.

• The EU Clinical Trial Regulation 2014/536 – overview and impact for sponsors and investigators performing trials in Europe. Changes include using an electronic portal to obtain a single authorization with no direct contact with ethics committees! This Regulation will replace current clinical trial legislation.
• Overview of the new EU General Data Protection Regulation – tough new requirements affecting subjects' rights, data processing and transfer with massive fines for breaches!
• How Brexit will affect clinical trials in Europe and the UK – as the UK prepares to leave the EU in 2019 we look at the likely impact will this have on trials and marketing authorisations in the UK

All participants will receive a book entitled “A Guide to European Data Protection” and an opportunity to do an online training module, free of charge.

WORKSHOP - SCHEDULE

New European Regulations impacting global clinical trials

10.00 - Introduction and icebreaker
10.15 - The EU Clinical Trial Regulation 2014/536 – overview and impact for sponsors and investigators performing trials in Europe
11.15 - Break
11.30 - Overview of the new EU General Data Protection Regulation Followed by a short presentation on – How Brexit will affect clinical trials and requirements in Europe and the UK
12.30 - Questions and discussion
13.00 - Lunch & Close

DAVID HUTCHINSON, Founder and Academic Dean, Brookwood International Academy, Visiting Professor of Clinical Research & GCP, University of Surrey, UK

PRINCIPAL SPONSOR

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DAY TWO - 03rd October 2018

08:30 – Coffee and registration - An opportunity to meet and network with your conference colleagues.

09:30
BEN LOCWIN
President
Healthcare Science Advisors
Chairperson opening remarks

MARKET TRENDS & WAY FORWARD

09:40
DEREK ROY
Resident Agent in Charge
FDA, Office of Criminal Investigations (FDA OCI)
Morning Keynote Address 1 - FDA’s Office of Criminal Investigations - Drug Tampering and Online Pharmacies
- Overview of FDA’s Office of Criminal Investigations
- Trends in drug tampering investigations and case example
- Business model of Online pharmacies and case example

QUALITY - SAFETY

10:20
Morning Keynote Address 2 – Achieving quality and safety in an optimized PV management
- How to keep your safety department’s focus and driver’s right?
- How optimized PV management & risk minimization procedures can ensure drug safety
- How to meet the recommendation for safety assessment committees
- Risk based approaches to pharmacovigilance

10:50 – Morning Coffee/Tea & Discussion

11:10
KHAUDEJA BANO
Senior Medical Director Medical Affairs
Abbott
Impact of Combination product post market safety reporting on PV

CHALLENGES & OPPORTUNITIES

11:40
Keynote Panel Discussion: Optimising the overall PV ecosystem – Challenges, Opportunities and Newer directions
- Challenges and Opportunities for effective Pharmacovigilance in the 21st Century

- Update on PV in EU, USA & RoW - Current and new trends for PV, and future guidelines
- Globalization of Pharmacovigilance
- Creating a proactive drug safety culture
- Where is the market heading and what needs to be done?
- Strategies to stay ahead of the curve
- How Automation and AI can be used in PV
- Pharmacovigilance - The effect of Brexit

Moderator:
BEN LOCWIN
President
Healthcare Science Advisors

Panellists:
MELVA T. COVINGTON
Principal
AGAPE Strategic Solutions

MATTHEW MELDORF
Senior Group Medical Director, Safety Science
Genentech

ANAND ANANTHAKRISHNAN
Director, Pharmacovigilance Safety System Operations
Fresenius Medical Centre

12:20
DAVID HUTCHINSON
Founder
Brookwood International Academy
Impact on GDPR on pharmacovigilance
Massive fines for breaching the new EU General Data Protection Regulation effective from May 2018. What is its impact on pharmacovigilance activities?

12:40 – Networking luncheon

13:40
DAVID CHONZI
Vice President- Head of Patient Safety and Pharmacovigilance
Kite Pharma, A Gilead Company
Crisis management within drug safety
- Regulations & Guidelines in connection with serious safety issues
- What determines a crisis?
- Communications to Regulators – what is required
- Communications within the company
- What happens next?

14:10
WILLIAM BLUMENTALS
Sr. Director, Pharmacoepidemiology Team Lead
Sanofi Genzyme
Achieving Efficiency – Using Claims or Electronic Medical Records Databases to Address Background Event Rates
- Claims databases and electronic medical records are often underutilized in favor of literature reviews for the rapid evaluation of safety signals
Existing data sources may provide more detailed information on disease incidence and disease associations
Use of existing data sources can potentially expedite the signal evaluation process

14:40 Solution Provider Presentation

For sponsorship opportunities please contact info.uk@virtueinsight.com

15:00 – Afternoon Tea/Coffee

15:20 MICK FOY
Group Manager
MHRA (UK)

“WEB-RADR II, integrating mobile technologies for improved pharmacovigilance”

• How to mobilise ADR data collection
• Two way communication for effective stakeholder engagement
• Effective use of e-health for PV
• Bringing new technologies to low and middle income countries

16:00 DOUG COFFMAN
Chief of Staff/Senior Director, Strategy & Business Planning - Global Patient Safety Evaluation
Takeda Pharmaceuticals

Successful vendor oversight program

Pharma and Biotech companies continue to outsource more work in effort to focus in-house resource on the most strategic activities. This operating model has led to an increase in the scope of service that suppliers are taking on to support Pharmacovigilance activities. Given the expectation from global regulators and other stakeholders to have Pharma and Biotech companies accountability for delegated activities, implementing an appropriate vendor oversight framework is critical. This discussion will focus on the key elements that make up a successful vendor oversight program.

