19th Pharmacovigilance 2019

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

08th – 10th October 2019,
Double Tree Suites by Hilton Hotel,
Boston, MA, USA

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

DEREK ROY
Resident Agent in Charge
FDA

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

MARIETTE BOERSTOEL-STREEFLAND
Sr. VP PharmacoVigilance & Drug Safety
Alexion Pharmaceuticals

COLLEEN WALSH
Senior Director, Pharmacovigilance & Regulatory Quality Management Operations
Alexion Pharmaceuticals

GERSON PELTZ
Senior Director - Oncology Safety Risk Lead
Pfizer

SANDRA RAFF
Senior Director, Global Drug Safety and Risk Management Takeda Pharmaceuticals

BRUCE DONZANTI
Senior Group Director, Regulatory Pharmacovigilance Policy
Genentech

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

MELVIN MUNSAKA
Senior Director, Head Safety Statistics
Abbvie

XIAO NI
Director, Scientific Computing and Consulting
Novartis

SHARON REID
Director, Risk Management Product Lead
Pfizer

WILLIAM BLUMENTALS
Sr. Director, Head of Pharmacoepidemiology
Sanofi Genzyme

ANNAYA BHATTACHARYA
Global Lead for Safety & Risk Management
Bristol-Myers Squibb

HARISHA KADALI
Associate MedicalDirector
Takeda Pharmaceuticals

JAYLAXMI NALAWADE
Associate Director - Pharmacovigilance and REMS
Lupin

RICHARD WOLF
Executive Director, Pv Operations
CSL Behring

PHIL TREGUNNO
Group Manager - Vigilance, Intelligence and Researc Group
MHRA (UK)

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency (UK)

HEATHER LEIGH FLANNERY
Global Lead
ConsenSys Health

TOYIN ADEWOLE
Associate Director, Drug Safety - Clinical Research
Supernus Pharmaceuticals

RICKY RUDRARAJU
Sr. Principal Scientist - Global Patient Safety Evaluation Takeda Oncology

SANJEEV MIGLANI
Founder and Director
AWINSA Life Sciences

MUGDHA CHOPRA
Cofounder & Director
AWINSA Life Sciences

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Consultant, Global Clinical Safety and Pharmacovigilance
CSL Behring

MISRAEL GUTIERREZ
VP Pharmacovigilance & Drug Safety
Geron Corporation

SHEETAL KHEDAR
Senior Director, Regulatory Science
Sarah Cannon Development Innovations

DAVID HUTCHINSON
Academic Dean, Founder and Owner
Brookwood International Academy

MELVA COVINGTON
Senior Director
EVERSANA

BEN LOCWIN
Senior Vice President, Quality
Lumicell

Plus many more COMING SOON.....

WHO ATTENDS?

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

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"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

AGENDA AT A GLANCE

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AB-Cube Making Safety Easy

AWINSA

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"Panel discussions are very interactive as well as address real world and practical issues"

Head – Medical Affairs, Wockhardt

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

U.S. Pharmacovigilance showcase estimate was esteemed over USD 1 billion of every 2015, and anticipated to witness 10.7% CAGR from 2016 to 2024 to outperform USD 2.5 billion by 2024. The global pharmacovigilance (PV) & drug safety software market size was estimated at USD 124.6 million in 2016 and is expected to exhibit a CAGR of 6.5% over the forecast period. Increasing incidence of adverse drug reactions (ADR) are expected to propel the demand for pharmacovigilance (PV) software in the coming years. Increasing death rates attributable to antagonistic medication occasions and emerging patient concerns relating to wellbeing and viability of medications will drive industry development. 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. The rapid induction in the market throws up the challenges of monitoring Adverse Drug Reactions (ADRs) over large population base.

