18th Pharmacovigilance 2019

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

27th & 28th February 2019,
Pestana Chelsea Bridge Hotel,
London, UK

#VIphv

AGENDA AT A GLANCE

- Key Speakers
- Conference Info
- Day One
- Day Two
- Floor Plan
- Booking Details

Key Speakers Include

JACKIE ROBERTS
Executive Director Regulatory, Pharmacovigilance and Medical / QPPV
Accord Healthcare

JABEEN AHMAD
Regional PV Director, EEMEA
Abbvie

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

RICARDA TIEMEYER
Head of Drug Safety & PoC Medical Information
Roche

PAOLO VOLTOLINA
Associate Director Regulatory Affairs
CSL Behring

MIROSLAVA NOVAKOVA
Medical Advisor
Sanofi Pasteur (Slovak Republic)

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

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

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

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

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

MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Johnson & Johnson

EMANUEL LOHRMANN
Lead Safety Physician
Boehringer Ingelheim

STEINAR MADSEN
Medical Director
Norweigen Medicines Agency

PAUL WANG
Director, Safety Science
Kite Pharma (USA)

DORIS STENVER
Chief Medical Officer, Member of the Pharmacovigilance Risk Assessment Committee (PRAC)
Danish Medicines Agency

ALEJANDRA PADOVANI
Safety Scientist
Roche

SABINE POLTERMANN
Head Scientific Product Information
Novartis

HEINZ WEIDENTHALER
Director Pharmacovigilance, QPPV
Bavarian Nordic

MIRCEA CIUCA
Global Head Medical & Clinical Drug Safety
Vifor Pharma

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

HARIS SHAIKH
Senior Director PV
Orchard Therapeutics

ALINA TUDOR
Associate Director, Senior PV Physician/Deputy EUQPPV
Norgine

RAJ BHOGAL
Safety & International Director, Regulatory Inspections, R&D QA&C
Shire Pharmaceuticals

Plus many more COMING SOON.....

WHO ATTENDS?

30+ 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

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CONFERENCE INTRODUCTION:-

Global pharmacovigilance market is expected to reach USD 5.51 billion by 2020, according to a new study by Grand View Research, Inc. Increasing incidence rates of adverse drug reaction and the introduction of stringent drug safety regulations are some key drivers of this market. ADR is responsible for approximately 5% of the hospitalization in developed countries annually, and this is expected to boost usage rates over the next six years. Pharmacovigilance has witnessed a significant rise in usage rates in the recent times owing to growing global geriatric population triggering a growth in demand for new drug development. Additionally, health regulatory authorities such as the U.S. FDA and EMEA (European Medicines Agency) are now emphasizing on electronic submission of data which is also expected to drive the pharmacovigilance market.

BREXIT's another big issue is medicines. Every month the UK exports 45 million packs of medicines to the EU and EEA countries, and imports more than 37 million. Again, prolonged disruption at borders could threaten supplies of drugs and other vital healthcare products – both in the UK and elsewhere in Europe. There is more scope with medicines than with food to increase stocks of things like tablets, but other imported drugs such as insulin often need to be refrigerated and may therefore pose bigger logistical challenges.

18th Annual 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. This conference will help the drug safety representatives from the pharmaceutical industry and academic 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 organisations' 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 18th 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:-

- Brexit Implications for the UK Pharmaceutical (pharmacovigilance) Industry
- What would 'no deal' mean for medicine?
- New Technologies in Pharmacovigilance (AI/ Machine Learning, IoT)
- Quality, Safety and Signal Detection - Future of 2020
- PV Audit & Inspections – Knowing what is to be done
- Drug safety work in the pre-clinical/clinical transition and early clinical development phase
- 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
- Benefit/Risk ratio: the common denominator
- Market analysis – What is our current stand? – Moving towards the new successful PV era
- PV – Risk Management and Planning
- Risk management in the lifecycle of a drug
- 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
- Quality, Safety and Signal Detection - Future of 2020
- Medical devices – Increasing safety perspective
- Case studies from various countries on the PV frameworks around the world
- Good Clinical Practices and Good Pharmacovigilance practices
- Proper communication - Sponsor – Site – CRO & Patients
- Patient centric approach to help improve patient safety
- Outsourcing activities - How to set it right?
- 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

18th Pharmacovigilance 2019 – "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

Key Speakers
Conference Info
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Floor Plan
Booking Details

DAY ONE - 27th February 2019

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 **JABEEN AHMAD**
Regional PV Director, EEMEA
Abbvie

Pharmacovigilance in Emerging Markets: Inspiration Challenge

Initiatives to build PV capacity in emerging markets have resulted in an explosion of global PV legislation. This session will examine the triggers for this dynamic change. The session will provide an overview of PV capacity building with a global overview of the regulatory landscape, and the triggers for change. We will evaluate the challenges for pharmaceutical companies and regulatory agencies, and highlight the need for "right-size" PV systems. The session will also highlight the ways in we can speak with one industry voice in this fast-paced environment.

