15th Pharmacovigilance 2018

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

21st & 22nd February 2018,
Holiday Inn, Kensington High Street,
London, UK

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

VICKI R EDWARDS
Vice President, Pharmacovigilance Excellence and QPPV
Abbvie

KARSTEN LOLLIKE
Corporate Vice President and QPPV
Novo Nordisk

KHAUDEJA BANO
Senior Medical Director Medical Affairs
Abbott (USA)

RENE HALTINER
Managing Director / Senior PV Strategy Lead
Conceptual Process Solutions / F. Hoffmann-La Roche

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

YUUNG YUUNG YAP
Senior International Regulatory Counsel, EU and International Regulatory Law
Pfizer

DAVID J LEWIS
Senior Adviser Pharmacovigilance
Novartis

TANJA PETERS
Global Head of PV Intelligence, Deputy EU QPPV
Boehringer Ingelheim

MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Janssen Pharmaceutical

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

HELEN MCASKILL
Interim Head of Research and Development at Department of Health
Isle of Man Government

FRANCK SCHWARTZ
QA Global Inspection, Intelligence Lead - Compliance and Regulatory Affairs
Novartis

RICARDA TIEMEYER
Head of Drug Safety & PoC Medical Information
Roche

MICHAEL RICHARDSON
VP International GPV&E and EU QPPV
Bristol-Myers Squibb

RUDI SCHEERLINCK
Head Global Drug Safety
Basilea Pharmaceuticals

SUMIT MUNJAL
Global Director, Pharmacovigilance & EU Region Medical Advisor - Lead Oncology Portfolio
Takeda Pharmaceuticals

MICK FOY
Group Manager, Vigilance Intelligence and Research
Group Vigilance and Risk Management
MHRA

ULRICH VOGEL
Head Strategic Data Analysis, Global Pharmacovigilance
Boehringer Ingelheim

JACKIE ROBERTS
Executive Director Regulatory, Pharmacovigilance and Medical
Accord Healthcare

STEINAR MADSEN
Medical Director
Norweigen Medicines Agency

PHILIP EICHORN
Senior Director (Worldwide Safety and Regulatory)
Pfizer

HEINZ WEIDENTHALER
Director Pharmacovigilance, QPPV
Bavarian Nordic

KATHRIN WAWRA-HEHENBERGER
Director, Clinical Safety Physician
CSL Behring

MIRCEA CIUCA
Global Head Medical & Clinical Drug Safety
Vifor Pharma

KAREN CHENG
Safety Risk Lead
Pfizer

MODESTAS JARUTIS
Medical Manager
Roche

G. NARAYANAN
Vice President, Disruptive Biologics
Voisin Consulting Life Sciences

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London, UK

"This kind of conference is very important for younger generations and professionals to get mere awareness and day to day updates in markets"

CIO, Qtech Solutions

AGENDA AT A GLANCE

JORGE GONZALEZ BORROTO
Pharmacovigilance Officer / Nonclinical Toxicology Expert
Ferrer Internacional

ANDREA MAULWURF
Head of Pharmacovigilance, EU-QPPV
Allergy Therapeutics

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

CHETAN SHATAPATHY
Director
Sanjeevani Pharma

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

HILARY JONES
Of Counsel
Bristows

Plus many more COMING SOON.....

WHO ATTENDS?

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

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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:-

The global pharmacovigilance (PV) market is expected to reach USD 10.27 billion by 2025. The market is expected to witness growth at 13.1% CAGR owing to Increasing incidence of ADR is key driver for the growth of pharmacovigilance market. As of 2015, the U.S. FDA received approximately 253,017 serious adverse events and 44,693 deaths associated with adverse drug reactions (ADRs). This shows the potential demand for implementing safety and pharmacovigilance services over the forecast period. The rapid induction in the market throws up the challenges of monitoring Adverse Drug Reactions (ADRs) over large population base. New drug approvals by the FDA have risen to near-record levels in the past two years: of the 45 medicines approved by the agency in 2015, 60 per cent went through one of the agency's fast-track processes. The number of pharmacovigilance inspections for centrally authorized products rose in 2016, mainly driven by an increase in routine inspections carried out under national inspection programs.