19th Pharmacovigilance 2019 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. 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 19th Pharmacovigilance 2019 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 **19th Pharmacovigilance 2019**. 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
- Challenges and Opportunities for Effective Pharmacovigilance in the 21st Century
- Why does pharmacovigilance sometimes fail and where could the fault lie?
- Pharmacovigilance and healthcare system
- Future of Signal Detection - Growing companies and safety efficiencies
- Technology Impact - Cloud – Big data – Analytics – AI – Machine learning
- 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

AN EVENT TO VOW

19th Pharmacovigilance 2019 – "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

WHO WILL YOU MEET

CEO's, CTO's, CIO's, Presidents, VPs, Directors, Heads, Managers, Scientific Advisors, Consultants of:

Pharmacovigilance, Pharmacoepidemiology, Pharmacogenomics, Drug/Product Safety, Drug Development, Information and Clinical Data Management, Clinical Pharmacology, Clinical Safety, Periodical safety update Reports, Risk Management, Research & Development, Quality Assurance, Patient Safety, Signal Detection, Safety Surveillance, Outcomes Research, Data Analysis, Epidemiology, Medical Affairs, Regulatory Affairs and Compliance, Information technology, Sales and Marketing

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"Very good platform to meet other pharmacovigilance expertise and interact with them about the advances & opportunites in pharmacovigilance. Virtue Insights is really good at coordinating and organizing"

Safety Physician, Sciformix

HALF DAY PRE-CONFERENCE WORKSHOP
08th October 2019 – 14:00 hrs to 17:00 hrs

Are you up to date with the latest developments affecting clinical trials in the EU? Why not ensure you are and attend our EU Clinical Research Update.This short workshop is delivered by Professor Dr David Hutchinson a renowned GCP trainer and founder and owner of Brookwood International Academy in the UK.

Brookwood has been delivering courses under Prof Hutchinson's leadership since 1985. In 2020,Brookwood celebrates 35 years of providing high quality, up to date training in clinical research and GCP. They are pioneers by offering, in 1996, for the first time, short courses with examinations and certification in GCP. Since that time they have provided training to more than 30,000 people from over 60 countries through its face to face and dynamic online training courses.

You should not miss this opportunity to learn from one of the masters of clinical research training.

What you will learn

Two new regulations in Europe have a major impact on the way trials are to be performed. You will learn what these are, the basics of each and how they interplay. You will also learn about inspectors expectations regarding the Trial Master File – one of the most common areas for critical and major inspection findings. Finally you will learn about some new developments that will have an impact on how trials are performed.

How is the course delivered?

The sessions will be a mix of presentations and non-threatening interactions such as keypad Q&As. You will have plenty of time to ask questions and chat with the presenter.

What topics are being covered?

- Overview of and interplay between the new EU Clinical Trial Regulation(2014/536) andthe General Data Protection Regulation (GDPR).
- EU Inspectors Working Group guidelines on the Trial Master File - thwarting in spection findings
- What's new? What's important? How forthcoming changes may impact you, including the impact of Brexit – if known, and the modernization of ICH E6 and E8.

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Safety Physician, Sciformix

AGENDA AT A GLANCE

DAY TWO - 09th October 2019

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

09:30 **BEN LOCWIN**
Senior Vice President, Quality
Lumicell

Chairperson opening remarks

MARKET TRENDS & WAY FORWARD

09:40 **Morning Keynote Address 1 - Pharmacovigilance in the US: Emerging Markets**

- Pharmacovigilance in the US: What comes next for the industry?
- Postmarketing safety monitoring
- Does the shift towards emerging markets pose a risk to drug safety and biased data reports?

QUALITY - SAFETY

10:20 **JAYLAXMI NALAWADE**
Associate Director - Pharmacovigilance and REMS
Lupin

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 **XIAO NI**
Director, Scientific Computing and Consulting
Novartis

MELVIN MUNSAKA
Senior Director, Head Safety Statistics
Abbvie

Safety Visual Analytics and its Application

CHALLENGES & OPPORTUNITIES

11:40 **Keynote Panel Discussion: Challenges and Opportunties for Effective Pharmacovigilance in the 21st Century**

- Challenges and Opportunities for effective Pharmacovigi lance 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
- Pharmacovigilance - The effect of Brexit

