16th Pharmacovigilance 2018

"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

#VIphv

AGENDA AT A GLANCE

Key Speakers Include

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

ANNAYA BHATTACHARYA
Director Global IO Implementation Lead
Bristol-Myers Squibb

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 SCHRANDT
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

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"The Breadth of expertise from Industry was exceptional"

PV Audit Manger, Allergan

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, PBRERs, 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

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

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 nice opportunity to share own challenges with other Pharmacovigilance experts and hear about future initiatives. I would like to thank Virtue Insight for organising the conference"

Associate Director, Pharmacovigilance Operations, INCYTE Biosciences International

AGENDA AT A GLANCE

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**

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"Good opportunity to network with colleagues. Mostly the speakers/panel members were of high calibre and experienced."

Safety Executive Director, Amgen

AGENDA AT A GLANCE

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 **Morning Keynote Address 1 - Strengthening and rationalizing Pharmacovigilance in the US: where are we heading?**

- Pharmacovigilance in the US: What comes next for the industry?
- Updates from the Office of Surveillance and Epidemiology (OSE) within CDER.
- Postmarketing safety monitoring
- Does the shift towards emerging markets pose a risk to drug safety and biased data reports?

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

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"The session was knowledge transfer/sharing and valuable too"

Associate Manager, IQVIA (formerly known QuintilesIMS)

DAY TWO - 03rd October 2018

- 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.

SPONSOR – SITE – CRO - PATIENTS

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 GCSP Regions & PV Operations
CSL Behring

WILLIAM BLUMENTALS
Sr. Director, Pharmacoepidemiology 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 - delegate.uk@virtueinsight.com

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"Thanks Virtue Insight Piyush Patel for providing the stupendabulous experience of 13th Pharmacovigilance Conference in Chicago (27-28 Sep). Really worth attending this platform which constituted of wonderful people of the industry around from brilliant experience and background. Very well planned and coordinated; flawless activities all 2 days long. All the best to you and the team for events ahead."

Region Head, Business Development and Program Delivery, Turacoz Healthcare Solutions

AGENDA AT A GLANCE

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

SIGNAL DETECTION

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

OUTSOURCING

10:10 **ANAND ANANTHAKRISHNAN**
Director, Pharmacovigilance Safety System Operations
Fresenius Medical Centre

PV and Outsourcing - Hosted vs On premise safety databases – challenges and considerations for effective management of them

- Preliminary set up steps – what are all to be looked into?
- Moving forward – what are the deals that are to be communicated
- Steps to be taken in order to maintain efficacy and quality
- Monitoring constantly and effects of proper communication
- Benefits and risks of managing a pharmacovigilance-out sourced organization

BUSINESS MODELS

10:40 **Solution Provider Presentation**

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

11:00 – **Morning Coffee/Tea & Discussion**

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:

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Executive Director, Clinical Safety Statistics
Merck

PEDRO L. OYUELA
Medical Director, Global Patient Safety
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"Content very relevant. I learnt many things / got clarification on several points."

Sr. Manager PVCompliance, Gilead Sciences

DAY THREE - 04th October 2018

SUZANNE SCHRANDT
Director, Patient Engagement
Arthritis Foundation

SHEILA WEISS
Senior Research Leader
Evidera

12:50 – **Networking luncheon**

PATIENT CENTRIC

14:00 ALEXANDRE KIAZAND
Global Head Safety Science
AstraZeneca

Safety Science: Integrative Approach to Patient Safety

- Investing in safety- How failures in safety programs have resulted in in of more than half of all project closures in pharmaceuticals?
- How to predict clinical reactions to the drugs by integrating pharmacology, subject's predisposition, and drug structure to mitigate ADE's
- How a thorough understanding of target, drug structure, and pharmacology at discovery can help predict up to 75% of the adverse drug reactions in the market

DATA COLLECTION & QUALITY CONTROL

14:30 DEEPA ARORA
Vice President - Pharmacovigilance & Global Head-Drug Safety & Risk Management
Lupin (India)