15th Annual 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 quality research organisations 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 pharmacovigilance requirements, and to improve their organisation's compliance with pharmacovigilance 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 pharmacovigilance development.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 15th 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 2020 - future horizons and efficiencies
- Updates towards of legislation, policies, systems, technology, communication strategies and best practice in PV
- Possible effects of Brexit on Pharmacovigilance
- Strategies for best practice in bene t-risk management
- Market analysis – What is our current stand? – Moving towards the new successful PV era
- Implementing risk minimization procedures - Making sure we succeed
- Examining developments in GVP measures and status of the new Module VI
- Improving in signal management and their implications
- Latest updates and hot topics relating to the role of the QPPV
- Challenges and Opportunities to optimize the overall PV ecosystem for maximum benefit
- Safety information for signal detection and management
- Medical devices – Increasing safety perspective
- Case studies from various countries on the PV frameworks around the world
- Good Clinical Practices and Good Pharmacovigilance practices
- IT and new technologies for improvement of PV and clinical research
- Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients
- Patient centric approach to help improve patient safety
- Outsourcing activities - How to set it 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
- How to involve patients better to develop drugs
- The developing regulatory framework in advanced and developing markets – EU, USA & ROW
- Accelerating new medicine introduction in developing world & overcoming challenges
- Be part of a major networking opportunity

AN EVENT TO VOW

15th Pharmacovigilance 2018 – "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

AGENDA AT A GLANCE

DAY ONE - 21st February 2018

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

09:30 SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Chairperson opening remarks

MARKET TRENDS & WAY FORWARD

09:40 Pharmacovigilance in 2020 - future horizons and efficiencies in data acquisition, evaluation and risk management

- Market analysis – What is our current stand?
- Initiating a new product portfolio and PV implications to enable a successful launch into market
- An overview of pharmacovigilance, pharmacoepidemiology, pharmaceutical risk management, and medication error prevention.
- Does the shift towards emerging markets pose a risk to drug safety and biased data reports?

10:20 KARSTEN LOLLIKE
Corporate Vice President and QPPV
Novo Nordisk

Crisis management within drug safety

- Handling of a safety crisis
- Decision process – relevant parties
- Communication - Authorities, DHCP letter, stock markets, internally
- Role of legal
- Execution
- Conclusions / Discussion

10:50 – Morning Coffee/Tea & Discussion

11:10 – Solution Provider Presentation

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11:30 – Solution Provider Presentation

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

CHALLENGES & OPPORTUNITIES

11:50 Keynote Panel Discussion: Challenges and Opportunities Optimize the overall PV ecosystem for maximum benefit

- Discuss on the possible impacts of Brexit
- Staying ahead in the race - Update on PV in EU, USA & RoW - Current trends for PV, and new and future guidelines
- Develop measures that achieve a more patient centric approach to drug safety
- Engaging Key Stakeholders
- Technology impact - The role of social media
- Explore long term PV visions, future directions of the 'PV world', and potential impact on the role of QPPV
- Best practices for license partner audits
- Legislation update worldwide

Moderator :

RUDI SCHEERLINCK
Head Global Drug Safety
Basilea Pharmaceuticals

Panellist :

MICHAEL RICHARDSON
VP International GPV&E and EU QPPV
Bristol-Myers Squibb

TANJA PETERS
Global Head of PV Intelligence, Deputy EU QPPV
Boehringer Ingelheim

RICARDA TIEMEYER
Head of Drug Safety & PoC Medical Information
Roche

JACKIE ROBERTS
Executive Director Regulatory, Pharmacovigilance and Medical
Accord Healthcare

12:30 – Networking luncheon

PV FOR TOMORROW

13:40 Panel Discussion - Future of PV - Where are we heading?

- Strategies for best practice in benefit-risk management
- Using technology to enhance interactive connection with patients
- Providing valuable insight into the functioning of the PRAC
- Who are the most important stakeholders and how does the PRAC cooperate with them?
- Latest updates and hot topics relating to the role of the QPPV

Moderator :

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

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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

AGENDA AT A GLANCE

DAY ONE - 21st February 2018

Panellist :

VICKI R EDWARDS
Vice President, Pharmacovigilance Excellence and QPPV
Abbvie

SUMIT MUNJAL
Global Director, Pharmacovigilance & EU Region Medical Advisor - Lead Oncology Portfolio
Takeda Pharmaceuticals

DAVID J LEWIS
Senior Adviser Pharmacovigilance
Novartis

ANDREA MAULWURF
Head of Pharmacovigilance, EU-QPPV
Allergy Therapeutics

MIRCEA CIUCA
Global Head Medical & Clinical Drug Safety
Vifor Pharma

TRAILS & POST-MARKETING SURVELLANCE

14:20 **Clinical data strategy and analytics:**

- Enabling Data Driven Trials
- Centralised monitoring
- Analytics to drive better decisions in clinical development
- Analytics linked to strategy & execution
- Quality, Risk, Analytics, and Speed: Industry trends and the impact on the direction of clinical data management