Moderator:

BEN LOCWIN
Senior Vice President, Quality
Lumicell

Panellists:

WILLIAM BLUMENTALS
Sr. Director, Head of Pharmacoepidemiology
Sanofi Genzyme

COLLEEN WALSH
Senior Director, Pharmacovigilance & Regulatory Quality Management Operations
Alexion Pharmaceuticals

RICHARD WOLF
Executive Director, Pv Operations
CSL Behring

TOYIN ADEWOLE
Associate Director, Drug Safety - Clinical Research
Supernus Pharmaceuticals

MELVA COVINGTON
Senior Director
EVERSANA

12:20 Speaker TBC, **AB Cube**

Speaking Session: Integrating your clinical database to your pharmacovigilance data base

- The advantages : Data intergrity, far less reconciliation work, time efficient
- The challenges : Each EDC is different, each study is different, not all clinical databse providers prefer different types of technology for the intergration. Alot of collaboration is needed between the end user, the clinical databse provider and the safety databse provider during the installation and validation
- Case study

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"Very well organized and the sessions were so well placed. Got enough time for networking and well time managed"

Country Safety Lead, Pfizer Limited

DAY TWO - 09th October 2019

12:40 – Networking luncheon

13:50 HARISHA KADALI
Associate MedicalDirector
Takeda Pharmaceuticals

Topic TBC

PRE-CLINICAL & CLINICAL TRAILS

14:20 DEREK ROY
Resident Agent in Charge
FDA

Investigations relating to Clinical Trial Fraud

- Overview of FDA OCI
- Blue Print of a Clinic Trial Fraud Investigation
- Case Example of Clinic Trial Fraud Investigation

14:50 – Solution Provider Presentation

For sponsorship opportunities please contact
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15:10 - Afternoon Tea/Coffee

AI – MACHINE LEARNING

15:30 Addressing the Data Challenges of Pharmacovigilance

- Artificial intelligence in adverse event processing
- Implementing Artificial Intelligence In AE Case Processing
- Deterrents To Implementing AI In AE Case Processing
- Detecting Safety Signals – Data Sources
- Safety Solutions In The Cloud

16:00 DAVID HUTCHINSON
Academic Dean, Founder and Owner
Brookwood International Academy

The EU General Data Protection Regulation and its impact on trials and safety data collection Topic TBC

- The scope of the GDPR.
- How and when non-EU trials are affected
- 5 key things to ensure compliance
- Interplay with other regulations

16:30 - Chairperson's closing remarks and end of conference

16:40 - 18:00 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 - delegate.uk@virtueinsight.com

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"Informative session focusing on new and grey areas of Pharmacovigilance patient care being the utmost priority on minds of all the pharma company new aspect discussion and light on the grey areas had open new arena for Pharmacovigilance thank you"

Drug Safety Associate, Cipla

AGENDA AT A GLANCE

Day 3 - 10th October 2019

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

09:30 **BEN LOCWIN**
Senior Vice President, Quality
Lumicell

Chairperson opening remarks

MOBILE & AI IN PV

09:40 **PHIL TREGUNNO**
Group Manager - Vigilance, Intelligence and Research Group
MHRA (UK)

Morning Keynote Address 1 – Use of mobile applications and AI in Pharmacovigilance

- Opportunities to exploit the use of mobile technology
- An update from the Innovative Medicines Initiative WEB-RADR Project
- Regulatory expectations for the use of AI
- Requirements to move AI pilots to production

SIGNAL DETECTION

10:10 **Morning Keynote Address 1 – Signal detection & management**

- Methods on signal detections
- Challenges of signal detection in spontaneous reporting
- 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
- Signal Detection: Innovations and challenges