10:20 **Risk management in the lifecycle of a drug**

- Challenges in Pharmaceutical product life cycle management
- Research and development improvement
- Integrated Quality and Risk Management
- Quality Risk Management within the Pharmaceutical Industry
- Managing Risk and Uncertainty through the drug life cycle

10:50 – **Morning Coffee/Tea & Discussion**

11:20 **Solution Provider Presentation**

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

11:40 **Solution Provider Presentation**

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

CHALLENGES & OPPORTUNITIES

12:00 **Keynote Panel Discussion: Optimising the PV ecosystem for betterment**

- 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
- Pharmacy practice and its guidelines
- Future Drivers for Pharmacovigilance
- New ways to generate evidence including real world evidence
- The role of social media
- Best practices

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellists:

JABEEN AHMAD
Regional PV Director, EEMEA
Abbvie

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

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

12:40 – **Networking luncheon**

QUALITY - SAFETY – SIGNAL DETECTION

13:50 **Panel Discussion – Quality, Safety and Signal Detection - Future of 2020**

- Strategies for best practice in Signal Detection
- PRAC signal recommendations
- PSUR and PSUSA recommendations
- How should we approach?
- Using technology to enhance interactive connection with patients
- Statistical signal detection as a routine pharmacovigilance practice
- Latest updates and hot topics

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellists:

EMANUEL LOHRMANN
Lead Safety Physician
Boehringer Ingelheim

ALEJANDRA PADOVANI
Safety Scientist
Roche

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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

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DAY ONE - 27th February 2019

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

MIRCEA CIUCA
Global Head Medical & Clinical Drug Safety
Vifor Pharma

14:30 **DORIS STENVER**
Chief Medical Officer, Member of the Pharmacovigi -lance Risk Assessment Committee (PRAC)
Danish Medicines Agency

PRAC activities update

15:00 **Solution Provider Presentation**

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15:20 – Afternoon Tea/Coffee

15:50 **JOHN SOLOMON**
Head of Pharmacovigilance - UK & Ireland
Sanofi

Topic TBC

IMPACT OF TECHNOLOGY

16:20 **New technologies in Pharmacovigilance**

- Artificial intelligence/Machine learning in Pharmacovigilance
- Can PV keep up with the pace of innovation?
- Are stakeholders and PV systems ready to embrace AI?
- Information technology in pharmacovigilance
- Decision process
- Conclusions / Discussion

16:50 – Chairperson's closing remarks and end of conference

17:00 - 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 - piyush@virtueinsightevents.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

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DAY TWO - 28th February 2019

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

PV FOR 2020

09:40 **PAUL WANG**
Director, Safety Science
Kite Pharma (USA)

Topic TBC

PATIENT SAFETY

10:20 **Pharmacovigilance and Patient Safety**

- Pharmacovigilance as a tool for safety and monitoring
- A review of general issues and the specific challenges with patients
- A practical approach to reshaping patient safety
- Next generation pharmacovigilance for enhanced patient safety

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

SPONSOR – SITE – CRO - PATIENTS

11:50 **Keynote Panel Discussion – Proper communication - Sponsor – Site – CRO & Patients**

- Maintaining relationships: Sponsor – Site – CRO & Patients
- Tips for improving communication between sponsors and CROs
- How Improved communications could change the clinical research industry
- Importance of patients involvement in the communication
- Communication - Best practices
- Training and Preparedness
- Considerations for good PV outsourcing practices

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellists:

MIROSLAVA NOVAKOVA
Medical Advisor
Sanofi Pasteur (Slovak Republic)

HEINZ WEIDENTHALER
Director Pharmacovigilance, QPPV
Bavarian Nordic

HARIS SHAIKH
Senior Director PV
Orchard Therapeutics

12:30 – **Networking luncheon**

RISK MANAGEMENT & PLANNING

13:30 **Panel Discussion – PV – Risk Management and Planning**

- Implementation and maintenance of RMP's – Overcoming its challenges
- Risk management in different jurisdictions
- Risk communication: Interface between pharmacovigilance, sales and marketing
- Benefit/Risk ratio: the common denominator
- How effective is your risk management
- New approaches to managing benefit-risk
- Updating signal management processes in big pharma

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellists:

RICARDA TIEMEYER
Head of Drug Safety & PoC Medical Information
Roche

MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Johnson & Johnson

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"Very nice opportunity to share current challenges within its own organisation with other Pharmacovigilance agents and hear about future initiatives to make our contribution to PV, safety, more efficiently moving forward."

Associate Director, Pharmacovigilance Operations, INCYTE Biosciences International

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DAY TWO - 28th February 2019

14:10 **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?