14:50 **PHILIP EICHORN**
Senior Director (Worldwide Safety and Regulatory)
Pfizer

PV considerations in Patient Support Programmes (PSPs), and other External Engagement Activities

- Why should the role of safety/PV colleagues be in PSPs, Market Research, and other non-study outward-facing activities? What are the regulatory expectations?
- How to effectively partner with other colleagues to mitigate unexpected safety-related issues.
- How to promote quality of safety-related information from these programmes

15:20 – Afternoon Tea/Coffee

15:40 – Solution Provider Presentation

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16:00 **Brexit and the impact on Pharmacovigilance**

- Impact of Brexit on QPPV
- Impact of Brexit on EMA
- Impact of Brexit on Eudravigilance and XEVMPD
- Other possible implications

16:30 **RENE HALTINER**
Managing Director / Senior PV Strategy Lead
Conceptual Process Solutions / F. Hoffmann-La Roche

Automated PV data processing and its game changing prospect

17:00 - Chairperson's closing remarks and end of conference

17:10 - 18:10 **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 TWO - 22nd February 2018

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

09:30 SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Chairperson opening remarks

QUALITY - SAFETY – SIGNAL DETECTION

09:40 HEINZ WEIDENTHALER
Director Pharmacovigilance, QPPV
Bavarian Nordic

Integrating Signal and Risk Management from a Small to Medium sized company's perspective

- Summary of available systems
- First learnings from upgraded EudraVigilance platform
- Aligning the processes of Signal management and Risk management
- Can small companies learn from large ones or vice-versa?

BUSINESS MODELS

10:20 KHAUDEJA BANO
Senior Medical Director Medical Affairs
Abbott (USA)

Changes in the PV world to accommodate combination product safety requirements

- Combination product safety reporting poses some unique challenges for the PV organization at a strategic and at an individual report level
- Simple and Effective processes including organizational changes to adapt to the needs support a timely and compliant implementation
- Use of scenarios to gain the knowledge with real-world examples help audience find solutions for these challenges.

10:50 – Morning Coffee/Tea & Discussion

SPONSOR – SITE – CRO - PATIENTS

11:10 Keynote Panel Discussion – Enhancing communications between - Sponsor – Site – CRO & Patients

- Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients
- How improved Sponsor-Site communications could change the clinical research industry
- Importance of involving patients in the communication
- Communication best practices
- Level of training and preparedness
- Putting communicatons to actions
- Considerations for good PV outsourcing practices

Moderator :

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellist :

FRANCK SCHWARTZ
QA Global Inspection, Intelligence Lead - Compliance and Regulatory Affairs
Novartis

MODESTAS JARUTIS
Medical Manager
Roche

HELEN MCASKILL
Interim Head of Research and Development at Department of Health
Isle of Man Government

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

CHETAN SHATAPATHY
Director
Sanjeevani Pharma

11:50 PV in low & middle income countries & how high in come countries and the industry can do more to improve patient safety in these resource scarce settings

MICK FOY
Group Manager, Vigilance Intelligence and Research Group Vigilance and Risk Management
MHRA

12:20 – Solution Provider Presentation

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

12:40 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:30 Panel Discussion - Implementing risk minimization procedures - Making sure we succeed

- Implementation and maintenance of RMP's – Overcoming its challenges

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"I would truly like to appreciate the efforts and initiative of Virtue Insight in organizing this PV dedicated conference. I think its one of its kind in India, where the meeting is focused only on Pharmacovigilance. Kudos to the team for the well- organised and well –planned meeting. Its one event resulting in the confluence of PV personnel, networking and exchange of knowledge. Keep up the good work. Thanks and good luck"

Drug Safety Associate, Cipla

DAY TWO - 22nd February 2018

- New tools in drug safety and optimizing benefit t risk management
- What should we learn from previous experiences?
- New approaches to managing benefit-risk
- Making the RMP a useful tool in pharmacovigilance

Moderator :

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellist :

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

JORGE GONZALEZ BORROTO
Pharmacovigilance Officer / Nonclinical Toxicology Expert
Ferrer Internacional

KAREN CHENG
Safety Risk Lead
Pfizer

KATHRIN WAWRA-HEHENBERGER
Director, Clinical Safety Physician
CSL Behring

DATA COLLECTION – MANAGEMENT

14:10 MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Janssen Pharmaceutical

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

14:40 ULRICH VOGEL
Head Strategic Data Analysis, Global Pharmacovigilance
Boehringer Ingelheim

Case study: EudraVigilance Monitoring

- What has changed since Nov 22, 2017
- Transitional arrangements
- EVDAS access for MAHs
- Initial learning and practical considerations

15:10 – Afternoon Tea/Coffee

15:30 STEINAR MADSEN
Medical Director,
Norweigen Medicines Agency

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?