SAFETY

10:40 **MUGDHA CHOPRA**
Cofounder & Director
AWINSA Life Sciences

Safety reporting requirements in Global clinical trials: Regulations demystified

10:55 **SANJEEV MIGLANI**
Founder and Director
AWINSA Life Sciences

Safety Management in Global Clinical trials: Unraveling the enigma

11:10 – **Morning Coffee/Tea & Discussion**

IMPACT OF TECHNOLOGY

11:30 **HEATHER LEIGH FLANNERY**
Global Lead
ConsenSys Health

Blockchain and the Advancement of Pharmacoviglance (PV)

- The big picture of blockchain in healthcare and life sciences
- Benefits and risks of utilizing blockchain for PV and Re al-World Evidence
- Blockchain-based PV program through the lens of each stakeholder group
- Real-world initiatives and consortia piloting these capabilities
- Bioethics of blockchain, advanced privacy preserving technologies, and PV
- Steps to assessing whether and how to use blockchain in your PV program

PV - RISK MANAGEMENT & PLANNING

12:10 **Panel Discussion - Evaluating risk management requirements – What and how to do?**

- Risk management development: Making the best out of it
- 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?
- Periodic Benefit-Risk Evaluation Report
- Working together - Managing communications between - Sponsor – Site – CRO & Patients

Moderator:

GERSON PELTZ
Senior Director - Oncology Safety Risk Lead
Pfizer

Panellists:

SANDRA RAFF
Senior Director, Global Drug Safety and Risk Management
Takeda Pharmaceuticals

SHARON REID
Director, Risk Management Product Lead
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Associate Director, Pharmacovigilance Operations, INCYTE Biosciences International

AGENDA AT A GLANCE

Day 3 - 10th October 2019

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency (UK)

ANNAYA BHATTACHARYA
Global Lead for Safety & Risk Management
Bristol-Myers Squibb

12:50 - **Networking luncheon**

13:50 **STEINAR MADSEN**
Medical Director
Norwegian Medicines Agency (UK)

Why does pharmacovigilance sometimes fail and where could the fault lie?

- Risk blindness - industry or drug authorities?
- It's not my fault – but whom to blame?
- Hard to detect adverse reactions
- Do we learn from previous experiences?

SAFETY

14:20 **Panel Discussion: Safety - Growing companies and safety efficiencies**

- The future of signal detection
- Maximizing safety efficiency – Building safety programs of scale and implementing them across company locations
- Developing signal detection capabilities in real world data
- Statistical methods for signal management
- Role of local safety officers in evolving pv market
- Improving safety and lowering cost
- Using technology as intricate part of modern pv

Moderator:

BEN LOCWIN
Senior Vice President, Quality
Lumicell

Panellists:

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Associate Director - Pharmacovigilance and REMS
Lupin

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ISRAEL GUTIERREZ
VP Pharmacovigilance & Drug Safety
Geron Corporation

KEVIN TYNAN
Consultant, Global Clinical Safety and Pharmacovigilance
CSL Behring

15:00 **WILLIAM WANG**
Executive Director, Clinical Safety Statistics
Merck

Safety and Benefit Risk Assessment Planning

15:30 – **Afternoon Tea/Coffee**

PV AUDIT & INSPECTIONS

15:50 **BRUNO MENDEZ**
VP Global Quality Head Pharmacovigilance
Sanofi

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 frame work**

- Ever-changing global regulatory requirements – Where is the current stand?
- 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
Senior Vice President, Quality
Lumicell

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Associate Director, Pharmacovigilance Operations, INCYTE Biosciences International

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Senior Group Director, Regulatory Pharmacovigilance Policy
Genentech

PHIL TREGUNNO
Group Manager - Vigilance, Intelligence and Research Group
MHRA (UK)

HEATHER LEIGH FLANNERY
Global Lead
ConsenSys Health

SHEETAL KHEDAR
Senior Director, Regulatory Science
Sarah Cannon Development Innovations