DATA COLLECTION – MANAGEMENT

14:50 **SABINE POLTERMANN**
Head Scientific Product Information
Novartis

PV Audit & Inspections – Knowing what is to be done

- Data Quality Management and Analysis
- PV Inspection readiness: What to expect? How ready can we be?
- Risk based selection criteria for auditing
- Methodologies, scope and oversight
- Preparing and managing safety data exchange agreements
- Relationship to other GxPs

15:30 – Afternoon Tea/Coffee

DATA COLLECTION – MANAGEMENT

15:50 **ALINA TUDOR**
Associate Director, Senior PV Physician/Deputy EUQPPV
Norgine

Outsourcing activities - How to set it right?

- Outsourcing PV: How to be easily ready for a quick upscaling in the portfolio, without jeopardizing safety
- Safety Database outsourcing: one model fits all?
- Risk-benefit evaluation: how best can this be outsourced?
- Secret recipe for a successful relationship between the MAHs and the PV vendors

REGULATION OVERVIEW & UPDATE

16:20 **Panel Discussion: PV - Regulatory Updates**

- Key current changes and their impact on current PV
- Impact of Brexit – Regulatory aspect
- Pharmacovigilance and the role of regulatory affairs: How to achieve compliance across the business
- Future Legislation: Pharmacovigilance – Industry Vision
- PV System Legislation Updates
- Current PV practices in the EU & US
- Enhancing communication between regulators, regional authorities and patients

Moderator:

SUSAN WELSH
Chief Safety Officer
CSL Behring (USA)

Panellists:

JACKIE ROBERTS
Executive Director Regulatory, Pharmacovigilance and Medical / QPPV
Accord Healthcare

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

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

PAOLO VOLTOLINA
Associate Director Regulatory Affairs
CSL Behring

RAJ BHOGAL
Safety & International Director, Regulatory Inspections, R&D QA&C
Shire Pharmaceuticals

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.

Sponsorship Enquires - piyush@virtueinsightevents.com

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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

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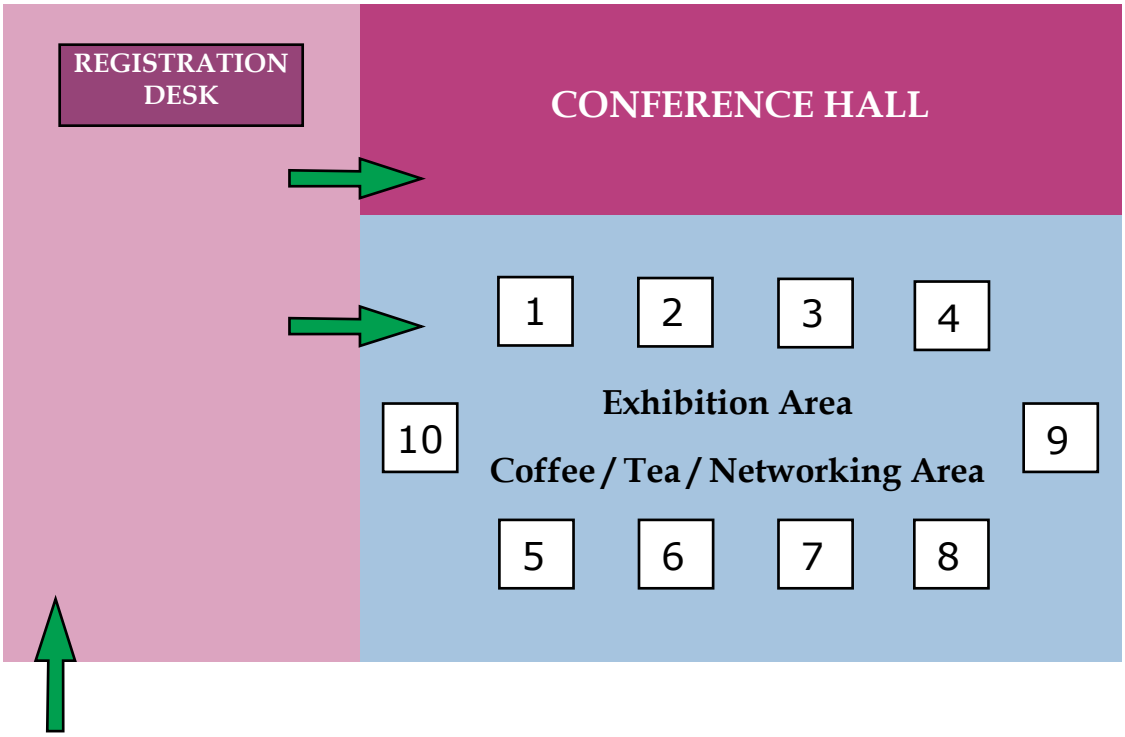
FLOOR PLAN - Book your stalls now before they run out !!!



1 5 9

2 6 10

3 7

4 8

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

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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

Fax

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(Choose one of the following payment options)

RESERVATION PRICING:

Super Early Bird - £750 + VAT per delegate (Valid Till 21st November 2018)

Standard Rate - £1150 + VAT per delegate

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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

Pestana Chelsea Bridge Hotel

Address: 354 Queenstown Rd, London SW8 4AE, UK

Phone: +44 20 7062 8000

MAP & DIRECTIONS

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