TECHNOLOGY IMPACT

16:00 **IT business 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
- Use of mobile technologies and social media in pharmacovigilance

REGULATION OVERVIEW & UPDATE

16:20 **Panel Discussion: Keeping abreast with the changing regulations of PV**

- Key current changes and their impact on current PV
- Current PV practices in the EU & US
- Enhancing communication between regulators, regional authorities and patients be further enhanced?
- Examining developments in GVP measures and status of the new Module VI
- Market access and complying with PV regulations
- Moving positively towards the new era

Moderator :

G. NARAYANAN
Vice President, Disruptive Biologics
Voisin Consulting Life Sciences

Panellist :

YUUNG YUUNG YAP
Senior International Regulatory Counsel, EU and International Regulatory Law
Pfizer

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

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"Good efforts, well organised, experienced speakers, current and concrete topics. Promises delivered"

Pharmacovigilance Manager, Cheplapharm Arzneimittel GmbH

DAY TWO - 22nd February 2018

HILARY JONES
Of Counsel
Bristows

17:00 – 17:10 – **Chairperson's closing remarks and end of the 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.

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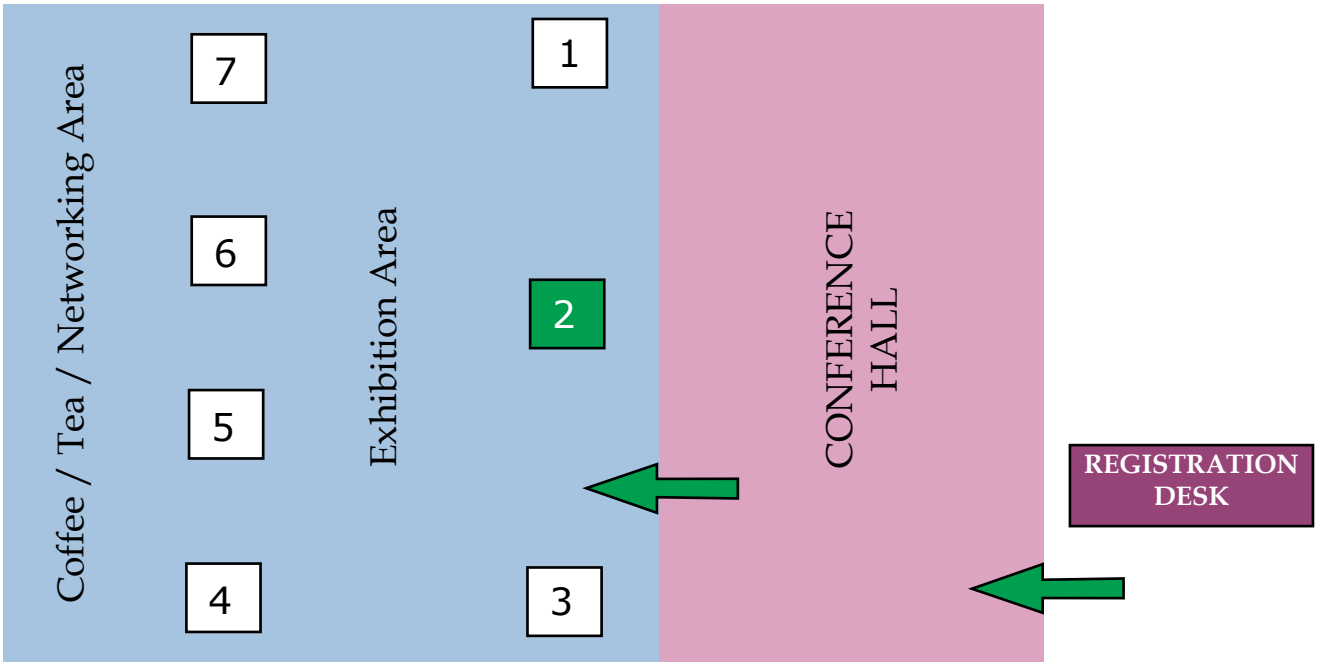
"This conference was very good for the pharmacovigilance professionals as well as business people. Organising this event and the event management was nicely done by Virtue Insight"

IT Administrator, Oviya Med Safe Pvt. Ltd

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



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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

AGENDA AT A GLANCE

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

Pincode

Telephone

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3 for 2 Offer

*Only few more seats left

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 + VAT

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 + VAT

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

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Phone: +44 20 7368 4023

MAP & DIRECTIONS

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