17:00 – 17:10 – Chairperson's closing remarks

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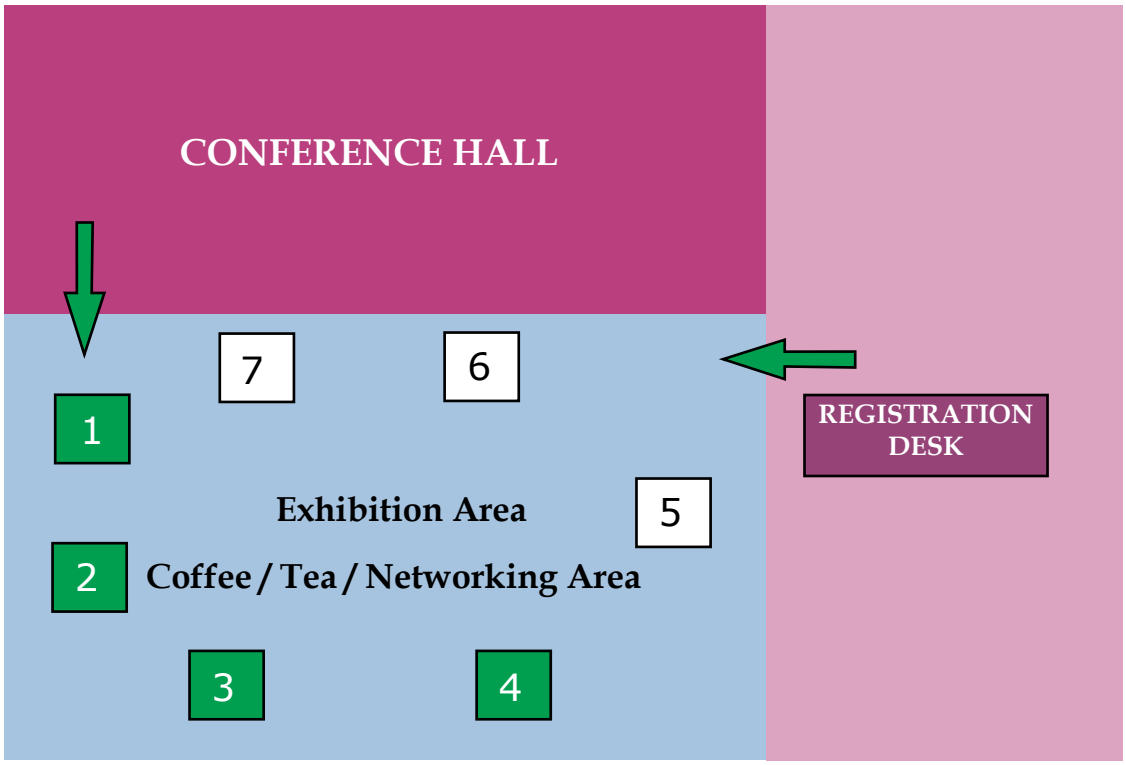
"This conference was very good for the pharmacovigilance professionals as well as business people. Organising this event and the event management was nicely done by Virtue Insight"

IT Administrator, Oviya Med Safe Pvt. Ltd

AGENDA AT A GLANCE

FLOOR PLAN - Book your stalls now before they run out !!!



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5

6

7

Note :- The floorplan is subject to change at the discretion of the organisers.

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"The conference was interesting and was a good platform for networking. The audience and the panelists were from varying backgrounds giving an insight to various challenges being faced by the Indian industry"

Manager - BD, ELC Research

For Multiple Bookings - Photocopy this form and send it to delegate.uk@virtueinsight.com; Tel:+44 2036120886

Delegate Details:

Title Mr ☐ Mrs ☐ Ms ☐ Dr ☐

First Name

Surname

Company

Position

Address

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1 Delegate @ £1299 Conference Only (Valid till 19th August 2019)
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Workshop Only - £399 (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 £500

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 Hotel, Boston, MA, USA

Address: 400 Soldiers Field Road, Boston, MA 02134

Phone: +1 617-783-0090

MAP & DIRECTIONS

Organized by

Virtue Insight

29 Gary Court,
189 London Road,
Croydon,
Surrey CR0 2DR

+44-2036120886

info.uk@virtueinsight.com