Data quality management and analysis – Analysing the new guidelines

- Describe electronic case reporting to Adverse Event Reporting System
- Explain data quality issues encountered with electronic ICSR submissions
- Discuss data quality issues related to suspect product identification, using examples
- Discuss data quality issues related to MedDRA coding for adverse events and medication errors, using examples
- Periodic Benefit-Risk Evaluation Report

15:00 **Data sources for signal detection: Advantages, limitations and relevant challenges**

- Signal detection – Both clinical trials and post marketing data
- Discussion of different signal detection methods available
- Medical context into signal detection approaches to automate qualitative signal detection

15:30 – **Afternoon Tea/Coffee**

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**

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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

DAY THREE - 04th October 2018

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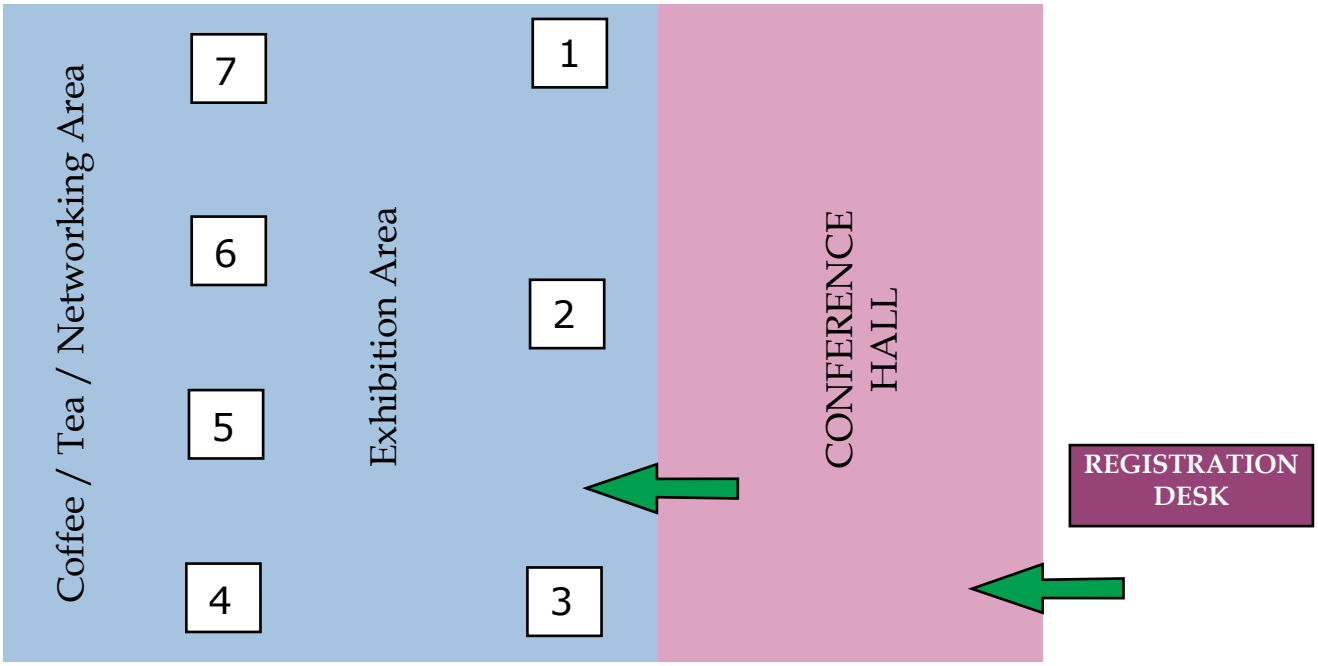
FLOOR PLAN - Book your stalls now before they run out !!!



1 4 7

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

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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

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

Fax

Email

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(Choose one of the following payment options)

RESERVATION PRICING:

Super Early Bird (Valid till 5th July 2018)

Conference Only - £799 per delegate ☐

Conference + Workshop - £999 per delegate ☐

Workshop Only - £250 ☐

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Special Offer:

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

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

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Phone: +44 61 7783 0090

MAP & DIRECTIONS

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