16:30 Panel Discussion – Maintaining proper communication between - Sponsor – Site – CRO & Patients

• Importance of proper communication between - Sponsor – Site – CRO & Patients
• Working together to improve drug safety
• Patients involvement for a better PV knowledge - Patient support programs
• Mistakes that will doom a CRO-Supplier partnership
• How poor communication, patient recruitment plague clinical Trials

Moderator:
BEN LOCWIN
President
Healthcare Science Advisors

Panellists:
RICHARD WOLF
Head of GCSU Regions & PV Operations
CSL Behring

WILLIAM BLUMENTAL
Sr. Director, Pharmacoeconomic Team Lead
Sanofi Genzyme

17:10 – Chairperson’s closing remarks and end of conference

17:20 – 18:20 Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting

Networking Drinks
Meet with your industry peers for a relaxed drink at the end of day one

FOR DELEGATE REGISTRATIONS:

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - piyush@virtueinsightevents.com

“Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management”
DAY THREE - 04th October 2018

08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:30 / BEN LOCWIN
President
Healthcare Science Advisors

Chairperson opening remarks

09:40 / WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

Morning Keynote Address 1 – Signal detection & management

• Challenges of signal detection in spontaneous reporting
• What are the new technologies to determine the risk in PV signal detection?
• Aligning expectations between industry and regulators on signal detection and investigation
• How to monitor safety in blinded clinical trials
• Statistical approaches to looking at blinded data and detecting signals
• Signals validated by MAHs – procedural options
• Signal Detection: Innovations and challenges

11:20 / Solution Provider Presentation
For sponsorship opportunities please contact info.uk@virtueinsight.com

IMPACT OF TECHNOLOGY

11:40 / Next generation technology - Opportunities in Pharmacovigilance
• Emerging technologies to efficiently collect, store and analyze data in a comprehensive data management system
• Opportunities for PV Software Services companies
• Cloud - Big data – Analytics – AI – Machine learning
• The value of machine learning in safety
• Use of mobile technologies and social media in pharmacovigilance

PV – RISK MANAGEMENT & PLANNING

12:10 / Panel Discussion - Evaluating risk management requirements – What and how to do?
• Requirements of risk management plans from an industry point of view
• How to put Benefit-risk assessments into practice?
• How to write a successful risk management plan?
• Including the patient in the benefit: risk assessment at an early stage in drug development?
• Improving risk:benefit assessment with comprehensive data and a quality, compliant safety system
• How to strengthen your organization by leveraging your safety platform?

Moderator:
BEN LOCWIN
President
Healthcare Science Advisors

Panellists:
WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

PEDRO L. OYUELA
Medical Director, Global Patient Safety
Amgen

ANKA G. EHRHARDT
Director, Clinical Research
CHDI Foundation

SUZANNE SCHRANDT
Director, Patient Engagement
Arthritis Foundation
**DAY THREE - 04th October 2018**

**PV AUDIT & INSPECTIONS**

15:50

PV Audit & Inspections - Preparation, implementation and lessons to be learnt

- Major and a vital role - Monitoring PV compliance
- PV Inspection readiness: What to expect? How ready can we be?
- PV Compliance: PV is at the Center but cannot do it alone. How to mobilize internal and external stakeholders?
- Risk based selection criteria for auditing
- Methodologies, scope and oversight
- Relationship to other GxPs

**REGULATORY**

16:20

Panel Discussion: The developing regulatory framework

- Current regulatory framework and its global impact - What’s new?
- What are the current regulatory and practical challenges of the Risk Management Plan and how can you identify potential improvements?
- PV - Laws, Regulations, Guidelines and Best Practices
- How do marketing authorisation holders ensure they are up-to-date with current legal regulatory regulations and guidelines?
- Up-to-date information on all aspects of compliance in pharmacovigilance (both pre-marketing and post-marketing)
- The effect of Brexit on Pharmacovigilance

Moderator:

BEN LOCWIN
President
Healthcare Science Advisors

Panellists:

TEGINDER SINGH
Senior Director Global Regulatory Affairs
Johnson & Johnson

SHEETAL KHEDKAR
Senior Director, Regulatory Science
Sarah Cannon Development Innovations

STEPHEN F. AMATO
Faculty Director Graduate Regulatory Affairs, Market Access and Life Sciences
Northeastern University

17:00 - 17:10 – Chairperson’s closing remarks and end of conference
FOR SPONSORSHIP OPPORTUNITIES:

Sponsorship or exhibition is the best way to speed network with decision makers. The world leader speakers in our conferences attract niche delegates from all over the world. This would be a wonderful opportunity to reach the right audience and save money and time on all your other advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/news letter about the event and advertise the event via different forms of media.

Sponsorship Enquires - piyush@virtueinsightevents.com

“Conference was very informative & added much knowledge about Pharmacovigilance systems, ADE, process flow of reporting, searching data & mobile networking”

Asst. Manager Regulatory Affairs, Emcure Pharmaceuticals
FLOOR PLAN - Book your stalls now before they run out !!!

Note: The floorplan is subject to change at the discretion of the organisers.
For Multiple Bookings - Photocopy this form and send it to piyush@virtueinsightevents.com; Tel:+44 2036120886

Delegate Details:

Title                                Mr           Mrs           Ms            Dr
First Name
Surname
Company
Position
Address
Pincode
Telephone
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Conference Only - £799 per delegate
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TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendor are subject to the following charges and refunds upon withdrawal or cancellation. Between 2-3 month’s prior 75% cancellation fee / 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven’t paid the attendance fee you will be liable to pay an administration fee of £ 200

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at not extra cost.

Presentation: If you cannot attend the conference, you can still purchase the presentations for £ 400

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will refund your registration fee and we will try to reschedule the event.

Fee: The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

VENUE

Double Tree Suites By Hilton Boston
Address: 400 Soldiers Field Rd, Boston, MA 02134, USA
Phone: +1 6177830090

MAP & DIRECTIONS